

**UNITED STATES DISTRICT COURT FOR
THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division**

TRIANAFYLLOS TAFAS,

Plaintiff,

v.

JON W. DUDAS, *et al.*,

Defendants.

CIVIL ACTION: 1:07-CV-846 (JCC/TRJ)

CONSOLIDATED WITH

**SMITHKLINE BEECHAM
CORPORATION, *et al.*,**

Plaintiffs,

v.

JON W. DUDAS, *et al.*,

Defendants.

CIVIL ACTION: 1:07-CV-1008 (JCC/TRJ)

**ANSWER TO PLAINTIFF TRIANAFYLLOS TAFAS'S FIRST AMENDED
COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF AND PETITION
FOR REVIEW OF RULEMAKING**

Pursuant to Federal Rules of Civil Procedure 8(b) and 8(c), Defendants, Jon W. Dudas, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and the United States Patent and Trademark Office (collectively "USPTO") respectfully answer The allegations of Plaintiff Triantafyllos Tafas's ("Plaintiff's") First Amended Complaint for Declaratory and Injunctive Relief and Petition for Review of Rulemaking ("Amended Complaint"), filed on September 7, 2007. 1:07-CV-846, Dkt. No. 14.

FIRST DEFENSE

The final rules¹ concerning the filing of continuing applications and claims that the USPTO published on August 21, 2007, see “Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications; Final Rule, 72 Fed. Reg. No. 46716, 46718 (Aug. 21, 2007), comport and were promulgated in accordance with the United States Constitution, United States Treaties such as the Patent Cooperation Treaty, Jan. 24, 1978, 28 U.S.T. 7645, and all statutes, including the Patent Act, 35 U.S.C. § 1, et seq., the Administrative Procedures Act (“APA”), 5 U.S.C. §§ 553, 701-706, and the Regulatory Flexibility Act (“RFA”), 5 U.S.C. §§ 601-612.

SECOND DEFENSE

Plaintiff has waived any objections to the Revised Rules that were not raised to the USPTO during the notice and comment period.

THIRD DEFENSE

Plaintiff lacks prudential standing to raise many of the arguments in his Amended Complaint.

FOURTH DEFENSE

The USPTO reserves the right to supplement, amend, or modify the foregoing defenses and to assert additional defenses.

¹ Throughout Plaintiff’s Amended Complaint, he refers to the Final Rules in general as the “Revised Rules.” For purposes of answering the Amended Complaint and to avoid confusion, Defendant will adopt Plaintiff’s shorthand abbreviation for purposes of answering Plaintiff’s Amended Complaint.

ANSWER TO NUMBERED PARAGRAPHS

The USPTO answers the correspondingly numbered paragraphs of Plaintiff's Amended Complaint as follows:

Parties

1. The USPTO admits that Plaintiff is named as an inventor on U.S. Patent Application No. 11/266948; that he subsequently filed four continuation-in-part applications of that application; and that he is a named inventor on more than seventeen pending patent applications and eight issued U.S. patents. The last sentence of paragraph one contains a conclusion of law to which no response is required. To the extent it is deemed an allegation of fact, the USPTO lacks knowledge sufficient to admit or deny the allegation. The USPTO is without knowledge or information sufficient to admit or deny the remaining allegations contained in paragraph one.

2. The USPTO denies the allegations contained in paragraph two. The USPTO is an agency of the United States, within the Department of Commerce. The USPTO is located in Alexandria, Virginia 22314 and occupies several buildings there, one of which is located at 600 Dulany Street.

3. The USPTO admits that Jon W. Dudas is the Under-Secretary of Commerce for Intellectual Property and the Director of the USPTO and is being sued in his official capacity. The USPTO denies that the service address for Under-Secretary Dudas is set forth in paragraph two of the Amended Complaint. The USPTO avers that the service address for Under-Secretary Dudas is P.O. Box 15667, Arlington, Virginia 22215.

Jurisdiction and Venue

4. The allegations contained in paragraph four are conclusions of law to which no response is required. To the extent they are deemed allegations of fact, they are denied.

5. The allegation contained in paragraph five is a conclusion of law to which no response is required. To the extent it is deemed an allegation of fact, it is admitted.

Nature of Action

6. The allegations contained in paragraph six represent Plaintiff's characterization of his lawsuit to which no response is required. To the extent they are deemed allegations of fact, they are denied.

7. The allegations contained in paragraph seven constitute conclusions of law to which no response is required. To the extent they are deemed allegations of fact, they are denied.

