UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2008-1097

IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION

ARKANSAS CARPENTERS HEALTH AND WELFARE FUND, PAPER, A.F. OF L. - A.G.C. BUILDING TRADES WELFARE PLAN, MARK ASTON, BOARD OF TRUSTEES OF THE UNITED FOOD & COMMERCIAL WORKERS OF ARIZONA HEALTH AND WELFARE FUND, ADELE BRODY, MICHELLE CROSS, DONNA FRANCK, KRISTINE GADDIS, DAVID GREEN, IBEW-NECA LOCAL 505
Plaintiffs-Appellants,

(*caption continued on inside cover*)

—against—

BAYER AG and BAYER CORP.,

Defendants-Appellees,

—and—

HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC. (doing business as Rugby Laboratories, Inc.), and WATSON PHARMACEUTICALS, INC.,

Defendants-Appellees,

—and—

BARR LABORATORIES, INC.,

Defendant-Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK, IN 1:00-MD-01383, SENIOR JUDGE DAVID G. TRAGER.

CORRECTED BRIEF OF *AMICI CURIAE* AARP, CONSUMER FEDERATION OF AMERICA, PRESCRIPTION ACCESS LITIGATION, and PUBLIC PATENT FOUNDATION IN SUPPORT OF APPELLANTS and REVERSAL

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(caption continued)

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CERTIFICATE OF INTEREST

Pursuant to Federal Rule of Appellate Procedure 26.1 and Federal Circuit Rule 47.4, counsel for *Amici* certifies as follows:

1. The full name of every party or amicus represented by me is:

AARP, Consumer Federation of America, Prescription Access Litigation, and Public Patent Foundation.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

4. The names of all law firms and the partners or associates that appeared for the party or *amicus* now represented by me in the trial court or agency or are expected to appear in this court are:

AARP, Consumer Federation of America, Prescription Access Litigation, and Public Patent Foundation.

February 7, 2008

Bruce Vignery
AARP Foundation Litigation
Attorney for Amici Curiae

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STATEMENT OF INTEREST OF *AMICI CURIAE*

AARP is a nonpartisan, nonprofit membership organization of nearly 40 million persons, age 50 or older, dedicated to addressing the needs and interests of older persons. As the country's largest membership organization, AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality. AARP therefore has a strong interest in this case since the challenged agreement here thwarted the entry of generic ciprofloxacin into the marketplace, thereby reducing access to affordable prescription drug treatments.

AARP is uniquely situated to provide the Court with insight into the impact the district court's ruling will have on consumers. Affordable prescription medication is particularly important to the older population which, because of its higher rates of chronic and serious health conditions, has the highest rate of prescription drug use. Persons over sixty-five, although only thirteen percent of the population, account for thirty-four percent of all prescriptions dispensed and forty-two cents of every dollar spent on prescription drugs.[1] Prescription drug spending has skyrocketed over the last decade and a half. National health expenditures on prescription drugs have quadrupled from $40 billion in 1990 to

[1] Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly*, 1992-2010 at 2 (July 2000).

$188 billion in 2004, thereby limiting AARP's members' access to medically necessary medicines.[2] AARP therefore advocates for broader access to prescription drugs and lower prescription drug costs for consumers. Since generic drugs generally cost much less than their brand-name counterparts, AARP has worked at the state and national levels to increase access to lower cost generic versions of drugs.

Consumer Federation of America (CFA) is a non-profit association of over 300 nonprofit organizations from throughout the nation with a combined membership exceeding 50 million people. CFA's membership is comprised of state and local affiliates representing consumer, senior citizen, low-income, labor, farm, public power, and cooperative organizations. CFA was founded in 1968 to advance the consumers' interest through advocacy and education. CFA appears regularly before legislative, judicial, and administrative bodies at the federal, state and municipal levels.

CFA's members include organizations and consumers interested in promoting vigorous competition at all levels and across all industries involved in our nation's economy. The ability of consumers to purchase affordable prescription drugs is of great concern to CFA and its members. Competition,

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[2] *See e.g.* AARP, *Rx Watchdog Report*, June 2007, Vol. 4, Issue 5, *available at* http://www.aarp.org/issues/rx_watchdog/a2004-10-25-watchdog-archive.html.

affecting the ultimate consumer price of prescription drugs must be vigorous and must include the unfettered entrance of generic drugs into the market. CFA has a strong interest in the proper application of antitrust laws, which, when accurately applied and enforced, serves to ensure the benefits of such competition to American consumers.

