

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

**TRANTAFYLLOS 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 SMITHKLINE BEECHAM'S  
VERIFIED AMENDED COMPLAINT**

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 in Plaintiff SmithKline Beecham Corporation et al.'s ("Plaintiff" or "GSK") Verified Amended Complaint ("Amended Complaint"), filed on October 11, 2007. 1:07-CV-1008, Dkt. No. 5.

**FIRST DEFENSE**

The Final Rules 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., and the Administrative Procedures Act (“APA”), 5 U.S.C. §§ 553, 701-706.<sup>1</sup>

**SECOND DEFENSE**

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

**THIRD DEFENSE**

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

**ANSWER TO SPECIFIC ALLEGATIONS**

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

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<sup>1</sup> The USPTO generally objects to Plaintiff’s inclusion of information and references in its Verified Amended Complaint that are not part of the administrative record certified by the USPTO. Materials outside the administrative record are not properly considered by this Court in adjudicating the merits of Plaintiff’s APA claims.

**I.**

1. The USPTO admits the first sentence of paragraph one. With respect to the second sentence of this paragraph, the USPTO refers the Court to the administrative record, which contains the text of the Final Rules, for a full, complete, and accurate statement of their content.

2. The USPTO admits the allegations in the first sentence of this paragraph. With respect to the remaining allegations of this paragraph, the administrative record contains the August 21, 2007 Federal Register notice, which details the effective dates of the Final Rules. The Court and the parties are referred to the administrative record for a full, complete, and accurate explanation of the applications to which the Final Rules apply. The USPTO avers that the November 1, 2007 effective date referenced in the August 21, 2007 Federal Register notice was suspended by this Court's issuance of an Order preliminarily enjoining the Final Rules on October 31, 2007.

3. The allegations of paragraph three are Plaintiff's request for relief, characterizations, and conclusions 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.

4. The USPTO is without knowledge or information sufficient to admit or deny the allegations in the first sentence of paragraph four regarding unspecified "damage" to unidentified "specific GSK patent applications." The USPTO is without knowledge or information sufficient to admit or deny the allegations in the second sentence of paragraph four regarding GSK's alleged pending patent applications.

5. The allegations of paragraph five are Plaintiff's request for relief, characterizations, and conclusions of law about the Patent Act and U.S. Constitution to which no

response is required. The Court and the parties are referred to the Patent Act and U.S. Constitution for a full, complete, and accurate statement of their content. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

6. The allegations of paragraph six are conclusions of law to which no response is required. The allegations in the second sentence are also Plaintiff's characterization of the Final Rules. The administrative record contains the text of the Final 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 that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

7. The allegations of paragraph seven are conclusions of law to which no response is required. The administrative record contains the August 21, 2007 Federal Register notice, which contains the text of the Final Rules. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of the content of the Federal Register notice and the Final Rules. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

8. The allegations in the third sentence of paragraph eight are Plaintiff's characterizations of the Final Rules. The administrative record contains the text of the Final Rules. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of their content. The remaining allegations of paragraph eight are conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

9. The allegations of paragraph nine are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

10. The allegations in paragraph ten are Plaintiff GSK's characterizations of the pleadings of Plaintiff Tafas, Plaintiff GSK, and defendant USPTO. The USPTO refers the Court and the parties to those pleadings for a full, complete, and accurate statement of their content.

11. The first sentence of paragraph eleven is Plaintiff GSK's characterizations of the pleadings of defendant USPTO. The USPTO refers the Court and the parties to those pleadings for a full, complete, and accurate statement of their content. The remaining sentences of paragraph eleven contain Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

12. The allegations of paragraph twelve are Plaintiff's characterizations and conclusions 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, except to admit that GSK has applied for patents using continuing applications and requests for continued examination and that GSK has presented multiple claims in at least some of its patent applications.

13. The allegations of paragraph thirteen contain Plaintiff's characterizations and conclusions of law regarding pending legislation. The Court and the parties are referred to the referenced bills for a full, complete, and accurate statement of their content. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied. The USPTO further avers that the quoted portion of H.R. 1908 is best read in context:

**SEC. 14. REGULATORY AUTHORITY.**

(a) REGULATORY AUTHORITY.—Section 2(c) is

amended by adding at the end the following:

“(6) **The powers granted under paragraph (2) of sub section (b) include** the authority to promulgate regulations to ensure the quality and timeliness of applications and their examination, including specifying circumstances under which an application for patent may claim the benefit under sections 120, 121 and 365(c) of the filing date of a prior filed application for patent.”