Facts Applicable to All Counts

8. The USPTO admits the allegations contained in paragraph eight.

9. The USPTO admits that the USPTO solicited comments from the public on Proposed Rules I (Continuing Applications) and II (Claims) and further admits that it did not hold formal public hearings on those rules.² The USPTO avers that formal hearings were not required under the APA. The USPTO avers that it held town hall meetings to inform the public about Proposed Rules I and II. The USPTO lacks knowledge sufficient to admit or deny the allegations of the second sentence of this paragraph regarding the comparative number of

² In using the shorthand abbreviation "Proposed Rule I" and "Proposed Rule II," Plaintiff Tafas is referring to proposed rules concerning the filing of continuing applications and claims that USPTO published in January of 2006. See Changes to Practice for Continuing Applications, Requests for Continuing Applications, Requests for Continued Examination Practice, and Applications Concerning Patentably Indistinct Claims, 71 Fed. Reg. 48-61 (Jan. 3, 2006);

“extensively briefed negative comments” in this rulemaking relative to all proposed rulemakings by the USPTO in its history. The third sentence of the paragraph refers to Plaintiff’s characterizations of the nature of the comments received by the USPTO about Proposed Rule II. The administrative record contains the public comments on the proposed rules; the Court and the parties are referred to that record for a full, complete, and accurate statement of the content of the public comments.

10. The USPTO lacks knowledge sufficient to admit or deny the allegations of paragraph ten regarding public rumors in April of 2007 about Proposed Rules I and II. The USPTO denies the remaining allegations in paragraph ten.

11. The USPTO admits that it received FOIA requests concerning the Proposed Rules, some of which may have encompassed the subjects referenced in the first sentence of paragraph 11. The USPTO denies the second sentence of paragraph eleven. The USPTO avers that it has responded to all FOIA requests in compliance with the requirements of 5 U.S.C. § 552 et seq. The third sentence of paragraph eleven, which refers to “non-privileged memoranda,” states a legal conclusion to which no response is required. To the extent this allegation is deemed to be an allegation of fact, the broad phrase “non-privileged memoranda,” which could encompass even legal memoranda filed in this litigation, lacks sufficient specificity to allow the USPTO to admit or deny the allegation.

12. The USPTO denies the allegations contained in paragraph twelve that the USPTO published a Final Rule in the Federal Register “purporting to issue” final regulations entitled “Changes to Practice for Continued Examination of Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications.” The USPTO

Changes to Practice for the Examination of Claims in Patent Applications, 71 Fed. Reg. 61-69 (Jan. 3, 2006).

avers that it did issue final regulations entitled “Changes to Practice for Continued Examination of Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications.” The USPTO admits that the Revised Rules amend 37 C.F.R. §§ 1.75, 1.78, 1.265, and 1.704, among other sections. The Court and the parties are referred to the administrative record, which contains the text of the Revised Rules, for a full, complete, and accurate statement of their content. The USPTO admits that the Revised Rules have an effective date of November 1, 2007 but avers that the effective date was suspended by this Court’s issuance of an Order preliminarily enjoining the Revised Rules on October 31, 2007.

13. The allegations of the first sentence of paragraph thirteen are Plaintiff’s characterizations of the provisions in Revised Rule I (i.e., 37 C.F.R. § 1.78(d)(1)(vi)). The administrative record contains the text of Revised Rule I. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of their content. The allegation of the second sentence of paragraph thirteen constitutes a conclusion of law to which no response is required. To the extent that any of the allegations of this paragraph are deemed to be allegations of fact, they are denied.

14. The allegations of paragraph fourteen are Plaintiff’s characterizations and legal conclusions regarding Revised Rule I (i.e., 37 C.F.R. § 1.78(d)(1)(vi)). The administrative record contains the text of Revised Rule I. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of their content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

15. The allegations of paragraph fifteen are Plaintiff’s characterizations and legal conclusions regarding Revised Rule I (i.e., 37 C.F.R. §1.78(f)). The administrative record contains the text of Revised Rule I. The Court and the parties are referred to the administrative

record for a full, complete, and accurate statement of their content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

16. The allegation of the first sentence of paragraph sixteen is a conclusion of law to which no response is required. To the extent it is deemed to be an allegation of fact, it is denied. The remaining allegations in paragraph sixteen are Plaintiff's characterizations and conclusions of law regarding Revised Rule I (i.e., 37 C.F.R. §1.78(d)). The administrative record contains the text of Revised Rule I. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of their content. To the extent these remaining allegations are deemed to be allegations of fact, they are denied.