Prescription Access Litigation LLC ("PAL") is a project of Community Catalyst, Inc., a nonprofit, nonpartisan organization that builds consumer and community participation in the shaping of the U.S. health system to ensure quality, affordable health care for all. PAL is a coalition of over 130 organizations in 35 states and the District of Columbia. The organizations in PAL's coalition have a combined membership of over 16 million people, and include state and local organizations representing consumers and seniors, statewide health care access coalitions, and labor unions. PAL works to end illegal prescription drug price inflation by pharmaceutical manufacturers and others by facilitating the participation of consumers, advocacy organizations and third party payors (health plans, union benefit funds and others) in class action litigation challenging such price inflation practices. PAL has long been concerned about the effects of "reverse payment settlements" on consumers' access to more affordable generic prescription drugs. Because of this concern, we join this amicus brief.

The Public Patent Foundation, Inc. ("PUBPAT") is a not-for-profit legal services organization that represents the public interest in the patent system, and most particularly the public interest against the harms caused by undeserved patents and unsound patent policy. PUBPAT provides the general public and specific persons or entities otherwise deprived of access to the system governing patents with representation, advocacy and education. PUBPAT has argued for sound patent policy before the Supreme Court, the Court of Appeals for the Federal Circuit, the USPTO, the European Union Parliament, and the United States House of Representatives. PUBPAT has also requested that the USPTO reexamine specifically identified undeserved patents causing significant harm to the public. The USPTO has granted each such request. These accomplishments have established PUBPAT as a leading provider of public service patent legal services and one of the loudest voices advocating for comprehensive patent reform.

PUBPAT has an interest in this matter because the decision below will have a significant negative effect on the public's interests represented by PUBPAT and because PUBPAT's mission is to represent those interests against the harm caused by unsound policy with respect to patents. More specifically, PUBPAT has an interest in ensuring that patent holders and their privy are not allowed to undermine otherwise sound competition law simply because they own a patent.

ARGUMENT

The district court granted Defendants' motions for summary judgment, ruling that exclusion payment agreements, such as the agreement at issue here, are with few exceptions per se *lawful* under Section 1 of the Sherman Act. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005) ("*Cipro III*"). According to the court, the statutory rebuttable presumption of validity enjoyed by patents, 35 U.S.C. § 282, entitles patentees to pay alleged infringers not to contest validity and to stay out of the market. *Cipro III*, 363 F. Supp. 2d at 535, 541. If left to stand, this ruling will have a devastating impact on American consumers.

Competition from generic drugs is one of the few effective means of slowing the spiraling cost of pharmaceuticals. Generics typically sell for a fraction of the cost of their branded counterparts and quickly capture the majority of unit sales, saving consumers literally millions of dollars on a blockbuster drug such as Defendant Bayer Corporation's Cipro. If Defendant Barr Laboratories won its patent challenge, it intended to enter the market at a 30% discount to the price of brand Cipro and expected to quickly capture a large percentage of the ciprofloxacin market. *Cipro III*, at 522; *see also id.* (Bayer estimated lost sales of up to $826 million during the first two years of generic competition).

Recognizing the clear consumer benefit that accompanies generic drug entry, Congress sought to speed up generic entry by enacting the Hatch-Waxman Act.[3] Through that Act, Congress has "institutionalize[d] and provide[d] incentive for a system of attacks on presumptively valid patents." *Innovation and Patent Law Reform: Hearings on H.R. 3285 H.R. 3286, and H.R. 3605 before the Subcommittee on Courts, Civil Liberties, and the Administration of Justice of the House Committee on the Judiciary*, 38th Cong. 2d Sess., Part 1, at p. 444 (1984) (hereinafter "*Hearings*") (Mem. of American Home Products, et al.). *See also* H. Rep. No. 98-857, pt. 1 at 71 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2681 (Minority View of Rep. Bliley) ("the patent provisions of this bill also encourage patent 'jumping' and litigation over the validity of patents"). Generic manufacturers have been given a substantial financial bounty for successfully challenging the validity of pharmaceutical patents.[4]

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[3] The Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355).