(b) CLARIFICATION.—The amendment made by subsection (a) **clarifies** the scope of power granted to the United States Patent and Trademark Office by paragraph (2) of section 2(b) of title 35, United States Code, as in effect since the enactment of Public Law 106–113.”

H.R. 1908 (emphasis added).

14. The allegations of paragraph fourteen are Plaintiff’s characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

15. The first sentence of paragraph fifteen states a conclusion of law to which no response is required. The second sentence of the paragraph contains Plaintiff’s characterizations and conclusions of law regarding Final Rule 37 C.F.R. § 1.265 to which no response is required. The administrative record contains the text of Final Rule 37 C.F.R. § 1.265. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of that rule. To the extent that any of the allegations of this paragraph are deemed to be allegations of fact, they are denied.

16. The allegations of paragraph sixteen are Plaintiff’s characterizations and conclusions of law regarding Final Rule 37 C.F.R. §1.265. The administrative record contains the text of Final Rule 37 C.F.R. § 1.265. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of that rule. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

17. The USPTO is without information or knowledge sufficient to admit or deny the allegations of paragraph seventeen that relate to GSK's knowledge of how to comply with the Final Rules. The remaining allegations of paragraph seventeen are Plaintiff's characterizations and conclusions of law regarding Final Rule 37 C.F.R. § 1.265(b). The administrative record contains the text of Final Rule 37 C.F.R. § 1.265. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of that rule. To the extent that these remaining allegations are deemed to be allegations of fact, they are denied.

18. The allegations of paragraph eighteen are Plaintiff's characterizations and conclusions of law regarding rule § 1.75(b), to which no response is required. The administrative record contains the text of rule § 1.75(b). The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of that rule. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

## II.

19. The allegations of paragraph nineteen are conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

20. The allegations in the first two sentences of paragraph twenty are conclusions of law to which no response is required. To the extent that the allegations of the first two sentences of the paragraph are deemed to be allegations of fact, they are denied. The USPTO lacks information or knowledge sufficient to admit or deny the remaining allegations in the third sentence of this paragraph.

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

22. The allegations of paragraph twenty-two are conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied, except to admit that the USPTO is located and has its principal office in Alexandria, Virginia.

23. The allegations of paragraph twenty-three are characterizations of the Plaintiff's lawsuit and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

24. The allegations of paragraph twenty-four relate to Plaintiff's requested relief and are conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

### **III. THE PARTIES**

25. The USPTO is without knowledge or information sufficient to admit or deny the allegations of paragraph twenty-five.

26. The USPTO is without knowledge or information sufficient to admit or deny the allegations of paragraph twenty-six.

27. The USPTO is without knowledge or information sufficient to admit or deny the allegations of paragraph twenty-seven.

28. The USPTO denies the allegation of the first sentence of paragraph twenty-eight. The USPTO avers that by statute, it is an agency of the United States, within the Department of Commerce. The USPTO admits the allegation of the second sentence of paragraph twenty-eight.



The allegations in the third and fourth sentences are Plaintiff's characterizations and legal conclusions about the duties and powers granted to the USPTO under 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 the duties and powers granted the USPTO under the Patent Act. To the extent that the allegations of the third and fourth sentences of this paragraph are deemed to be allegations of fact, they are denied.

29. The USPTO admits that Jon W. Dudas is the Under Secretary of Commerce for Intellectual Property and the Director of the USPTO ("Director"). The remaining allegations in the first sentence of this paragraph are Plaintiff's characterization of this suit, to which no response is required. The allegations in the second and third sentences of paragraph twenty-nine are Plaintiff's characterizations and legal conclusions about the duties and powers granted to the Director under 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 the duties and powers granted the USPTO under the Patent Act. To the extent that any of the allegations in the second or third sentence of this paragraph are deemed to be allegations of fact, they are denied.