17. The allegations of paragraph seventeen are Plaintiff's characterizations and conclusions of law regarding the rebuttable presumption of Revised Rule I (i.e., 37 C.F.R. §1.78(f)(2)(i)). The administrative record contains the text of Revised Rule I. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of their content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

18. The allegations of paragraph eighteen are Plaintiff's characterizations and legal conclusions regarding how to rebut the presumption of Revised Rule I (i.e., 37 C.F.R. §1.78(f)(2)(ii)). The administrative record contains the text of Revised Rule I. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of their content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

19. The allegations of paragraph nineteen are Plaintiff's characterizations and legal conclusions regarding Revised Rule II (i.e., 37 C.F.R. §1.75). The administrative record

contains the text of Revised Rule II. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of their content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

20. The allegations of paragraph twenty are Plaintiff's characterizations and legal conclusions regarding Revised Rule 37 C.F.R. § 1.704. The administrative record contains the text of Revised Rule 37 C.F.R. § 1.704. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of their content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

21. The allegations of paragraph twenty-one constitute conclusions of law to which no response is required. To the extent they are deemed to be allegations of fact, they are denied.

22. The USPTO is without knowledge or information sufficient to admit or deny the allegation of the first sentence of paragraph twenty-two regarding the importance of continuing applications to Plaintiff. The allegation of the second sentence of paragraph twenty-two regarding priority constitutes a conclusion of law to which no response is required. To the extent the allegation of this second sentence is deemed to be an allegation of fact, it is denied.

23. The allegations of the first sentence of paragraph twenty-three regarding current law for claims are legal conclusions to which no response is required. To the extent the allegations of this first sentence are deemed to be allegations of fact, they are denied. The USPTO is without knowledge or information sufficient to admit or deny the allegations of the second sentence of paragraph twenty-three.

24. The allegations of paragraph twenty-four are legal conclusions to which no response is required. To the extent they are deemed to be allegations of fact, they are denied.

25. The allegations of paragraph twenty-five are legal conclusions to which no response is required. To the extent they are deemed to be allegations of fact, they are denied.

26. The allegations of paragraph twenty-six include Plaintiff's characterizations and legal conclusions regarding prior law and the Revised Rules to which no response is required. To the extent they are deemed to be allegations of fact, they are denied.

27. The allegations of paragraph twenty-seven are Plaintiff's characterizations and legal conclusions as to the impact of the Revised Rules on applicants to which no response is required. To the extent they are deemed to be allegations of fact, they are denied.

28. The allegations of paragraph twenty-eight are Plaintiff's characterizations and legal conclusions as to the impact of the Revised Rules on applicants to which no response is required. The administrative record contains the text of the Revised Rules. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of their content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

29. The allegations of paragraph twenty-nine are Plaintiff's characterizations of the provisions of Revised Rule I (i.e., 37 C.F.R. 1.78(a)(2)) to which no response is required. The administrative record contains the text of Revised Rule I. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

30. The allegations of paragraph thirty are Plaintiff's characterizations and legal conclusions as to the provisions and impact of Revised Rule II (i.e., 37 C.F.R. 1.75(b)) on applicants to which no response is required. The administrative record contains the text of Revised Rule II. The Court and the parties are referred to the administrative record for a full,

complete, and accurate statement of their content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

31. The allegations of paragraph thirty-one state a legal conclusion to which no response is required. To the extent they are deemed to be allegations of fact, they are denied.

32. The allegations of paragraph thirty-two are Plaintiff's characterizations and legal conclusions regarding the Revised Rules and their effect on Plaintiff's "rights concerning the filing of future continuing applications" to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

33. The USPTO is without knowledge or information sufficient to admit or deny the allegations contained in paragraph thirty-three.

34. The allegations of paragraph thirty-four are Plaintiff's characterizations and legal conclusions regarding the Revised Rules and "the U.S. patent laws" to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

FIRST COUNT

35. The USPTO incorporates by reference the answers to paragraphs one to thirty-four herein.

36. The allegations of paragraph thirty-six are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the parties are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

37. The allegations of paragraph thirty-seven are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the

parties are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

38. The allegations of paragraph thirty-eight are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the parties are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

39. The allegations of paragraph thirty-nine are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the parties are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

40. The allegations of paragraph forty are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the parties are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

41. The allegations of paragraph forty-one are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the parties are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

42. The allegations of paragraph forty-two are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the parties are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

43. The allegations of paragraph forty-three are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the parties are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

44. The allegations of paragraph forty-four are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the parties are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

45. The allegations of paragraph forty-five are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the parties are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

46. The allegations of paragraph forty-six are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the parties are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