[4] The first applicant to file an Abbreviated New Drug Application with a Paragraph IV Certification is entitled to 180 days of generic market exclusivity beginning upon the first day the applicant brings its product to market, or upon a final decision by a court finding the patent to be invalid or not infringed, whichever is earlier. 21 U.S.C. § 355(j)(5)(B)(iv). This 180 days of generic market exclusivity is, of course, of tremendous value to a generic manufacturer. In the case of a "blockbuster" drug like Cipro, that 180 days of market exclusivity could be worth hundreds of millions of dollars to the generic "first filer." *See* Alfred Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA Journal of Law and Technology 389 (1999) (noting

Congress' program has been a huge success, with generic manufacturers prevailing in more than 73% of patent challenges litigated to conclusion. Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study, at 16 (July 2002), *available at* http://www.ftc.gov/os/2002/07 genericdrugstudy.pdf ("FTC Study"). As a result, generics make up 63 percent of drugs prescribed today, whereas generics constituted only 12% of prescription drugs dispensed prior to the passage of the Hatch-Waxman Act. Press Release, IMS Health, IMS Health Reports U.S. Prescription Sales Jump 8.3 Percent in 2006, to $274.9 billion (March 7, 2007) available at http://imshealth.com/ims/ portal/front/articleC/0,2777,6599_3665_80415465,00.html; Food And Drug Administration, From Test Tube to Patient: Protecting America's Health Through Human Drugs, Fourth Edition, (January 2006), available at http://www.fda.gov/ fdac/special/testtubetopatient/generics.html.

In creating the incentive to challenge patents, Congress was not seeking simply to line the pockets of the generic drug manufacturers. Hatch-Waxman challenges were supposed to be vehicles for earlier entry of generic drugs into the marketplace, thus giving consumers earlier access to lower-priced prescription drug alternatives. H. Rep. No. 98-857, pt. 1 at 1 (1984), *reprinted in* 1984

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the "large profit windfall which results from being the first . . . approved generic manufacturer able to compete for market share with a high-priced brand-name product").

U.S.C.C.A.N. 2647 (the purpose of the Hatch-Waxman Act "is to make available more low cost generic drug by establishing a generic drug approval procedure"). Exclusion payment agreements have exactly the opposite effect. Under the exclusion payment agreement here, for example, Bayer paid its generic competitors $398 million in exchange for the generics' agreement to stay out of the market for 6 1/2 of the remaining 7-year life of the Cipro patent.[5] In other words, Defendants' agreement ensured that consumers would have to wait another 6 1/2 years to buy lower-priced generic ciprofloxacin.

I. PERMITTING EXCLUSION PAYMENTS WOULD EVISCERATE THE HATCH-WAXMAN ACT'S PATENT-CHALLENGE PROVISIONS.

Rarely is there as direct a connection between a judge-made rule and a profound effect on consumers as there is in this case. If exclusion payments are lawful, pharmaceutical patentees will use them to terminate patent challenges that would otherwise generate *billions* of dollars in consumer savings.

The enormous consumer gains resulting from generic entry are well documented. The Federal Trade Commission ("FTC") has found that successful

[5] This is one of many facts that distinguishes the *Cipro* case from cases like *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2005). Unlike the agreement here, the agreement in *Tamoxifen* permitted Barr to enter for nine of the remaining ten years of the patent term. *Id.* at 194, 215. The agreement here foreclosed entry for all but six months of the remaining seven year patent term.

patent challenges to just four major brand-name drugs (Prozac, Zantac, Taxol and Platinol) have saved consumers more than $9 billion. Prepared Statement of the Federal Trade Commission, at 4 (Jan. 17, 2007), (hereafter "FTC Prepared Statement"), *available at* http://www.ftc.gov/speeches/leibowitz/070117 anticompetitivepatentsettlements_senate.pdf.

Had exclusion payments been permissible, none of these consumer savings likely would have occurred. In the midst of Barr Laboratories' challenge to the patents protecting Eli Lilly's drug Prozac, for example, Barr stated that it would settle only if the agreement included an exclusion payment of at least $200 million. *See* Bethany Mclean, *A Bitter Pill*, FORTUNE, Aug. 2001, at 5. Lilly refused the demand because, as acknowledged by Lilly's CEO, "such a settlement violated antitrust laws, and it isn't morally right." *Id.* So Barr continued litigating the case and ultimately obtained a judgment invalidating the Prozac patents. The resulting early entry of generic Prozac saved consumers an estimated $2.5 billion. *See* Comment of the Generic Pharmaceutical Ass'n in Support of Citizen Pet., FDA Docket No. 2004P-0075/CP1, at p. 3 (filed May 21, 2004), *available at http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00003-vol1.pdf.*