30. The USPTO is without knowledge or information sufficient to admit or deny the allegations of paragraph thirty.

31. The USPTO is without knowledge or information sufficient to admit or deny the allegations of paragraph thirty-one.

32. The USPTO is without knowledge or information sufficient to admit or deny the allegations of paragraph thirty-two.

33. The allegations of paragraph thirty-three are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

#### IV.

34. The allegations of paragraph thirty-four are Plaintiff's characterizations and conclusions of law 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 that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

35. The allegations of paragraph thirty-five are Plaintiff's characterizations and conclusions of law 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 that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

36. The allegations of paragraph thirty-six are Plaintiff's characterizations and conclusions of law about the purview of 35 U.S.C. § 120 to which no response is required. The Court and the parties are referred to Title 35, section 120 for a full, complete, and accurate statement of its content. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

37. The USPTO lacks knowledge or information sufficient to admit or deny the first sentence of the paragraph to the extent it relates to the importance of filing dates to GSK. The remaining allegations of paragraph thirty-seven are Plaintiff's characterizations and legal conclusions regarding the effect of filing date under 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 that these remaining allegations are deemed to be allegations of fact, they are denied.

38. The allegations in the first sentence of paragraph thirty-eight are Plaintiff's characterizations and conclusions of law about the historical use of and "reasons" for continuation applications to which no response is required. To the extent that any of the allegations of the first sentence are deemed to be allegations of fact, they are denied, except to admit that there have historically been valid reasons to file continuation applications. The second, third, and fourth sentences (exclusive of the citation sentence) contain allegations related to Plaintiff's reasons for filing unidentified patent applications. The USPTO is without knowledge or information sufficient to admit or deny these allegations. The fifth sentence is Plaintiff's characterization of extensive comments and responses found in five pages of the final rules (72 Fed. Reg. at 46772-77). The administrative record contains the text of the comments and responses. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of their content. The sixth sentence contains Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations in the fifth or sixth sentences are deemed to be allegations of fact, they are denied.

39. The first sentence of paragraph thirty-nine contains allegations related to GSK's reasons for filing unidentified patent applications. The USPTO is without knowledge or information sufficient to admit or deny these allegations. The second sentence is Plaintiff's characterizations and conclusions of law to which no response is required. The third sentence is Plaintiff's characterization and conclusions of law regarding extensive comments and responses found in the final rules (72 Fed. Reg. at 46773-74). The administrative record contains the text

of the comments and responses. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of their content. To the extent that the allegations of the second or third sentence are deemed to be allegations of fact, they are denied.

40. The first sentence of paragraph forty is Plaintiff's characterizations and conclusions of law regarding the Patent Act and the Final Rules to which no response is required. The second sentence is Plaintiff's characterization and conclusions of law with respect to comments and responses found in the August 21, 2007 Federal Register notice. The administrative record contains the August 21, 2007 Federal Register notice and the Final Rules. The Court and the parties are referred to the administrative record and the Patent Act for a full, complete, and accurate statement of their content. To the extent that 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 conclusions of law regarding the Final Rules to which no response is required. The administrative record contains the text of the Final Rules. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of the content of the Final Rules. To the extent that 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 conclusions of law to which no response is required. To the extent that 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 conclusions of law to which no response is required. To the extent that 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 conclusions of law to which no response is required. To the extent that 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 conclusions of law to which no response is required. To the extent that 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 conclusions of law to which no response is required. To the extent that 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 conclusions of law to which no response is required. To the extent that 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 conclusions of law to which no response is required. To the extent that 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 conclusions of law to which no response is required. To the extent that 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 conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

51. The allegations of paragraph fifty-one are conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

52. The USPTO is without knowledge or information sufficient to admit or deny the allegations of paragraph fifty-two.

53. The allegations of the first sentence of paragraph fifty-three are conclusions of law regarding FDA regulations to which no response is required. To the extent that the allegations of the 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 fifty-three.