47. The allegations of paragraph forty-seven are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the parties are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

48. The allegations of paragraph forty-eight are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the parties

are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

49. The allegations of paragraph forty-nine are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the parties are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

50. The allegations of paragraph fifty are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the parties are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

51. The allegations of paragraph fifty-one are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the parties are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

52. The allegations of paragraph fifty-two are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the parties are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

53. The allegations of paragraph fifty-three are Plaintiff's characterizations and legal conclusions regarding the Patent Act to which no response is required. The Court and the parties

are referred to the Patent Act for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

54. The allegations of paragraph fifty-four are Plaintiff's characterizations and legal conclusions regarding the APA to which no response is required. The Court and the parties are referred to the APA for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

55. The allegations of paragraph fifty-five are legal conclusions to which no response is required. To the extent they are deemed to be allegations of fact, they are denied.

56. The allegations of paragraph fifty-six, including The allegations of subparagraphs (a) to (n), are legal conclusions to which no response is required. To the extent they are deemed to be allegations of fact, they are denied.

57. The allegations of paragraph fifty-seven are legal conclusions to which no response is required. To the extent they are deemed to be allegations of fact, they are denied.

SECOND COUNT

58. The USPTO incorporates by reference the answers to paragraphs one to fifty-seven herein.

59. The allegations of paragraph fifty-nine are Plaintiff's characterizations and legal conclusions regarding the APA to which no response is required. The Court and the parties are referred to the APA for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

60. The allegations of paragraph sixty are legal conclusions to which no response is required. To the extent they are deemed to be allegations of fact, they are denied.

61. The allegations of paragraph sixty-one are legal conclusions to which no response is required. To the extent they are deemed to be allegations of fact, they are denied.

THIRD COUNT

62. The USPTO incorporates by reference the answers to paragraphs one to sixty-one herein.

63. The allegations of paragraph sixty-three are Plaintiff's characterizations and legal conclusions regarding the APA to which no response is required. The Court and the parties are referred to the APA for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

64. The allegations of paragraph sixty-four, including subparagraphs (a) through (c), are legal conclusions to which no response is required. To the extent they are deemed to be allegations of fact, they are denied.

65. The allegations of paragraph sixty-five are Plaintiff's characterizations and legal conclusions regarding the APA to which no response is required. The Court and the parties are referred to the APA for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

66. The allegations of paragraph sixty-six are Plaintiff's characterizations and legal conclusions regarding the APA to which no response is required. The Court and the parties are referred to the APA for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

67. The allegations of paragraph sixty-seven are Plaintiff's characterizations and legal conclusions regarding the APA and the Patent Act to which no response is required. The Court

and the parties are referred to those statutes for a full, complete, and accurate statement of their content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

68. The allegations of paragraph sixty-eight are Plaintiff's characterizations and legal conclusions regarding the Revised Rules to which no response is required. The Court and the parties are referred to the administrative record, which contains the Revised Rules, for a full, complete, and accurate statement of their content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

69. The allegations of paragraph sixty-nine are Plaintiff's characterizations and legal conclusions regarding the APA to which no response is required. The Court and the parties are referred to the APA for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

70. The allegations of paragraph seventy are legal conclusions to which no response is required. To the extent they are deemed to be allegations of fact, they are denied.

71. The allegations of subparagraphs (a) to (i) of paragraph seventy-one are Plaintiff's characterizations and legal conclusions to which no response is required. The administrative record is the best evidence of the content of the proposed and final rules and speaks for itself. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

72. The allegation of paragraph seventy-two is a legal conclusion to which no response is required. To the extent it is deemed to be an allegation of fact, it is denied.

73. The allegations of paragraph seventy-three are legal conclusions to which no response is required. To the extent they are deemed to be allegations of fact, they are denied.

FOURTH COUNT

74. The USPTO incorporates by reference the answers to paragraphs one to seventy-three herein.

75. The allegation of paragraph seventy-five is a legal conclusion to which no response is required. To the extent it is deemed to be an allegation of fact, the USPTO lacks sufficient knowledge to admit or deny the allegation.

76. The allegations of paragraph seventy-six are Plaintiff's characterizations and legal conclusions regarding the RFA to which no response is required. The Court and the parties are referred to the RFA for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

77. The allegations of paragraph seventy-seven are Plaintiff's characterizations and legal conclusions regarding the RFA to which no response is required. The Court and the parties are referred to the RFA for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

78. The allegations of paragraph seventy-eight are Plaintiff's characterizations and legal conclusions regarding the RFA to which no response is required. The Court and the parties are referred to the RFA for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

79. The allegations of paragraph seventy-nine are Plaintiff's characterizations and legal conclusions regarding the RFA to which no response is required. The Court and the parties are referred to the RFA for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied..