Another example involves Glaxo SmithKline's blockbuster drug, Paxil. In September 2003, after a district court ruled that Apotex did not infringe Glaxo

SmithKline's patents, Apotex launched its generic Paxil product. This launch came while the district court ruling was on appeal and more than three years before the patent was slated to expire. *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1052 (N.D. Ill. 2003). In April 2005, this Court affirmed the judgment in favor of Apotex. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1334 (Fed. Cir. 2005). Assuming an average generic penetration rate of 75%, a generic discount of 45% off the brand price, and a market of $2 billion per year (at the brand price), the savings to consumers from September 2003 until April 2005 (when the patent litigation concluded) are estimated at more than $1 billion; the savings from September 2003 until December 2006 (when the patent expired) exceeded $ 2 billion.

If exclusion payments were permissible under the antitrust law -- if the CEOs of Lilly and the other manufacturers are told that they are *wrong* to believe that an exclusion payment settlement "violate[s] antitrust laws, and it isn't morally right" -- such settlements would very likely become the norm.

The vast majority of pharmaceutical patent cases can be settled. Keith Leffler and Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F. L. Rev. 33, 42 (Fall 2004).[6] The

[6] Of course, not all pharmaceutical patent cases that can be settled are in fact settled. Factors extraneous to the merits of a particular case sometimes make settlement unattractive to one or more of the parties. For example, the patentee

wide disparity between the profits gained by a generic challenger and the profits lost by the brand manufacturer when a generic enters allows for a wide range of settlement possibilities. *Id.; see also* FTC Prepared Statement at 10-11 (given this disparity, "it will typically be more profitable for both parties if the brand-name manufacturer pays the generic manufacturer to settle the patent dispute and agree to defer entry"). Even if a generic challenger believes that there is a 100% certainty that the patent will be found to be invalid, the case can nevertheless be settled with either an exclusion payment or an early entry license if the patentee believes that there is anywhere from a 6% to a 100% chance of invalidity. Leffler, *Efficiency Trade-Offs*, at 42-43.

To consumers, settlements achieved by means of exclusion payments are vastly different from settlements achieved by means of early-entry licenses. Consumers benefit only from the latter. In the former, the patentee obtains exclusion based not on the strength of its patent, but on the strength of its capital. The generics firm, meanwhile, generates returns not by earning profits on sales, but by agreeing *not* to make sales in exchange for a share of the resulting monopoly rents. With a licensing settlement, the patentee obtains exclusion based only on the

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lacks incentive to settle if he has another entry-defeating tactic in reserve in the event of a loss in the patent litigation. *See, e.g., Abbott Laboratories v. Teva Pharms. USA Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006) (by the time patentee had lost patent litigation, patentee had switched branded product from capsules to tablets, thus preventing FDA from approving substitutable generic).

strength of the patent, and the generic earns profits only by selling a product to consumers at a price below that charged by the patentee.[7] In essence, the license settlement liquidates and delivers to consumers their expected (i.e., risk-adjusted) gains from the patent litigation.

Both the brand and generic manufacturers have a strong economic incentive to divide the monopoly profits between themselves by means of an exclusion payment rather than to share those profits with consumers by means of licensed generic entry. Leffler, *Efficiency Trade-Offs*, at 44. Licensed entry gains far less profits for the generic than it loses for the brand, and consumers get the difference. Both parties' economic incentive, therefore, is for the brand to simply pay the generic and split the amount that licensed entry would have brought to consumers. *See* FTC Prepared Statement at 11 ("by eliminating the potential for competition, the parties can share the consumer savings that would result if they were to

[7] Leffler, *Efficiency Trade-Offs*, 39 U.S.F. L. Rev. at 44 (" A licensing settlement is of value to a patent challenger only because it allows the challenger to enter the market in competition with the patent holder. The economic expectation is that the licensee will take sales from the patent holder by offering more favorable prices.") In this way, a licensing settlement void of cash payments will "mimic the consumer benefits that would be expected from the patent litigation rules and procedures enacted by Congress." *Id.* at 39. The royalty rate will reflect the parties' relative view of the strength of the patent: "[t]he greater the cash payments, the later the licensing entry date or the higher the royalty that will be acceptable to the generic." *Id.* at 45. Licensing settlements void of cash payments, therefore, reflect the very market forces that the antitrust laws work to preserve.

compete"). So, except in the rare instance in which each party believes that he is virtually certain to win, pharmaceutical patent cases can always be settled, and both parties' economic incentive is to settle with an exclusion payment rather than licensed entry.