54. The USPTO is without knowledge or information sufficient to admit or deny the allegations of paragraph fifty-four.

55. The USPTO is without knowledge or information sufficient to admit or deny the allegations of paragraph fifty-five.

56. The USPTO is without knowledge or information sufficient to admit or deny the allegations of paragraph fifty-six.

57. The USPTO is without knowledge or information sufficient to admit or deny the allegations of paragraph fifty-seven.

58. The USPTO is without knowledge or information sufficient to admit or deny the allegations of paragraph fifty-eight.

59. The allegations of paragraph fifty-nine are Plaintiff's characterizations and conclusions of law 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 that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

60. The allegations of paragraph sixty are Plaintiff's characterizations and conclusions of law 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 that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

61. The allegations of paragraph sixty-one are Plaintiff's characterizations and conclusions of law 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 that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

62. The allegations of paragraph sixty-two are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

63. The allegations of paragraph sixty-three are Plaintiff's characterizations and conclusions of law to which no response is required. 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 are Plaintiff's characterizations and conclusions of law regarding H.R. 2795 and S. 3818 to which no response is required. The Court and the parties are referred to the referenced bills for a full, complete, and accurate statement of their content. To the extent that the allegations of this paragraph are deemed to be

allegations of fact, they are denied, except to admit that H.R. 2795 and S. 3818 were proposed in, respectively, the House and Senate and that the bills have not been duly enacted into law.

65. The allegations of paragraph sixty-five are Plaintiff's characterizations and conclusions of law regarding pending legislation to which no response is required. The Court and the parties are referred to the pending legislation for a full, complete, and accurate statement of its content. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied. The USPTO further avers that the quoted portion of H.R. 1908 is best read in context:

SEC. 14. REGULATORY AUTHORITY.

(a) REGULATORY AUTHORITY.—Section 2(c) is amended by adding at the end the following:

“(6) **The powers granted under paragraph (2) of subsection (b) include** the authority to promulgate regulations to ensure the quality and timeliness of applications and their examination, including specifying circumstances under which an application for patent may claim the benefit under sections 120, 121 and 365(c) of the filing date of a prior filed application for patent.”.

(b) CLARIFICATION.—The amendment made by subsection (a) **clarifies** the scope of power granted to the United States Patent and Trademark Office by paragraph (2) of section 2(b) of title 35, United States Code, as in effect since the enactment of Public Law 106–113.”

H.R. 1908 (emphasis added).

66. The allegations of paragraph sixty-six are Plaintiff's characterizations and legal conclusions regarding section 112 of the Patent Act to which no response is required. The Court and the parties are referred section 112 of 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.



67. The allegations of paragraph sixty-seven are Plaintiff's characterizations and legal conclusions regarding section 112 of the Patent Act to which no response is required. The Court and the parties are referred section 112 of 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.

68. The allegations of paragraph sixty-eight are Plaintiff's characterizations and legal conclusions regarding section 112 of the Patent Act to which no response is required. The Court and the parties are referred section 112 of 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.

69. The allegations of paragraph sixty-nine are Plaintiff's characterizations and legal conclusions regarding section 132 of the Patent Act to which no response is required. The Court and the parties are referred to section 132 of 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.

70. The allegations of paragraph seventy are Plaintiff's characterizations and legal conclusions regarding section 132 of the Patent Act to which no response is required. The Court and the parties are referred section 132 of 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.

71. The allegation in paragraph seventy-one is admitted.

72. The allegation in paragraph seventy-two is admitted.

73. The allegation in paragraph seventy-three is admitted.<sup>2</sup>

74. The allegations of paragraph seventy-four are Plaintiff's characterizations and conclusions of law regarding NPRM 1 to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied. The administrative record contains the text of NPRM 1. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of its content.

75. The allegations of paragraph seventy-five are Plaintiff's characterizations and conclusions of law regarding the NPRM 1 to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied. The administrative record contains the text of the NPRM 1. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of its content.

76. The USPTO admits that it solicited and received comments on NPRM 1, including a comment from GSK. The allegations of paragraph seventy-six are otherwise Plaintiff's characterizations regarding comments received on the NPRM 1. The administrative record contains the public comments on NPRM 1. The Court and the parties are referred to that record for a full, complete, and accurate statement of the content of the public comments. To the extent that any of the allegations of this paragraph that have not already been admitted are deemed to be allegations of fact, they are denied.