80. The allegations of paragraph eighty are legal conclusions to which no response is required. To the extent they are deemed to be allegations of fact, they are denied.

81. The allegations of paragraph eighty-one are legal conclusions to which no response is required. To the extent they are deemed to be allegations of fact, they are denied.

82. The allegations of paragraph eighty-two are Plaintiff's characterizations and legal conclusions regarding the USPTO's certification pursuant to the RFA to which no response is required. The Court and the parties are referred to the administrative record, which contains the USPTO's certification pursuant to the RFA, for a full, complete, and accurate statement of its content. To the extent the allegations of this paragraph are deemed to be conclusions of fact, they are denied.

83. The allegations of paragraph eight-three are denied.

84. The allegations of paragraph eighty-four are legal conclusions to which no response is required. To the extent they are deemed to be allegations of fact, they are denied.

85. The allegations of paragraph eight-five are denied.

86. The allegations of paragraph eighty-six contain legal conclusions to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

The remaining allegations in the Amended Complaint are contained in a "Prayer for Relief" to which no response is required.

GENERAL DENIAL

Any allegation not specifically admitted or denied is expressly denied.

Jennifer M. McDowell
Associate Counsel

United States Patent and Trademark Office

CERTIFICATE OF SERVICE

I hereby certify that on November 14, 2007, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send a notification of such filing (NEF) to the following:

Joseph Dale Wilson, III
Kelley Drye & Warren LLP
Washington Harbour
3050 K Street NW
Suite 400
Washington, DC 20007
Email: jwilson@kelleydrye.com

Joanna Elizabeth Baden-Mayer
Collier Shannon & Scott PLLC
3050 K St NW
Suite 400
Washington, DC 20007-5108
E-mail: jbaden-mayer@kelleydrye.com

Counsel for Plaintiff Triantafyllos Tafas, 1:07cv846

Elizabeth Marie Locke
Kirkland & Ellis LLP
655 15th St NW
Suite 1200
Washington, DC 20005
Email: elocke@kirkland.com

Craig Crandell Reilly
Richard McGettigan Reilly & West PC
1725 Duke St
Suite 600
Alexandria, VA 22314
Email: craig.reilly@rmrwlaw.com

Daniel Sean Trainor
Kirkland & Ellis LLP
655 15th St NW
Suite 1200
Washington, DC 20005
Email: dtrainor@kirkland.com

Counsel for Plaintiffs SmithKline Beecham Corp. d/b/a GlaxoSmithKline, SmithKline Beecham PLC, and Glaxo Group Limited, d/b/a GlaxoSmithKline

Thomas J. O'Brien
Morgan, Lewis & Bockius
1111 Pennsylvania Ave, NW
Washington, DC 20004
Email: to'brien@morganlewis.com

Counsel for Amicus American Intellectual Property Lawyers Association

Dawn-Marie Bey
Kilpatrick Stockton LLP
700 13th St NW
Suite 800
Washington, DC 20005
Email: dbey@kslaw.com

Counsel for Amicus Hexas, LLC, The Roskamp Institute, Tikvah Therapeutics, Inc.

James Murphy Dowd
Wilmer Cutler Pickering Hale & Dorr LLP
1455 Pennsylvania Ave NW
Washington, DC 20004
Email: james.dowd@wilmerhale.com

Counsel for Putative Amicus Pharmaceutical Research and Manufacturers of America

Randall Karl Miller
Arnold & Porter LLP
1600 Tysons Blvd
Suite 900
McLean, VA 22102
Email: randall_miller@aporter.com

Counsel for Putative Amicus Biotechnology Industry Organization

Rebecca M. Carr
Pillsbury Winthrop Shaw Pittman, LLP
2300 N Street, NW
Washington, DC 20037
Rebecca.carr@pillsburylaw.com

Scott J. Pivnick
Pillsbury Winthrop Shaw Pittman
1650 Tysons Boulevard
McLean, Virginia 22102-4856

Scott.pivnick@pillsburylaw.com

Counsel for Amicus Elan Pharmaceuticals, Inc.

_____/s/

LAUREN A. WETZLER
Assistant United States Attorney
Justin W. Williams U.S. Attorney's Building
2100 Jamieson Avenue
Alexandria, Virginia 22314
Tel: (703) 299-3752
Fax: (703) 299-3983
Lauren.Wetzler@usdoj.gov

Counsel for All Defendants