This economic analysis has been dramatically confirmed by recent events. In connection with a consent decree obtained in one of the early exclusion payment cases, the FTC announced in 2000 that it would henceforth aggressively prosecute exclusion payment pharmaceutical settlements. *Abbott Labs. and Geneva Pharms.*, No. C-3945, (FTC Mar. 16, 2000) (Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle and Thomas B. Leary), *available at* http://www.ftc.gov/os/2000/03/hoeschtandrxcommstmt.htm. Pharmaceutical manufacturers responded by no longer settling with exclusion payments. Instead, they settled at the same rate as they had before, but they did so the traditional way -- with early-entry licenses. FTC Prepared Statement at 13. But then came the Eleventh Circuit's reversal of the FTC's decision in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), the district court decision here and the Second Circuit's decision in *Tamoxifen* -- all of which found exclusion payment settlements to be lawful. The pharmaceutical manufacturers' response was swift and dramatic: in fiscal 2006, 9 of the 11 Hatch-Waxman litigation settlements with generic "first filers" included

exclusion payments. FTC Prepared Statement at 17. Based on what is publicly known about these nine settlements, they could deprive consumers of *billions* of dollars in expected savings.

If the district court's view prevails, *all* Hatch-Waxman cases that can be settled would likely be settled with exclusion payments. The patent-challenge provisions of the Hatch-Waxman Act would be eviscerated, and American consumers would be left to pay the price.

II. THE DISTRICT COURT'S JUSTIFICATION FOR DECLARING EXCLUSION PAYMENTS *PER SE* LAWFUL IS UNSUPPORTED.

The consumer loss that would result if exclusion payment settlements are permitted would not be ameliorated by any offsetting long-term benefits of such a ruling. While the district court offered a few such justifications, none withstands scrutiny. There is no evidence that outlawing exclusion payments would save society the costs of patent litigation. *Cipro III*, 363 F. Supp. 2d at 529. Nor is there any evidence that "the market would correct for any bolstering of flagrantly invalid patents by way of exclusion payments." *Id.* at 535.

A. Exclusion Payments Are Not Necessary To Save Litigation Costs.

According to the district court, permitting exclusion payment settlements is necessary for society to save the costs of patent litigation because prohibiting

exclusion payments "might chill patent settlements altogether." *See Cipro III*, 363 F. Supp. 2d at 529.[8] Several facts undercut this assumption.

First, exclusion payments will not "chill patent settlements altogether," but will just channel settlements into other, pro-competitive forms. Economic analysis shows that exclusion payments are not necessary to achieve any substantial number of efficient settlements. *See, e.g.*, Cristofer Leffler & Keith Leffler, *Settling the Controversy Over Patent Settlements: Payments by the Patent Holders Should be Per Se Illegal*, 21 Res. L. & Econ. 475, 483-86 (2004) (exclusion payments are necessary to achieve an efficient settlement in less than one-half of one percent of possible cases). Indeed, exclusion payment settlements were "virtually unheard of" until this recent spate of settlements in the pharmaceutical industry. Herbert Hovenkamp, et al., *Anticompetitive Settlement Of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1757 n.166 (2003). Patent litigants historically have settled their cases by means of licensed entry. During the period when the FTC was successfully prosecuting exclusion payment agreements, pharmaceutical

[8] This same faulty assumption was picked up and relied upon by Second Circuit in *Tamoxifen*. 466 F.3d at 204 (quoting *Cipro III*, 363 F. Supp. 2d at 529). With no record evidence on the issue, the *Tamoxifen* majority simply *assumed* that holding exclusion payments to be unlawful would "severely restrict [] patent settlements," *id.* at 203, and, indeed, that outlawing such payments would be tantamount to "outlaw[ing] all, or nearly all, settlement of Hatch-Waxman infringement actions," *id.* at 211, and "forcing patent litigation to continue," *id*. at 203.

manufacturers had no difficulty at all in settling cases without exclusion payments. FTC Prepared Statement at 13 (litigants settled at the same rate and simply found "different ways to resolve their disputes, presumably on the basis of the relative strength of their cases").