77. The USPTO admits that it did not hold formal public hearings on the proposed rules set forth in NPRM 1. The USPTO avers that such formal hearings were not required. The

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<sup>2</sup> In using the shorthand abbreviation "NPRM 1" and "NPRM 2," Plaintiff GSK is referring to proposed rules concerning the filing of continuing applications and claims that USPTO published in January of 2006 (collectively "Proposed Rules"). 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.

USPTO further avers that it held town hall meetings to inform the public about the Proposed Rules including those in NPRM 1.

78. The allegations of paragraph seventy-eight are Plaintiff's characterizations and conclusions of law regarding NPRM 2 to which no response is required. The administrative record contains the text of NPRM 2. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of its content. To the extent that 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 conclusions of law regarding the NPRM 2 to which no response is required. The administrative record contains the text of tNPRM 2. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of its content. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

80. The USPTO admits that it solicited and received comments on NPRM 2, including a comment from GSK. The allegations of paragraph eighty are otherwise Plaintiff's characterizations regarding comments received on the NPRM 2. The administrative record contains the public comments on NPRM 2. The Court and the parties are referred to that record for a full, complete, and accurate statement of the content of the public comments. To the extent that any of the allegations of this paragraph that have not already been admitted are deemed to be allegations of fact, they are denied.

81. The USPTO admits that it did not hold formal public hearings on the proposed rules set forth in NPRM 2. The USPTO avers that such formal hearings were not required. The

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48-61 (Jan. 3, 2006); Changes to Practice for the Examination of Claims in Patent Applications, 71 Fed. Reg. 61-69 (Jan. 3, 2006).

USPTO further avers that it held town hall meetings to inform the public about the Proposed Rules including those in NPRM 2.

82. The allegations of paragraph eighty-two are Plaintiff's characterizations regarding comments received on the Proposed Rules. 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.

83. The allegations of paragraph eighty-three are Plaintiff's characterizations and conclusions of law regarding comments received on the proposed to which no response is required. 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. To the extent that any of the allegations of this paragraph are deemed to be allegations of fact, they are denied.

84. The allegation in the first sentence of paragraph eighty-four is admitted. The remaining allegations are Plaintiff's characterization and conclusions of law regarding the Final Rules to which no response is required. The administrative record contains the Final Rules. The Court and the parties are referred to that record for a full, complete, and accurate statement of the content of the Final Rules. To the extent that any of the allegations in the second sentence or third sentences of this paragraph are deemed to be allegations of fact, they are denied.

85. The allegations of paragraph eighty-five are Plaintiff's characterization and conclusions of law regarding the Final Rules to which no response is required. The administrative record contains the Final Rules. The Court and the parties are referred to that record for a full, complete, and accurate statement of the content of the Final Rules. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied,

except to admit that the Final Rules have an effective date of November 1, 2007 and to aver that the effective date was suspended by this Court's issuance of an Order preliminarily enjoining the Final Rules on October 31, 2007.

86. The allegations of paragraph eighty-six are Plaintiff's characterization of the Final Rules and conclusions of law to which no response is required. The administrative record contains the Final Rules. The Court and the parties are referred to that record for a full, complete, and accurate statement of the content of the Final Rules. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

87. The allegations of paragraph eighty-seven are Plaintiff's characterization and conclusions of law regarding the Final Rules to which no response is required. The administrative record contains the Final Rules. The Court and the parties are referred to that record for a full, complete, and accurate statement of the content of the Final Rules. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

88. The allegations of paragraph eighty-eight are Plaintiff's characterization and conclusions of law regarding the Final Rules to which no response is required. The administrative record contains the Final Rules. The Court and the parties are referred to that record for a full, complete, and accurate statement of the content of the Final Rules. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

89. The allegations of paragraph eighty-nine are Plaintiff's characterization of the Final Rules and conclusions of law to which no response is required. The administrative record contains the Final Rules. The Court and the parties are referred to that record for a full, complete, and accurate statement of the content of the Final Rules. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

90. The allegations in paragraph ninety are Plaintiff's characterization of the Final Rules and conclusions of law to which no response is required. The administrative record contains the Final Rules. The Court and the parties are referred to that record for a full, complete, and accurate statement of the content of the Final Rules. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

#### **V. PRELIMINARY INJUNCTIVE RELIEF**

91. The allegations of paragraph ninety-one are conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

92. The allegations of paragraph ninety-two are Plaintiff's characterizations of the Final Rules and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

93. The allegations in the first and fourth sentences of paragraph ninety-three are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied. The USPTO is without knowledge or information sufficient to admit or deny the allegations in the second and third sentences regarding Plaintiff's unspecified "applications" and Plaintiff's filing strategies or reliance.