Second, the wide disparity between the profits gained by a generic challenger and the profits lost by the brand manufacturer when a generic enters allows for a wide range of settlement possibilities. Leffler, *Efficiency Trade-Offs*, 39 U.S.F.L. Rev. at 42. Even if a generic challenger believes that there is a 100% chance that the patent will be found to be invalid, the case can nevertheless be settled with an exclusion payment if the patentee believes that there is anywhere from a 6% to a 100% chance of invalidity.[9] *Id.*

Third, even if a rule permitting exclusion payments would save some litigation costs, they are dwarfed by the lost consumer welfare that would result from propping up weak patents. The annual costs for *all* patent litigation in the United States are approximately $1 billion. *Schering*, 402 F.3d at 1075. As noted

[9] Of course, not all pharmaceutical patent cases that can be settled are in fact settled. Factors extraneous to the merits of a particular case sometimes make settlement unattractive to one or more of the parties. For example, the patentee lacks incentive to settle if he has another entry-defeating tactic in reserve in the event of a loss in the patent litigation. *See* Complaint, *CVS Pharmacy, Inc., et al. v. Abbott Laboratories, et al.*, No. 05-340-KAJ (D. Del. Aug. 17, 2005) (alleging that by the time patentee had lost patent litigation, patentee had switched branded product from capsules to tablets, thus preventing FDA from approving A-B-rated generic).

in detail above, consumers saved more than $2.5 billion on *one drug* when the manufacturer refused to make an exclusion payment based on the CEO's belief that such payments are unlawful. Litigation expenses are trivial in comparison to the lost consumer welfare that results from exclusion payments. *See* Herbert Hovenkamp, et al., *Balancing Ease & Accuracy In Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712, 716-17 (2004) ("while patent litigation is not cheap, it is a tiny fraction of the amount of money that is at stake in the cases we are discussing"); *see also Blonder-Tongue Laboratories, Inc. v. Univ. of Illinois Found.*, 402 U.S. 313, 349 (1971) ("the economic consequences of [permitting the patentee to repeatedly litigate validity] are serious and any reduction of litigation in this context is by comparison an incidental matter").

The district court failed to appreciate "the importance to the public at large of resolving questions of patent validity" so that society does not "grant monopoly privileges to the holders of invalid patents." *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-101 (1993). While patent litigation is costly, Plaintiffs' analysis would permit payments up to the amount of saved litigation costs; therefore, by definition, exclusion payments found unlawful under this analysis would result in lost consumer welfare greatly disproportionate to the relatively modest costs of patent litigation. Hovenkamp., *Balancing Ease and Accuracy*, 88 Minn. L. Rev. at 717.

B. Exclusion Payment Agreements Delay Subsequent Challenges.

While the district court expressly acknowledged that "the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity," it set aside this concern because, in the court's view, "the answer to this concern lies in the fact that . . . [through challenges by other generic manufacturers] the market would correct for any bolstering of flagrantly invalid patents by way of exclusion payments." *Cipro III*, 363 F. Supp. 2d at 534-35. The *evidence* in this record belies that assumption.

Substantial entry barriers -- including an automatic 30-month stay of generic entry, 21 U.S.C. §355(j)(5)(B)(iii) -- prevent subsequent challengers from immediately picking up where the first challenger left off. *See also* Herbert Hovenkamp, et al., IP and Antitrust, §7.4 at 7-37 (2006 Supp.) ("The regulatory scheme for pharmaceutical patents means that by settling with an ANDA filer, a patent owner can delay entry by any other generic for three years or more").

The potential competition afforded by other generic manufacturers has economic significance only if they can *immediately* pick up where the settling generic left off. *See, e.g., Geneva Pharm. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 499 (2d Cir. 2004) (noting regulatory barriers and holding that they can be ignored only when there is "evidence that other generic pharmaceutical manufacturers could *quickly and* easily have entered the . . . market" (emphasis

added)). This is not likely to ever be the case with respect to exclusion payments, because in that circumstance the patentee would gain nothing by the payment and therefore would not make the payment. Put affirmatively, the fact that the patentee made the payment is good evidence that it will result in (at least) economically significant delay.