94. The allegations of paragraph ninety-four are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

95. The allegations of paragraph ninety-five are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

96. The allegations of paragraph ninety-six are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

97. The allegations of paragraph ninety-seven are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

98. The allegations of paragraph ninety-eight are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

99. The allegations of paragraph ninety-eight are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

## **CAUSES OF ACTION**

### **First Count**

100. The USPTO incorporates by reference the answers to paragraphs one to ninety-nine herein.

101. The allegations of paragraph one hundred one are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

102. The allegations of paragraph one hundred two are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

103. The allegations of paragraph one hundred three are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

104. The allegations of paragraph one hundred four are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

105. The allegations of paragraph one hundred five are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

106. The allegations in the first, second, and fifth sentences of paragraph one hundred six are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied. The USPTO is without knowledge or information sufficient to admit or deny the allegations in the third and fourth sentences regarding Plaintiff's unspecified "inventions," expectations, and filing strategies.

107. The allegations of paragraph one hundred seven are Plaintiff's characterizations, and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.



### **Second Count**

108. The USPTO incorporates by reference the answers to paragraphs one to ninety-nine herein.

109. The allegations of paragraph one hundred nine are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

110. The allegations of paragraph one hundred ten contain Plaintiff's characterization and legal conclusions regarding the effect of the Final Rules to which no response is required. The administrative record contains the Final Rules. The Court and the parties are referred to that record for a full, complete, and accurate statement of the content of the Final Rules. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

111. The allegations of paragraph one hundred eleven are Plaintiff's characterization and legal conclusions regarding the Final Rules to which no response is required. The administrative record contains the Final Rules. The Court and the parties are referred to that record for a full, complete, and accurate statement of the content of the Final Rules. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

112. The allegations of paragraph one hundred twelve are conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

113. The allegations of paragraph one hundred thirteen are conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

114. The allegations of paragraph one hundred fourteen are conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

115. The allegations of paragraph one hundred fifteen contain Plaintiff's characterization of the USPTO's reasons for adopting the Final Rules as stated in the August 21, 2007 Federal Register notice. The administrative record contains the August 21, 2007 Federal Register notice, and the Court and the parties are referred to that record for a full, complete, and accurate statement of its content.

116. The allegations in the first, second, and fourth sentences of paragraph one hundred sixteen are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of these sentences are deemed to be allegations of fact, they are denied. The third sentence contains Plaintiff's characterization of the August 21, 2007 Federal Register notice. The administrative record contains the August 21, 2007 Federal Register notice, and the Court and the parties are referred to that record for a full, complete, and accurate statement of its content.

117. The allegations of paragraph one hundred seventeen are conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

118. The allegations of paragraph one hundred eighteen are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

### **Third Count**

119. The USPTO incorporates by reference the answers to paragraphs one to ninety-nine herein.

120. The allegations of paragraph one hundred twenty are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

121. The allegations of paragraph one hundred twenty-one are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

122. The allegations of paragraph one hundred twenty-two are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

123. The allegations of paragraph one hundred twenty-three are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

### **Fourth Count**

124. The USPTO incorporates by reference the answers to paragraphs one to ninety-nine herein.

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

126. The allegations in sentences one, two, and three of paragraph one hundred twenty-six are Plaintiff's characterizations and conclusions of law to which no response is required. To

the extent the allegations of these sentences are deemed to be allegations of fact, they are denied. The allegations in sentence four are Plaintiff's characterization of unspecified comments received by the USPTO. The administrative record contains the text of the comments and responses. The Court and the parties are referred to the administrative record for a full, complete, and accurate statement of their content.

127. The allegations of paragraph one hundred twenty-seven are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

128. The allegations of paragraph one hundred twenty-eight are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

129. The allegations of paragraph one hundred twenty-nine are Plaintiff's characterizations and conclusions 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.

#### **Fifth Count**

130. The USPTO incorporates by reference the answers to paragraphs one to ninety-nine herein.

131. The allegations of paragraph one hundred thirty-one are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

132. The allegations of paragraph one hundred thirty-two are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

133. The allegations of paragraph one hundred thirty-three are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

#### **Sixth Count**

134. The USPTO incorporates by reference the answers to paragraphs one to ninety-nine herein.

135. The allegations of paragraph one hundred thirty-five are Plaintiff's characterizations and conclusions of law regarding NPRM 2, to which no response is required. The administrative record contains NPRM 2. The Court and the parties are referred to that record for a full, complete, and accurate statement of the content of NPRM 2.

136. The allegations of paragraph one hundred thirty-six are Plaintiff's characterizations and conclusions of law regarding extensive comments received by the USPTO and the Final Rules, to which no response is required. The administrative record contains the public comments on the Proposed Rules and the Final 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. To the extent that any of the allegations of this paragraph are deemed to be allegations of fact, they are denied.

137. The allegations of paragraph one hundred thirty-seven are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

138. The allegations of paragraph one hundred thirty-eight are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

### **Seventh Count**

139. The USPTO incorporates by reference the answers to paragraphs one to ninety-nine herein.

140. The allegations of paragraph one hundred forty are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

141. The allegations of paragraph one hundred forty-one are Plaintiff's characterizations and conclusions of law regarding Final Rule § 1.265 to which no response is required. The administrative record contains the Final Rule § 1.265. The Court and the parties are referred to that record for a full, complete, and accurate statement of the content of the rule. To the extent that any of the allegations of this paragraph are deemed to be allegations of fact, they are denied.

142. The allegations in the first and fourth sentences of paragraph one hundred forty-two are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of these sentences are deemed to be allegations of fact, they are denied. The second and third sentences are Plaintiff's characterizations of Final Rule § 1.265. The administrative record contains the text of Final Rule § 1.265. The Court and the parties are referred to that record for a full, complete, and accurate statement of the content of the rule.

143. The allegations in the first sentence of paragraph one hundred forty-three are Plaintiff's characterizations and conclusions of law regarding Final Rule § 1.75(b), to which no response is required. The administrative record contains the text of Final Rule § 1.75(b). The Court and the parties are referred to the administrative record for a full, complete, and accurate

statement of that rule. To the extent that the allegations of this paragraph are deemed to be allegations of fact, they are denied.

144. The allegations of paragraph one hundred forty-four are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

### **Eighth Count**

145. The USPTO incorporates by reference the answers to paragraphs one to ninety-nine herein.

146. The allegations of paragraph one hundred forty-six are Plaintiff's conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

147. The allegations of paragraph one hundred forty-seven are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

148. The USPTO is without knowledge or information sufficient to admit or deny the allegations of paragraph one hundred forty-eight regarding GSK's alleged reliance, investments, development cycle, filing strategies, or expectations. The remaining allegations are Plaintiff's characterizations and conclusions of law, to which no response is required. To the extent that these remaining allegations are deemed to be allegations of fact, they are denied.

149. The USPTO is without knowledge or information sufficient to admit or deny the allegations of paragraph one hundred forty-nine regarding GSK's alleged expectations. The remaining allegations are Plaintiff's characterizations and conclusions of law, to which no

response is required. To the extent that these remaining allegations are deemed to be allegations of fact, they are denied.

150. The allegations of paragraph one hundred fifty are conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

151. The allegations of paragraph one hundred fifty-one are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

152. The allegations of paragraph one hundred fifty-two are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

153. The allegations of paragraph one hundred fifty-three are Plaintiff's characterizations and conclusions of law to which no response is required. To the extent the allegations of this paragraph are deemed to be allegations of fact, they are denied.

**GENERAL DENIAL**

Any allegation not specifically admitted or denied is expressly denied.

**USPTO'S PRAYER FOR RELIEF**

WHEREFORE, the USPTO, having fully answered the allegations contained in GSK's Verified Amended Complaint, prays that the Court dismiss the Amended Complaint, enter judgment in the USPTO's favor, and grant the USPTO such further relief as the Court may deem just and proper.



Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on December 10, 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:

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