III. THE DISTRICT COURT'S ANALYSIS CONFLICTS WITH THE FACTS AND CONGRESSIONAL INTENT.

The district court's analysis also conflicts with the fundamental economic facts and with clear Congressional intent. The factual conflict is evident. As two other Courts of Appeals have held, the assertion that a patent has ironclad exclusionary power until invalidated in court is contrary to the fundamental reality that the patentee in fact paid the generic to withdraw the patent challenge. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 914-15 (6th Cir. 2003); *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 813 (D.C Cir. 2001). If the patent had ironclad exclusionary power, why did the patentees pay their generic competitors tens or hundreds of millions of dollars to abandon their challenges? The *Cipro* analysis cannot explain the fundamental economic fact in the case -- the fact that the patentee paid huge sums to the challenger.

The patentee made this payment because Congress created a patent system in which the rebuttable presumption of validity is only one small, relatively insignificant part. The far more economically relevant parts of that system are that

patents are issued *ex parte* and are subject to plenary review in the courts. Courts in fact find approximately half of all litigated patents to be invalid. *See* John Allison and Mark Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q. J. 185, 206 (1998). And in pharmaceutical patent cases, the generic challengers succeed more than 70% of the time. FTC Study at 16.

As to pharmaceutical patents, Congress not only made court review plenary, but also offered a bounty for successful generic challengers. 21 U.S.C. §355(j)(5)(B)(iv) (offering 180 days of exclusivity to the first generic manufacturer to lodge a patent challenge). There is simply no basis for courts to permit patentees to pay generics to end challenges that Congress specifically encouraged.

Moreover, Congress granted pharmaceutical patentees the ability to automatically exclude generic challengers, but only for a limited period of time -- 30 months. After the expiration of 30 months, the FDA is free to approve a generic drug for marketing regardless of whether patent litigation is ongoing. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Having withheld automatic exclusion beyond 30 months, surely Congress did not intend for patentees to be permitted to pay for that exclusion.

Finally, exclusion payment agreements recently earned Congress' bipartisan condemnation and a requirement that all such agreements be provided to the FTC

and the Department of Justice for their scrutiny and action.[10] *See, e.g.*, 148 CONG. REC. S7566 (daily ed. July 20, 2002) (remarks of Sen. Hatch) ("As coauthor of the [Hatch-Waxman Act], I can tell you that I find these type of reverse payment collusive arrangements appalling"); 146 CONG. REC. E1538-02 (daily ed. Sept. 20, 2000) (remarks of Rep. Waxman) ("requir[ing] companies seeking to reach secret, anticompetitive agreements to disclose them to the FTC . . . [will] ensure that existing antitrust and drug approval laws are enforced to the letter"); 147 CONG. REC. S3711 (daily ed. Apr. 6, 2001) (remarks of Sen. Leahy) (legislation is intended to give to the FTC "the information they need to prevent manufacturers of patented drugs -- often brand-name drugs -- from simply paying generic drug companies to keep lower-cost products off the market"). Congress certainly did not intend such reporting to be a futile gesture.

CONCLUSION

American consumers, have been and will continue to be harmed if exclusion payment settlements are a viable option for branded manufacturers seeking to avoid generic competition. *Amici* respectfully submits that this Court should acknowledge that the statutory rebuttable presumption of patent validity does not entitle patentees to pay alleged infringers not to contest validity and to

[10] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

stay out of the market. The grant of summary judgment should be reversed and the Appellants' case should be remanded for further proceedings in the district court.

Respectfully submitted,

February 7, 2008

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CERTIFICATE OF COMPLIANCE

I, do hereby certify pursuant to Federal Rule of Appellate Procedure 32(a)(7)(B) that the foregoing Corrected Brief Of *Amici Curiae* AARP, Consumer Federation of America, Prescription Access Litigation, and Public Patent Foundation In Support Of Appellants conforms to Federal Rule of Appellate Procedure 32(a)(5), 32(a)(6), and 32(a)(7).

I further certify that according to the word count of the word processing system Microsoft Office Word 2003 used to prepare this brief, the relevant portion of this brief contains 3463 words. This brief was printed using a 14 point proportional Times New Roman font.

February 7, 2008

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CERTIFICATE OF SERVICE

I hereby certify that on February 7, 2008, the foregoing Corrected brief *amici curiae* in *Arkansas Carpenters Health and Welfare Fund, Paper, et al. v. Bayer AG and Bayer Corp, et al*. was filed with the Clerk of U.S. Court of Appeals for the Federal Circuit, and copies were mailed by first class mail to counsel listed below:

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