IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

WYETH LLC.
Madison, New Jersey,

and

JANSSEN ALZHEIMER IMMUNOTHERAPY
Dublin, Ireland

Plaintiffs,

v.

HON. DAVID J. KAPPOS
Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office
P.O. Box 1450
401 Dulany Street
Alexandria, VA 22314

Defendant.

CIVIL ACTION

CASE NO. 1:13cv49 TSE/JFA

COMPLAINT

Plaintiffs Wyeth LLC and Janssen Alzheimer Immunotherapy bring this complaint against the Honorable David J. Kappos ("Director Kappos") as follows:

NATURE OF THE ACTION

1. This is an action by Wyeth LLC and Janssen Alzheimer Immunotherapy, the joint owners and assignees of United States Patent Application No. 10/583,503 (the "'503 application") that issued as United States Patent No. 8,227,403 (the "'403 patent") for review of the determination by Defendant, pursuant to, *inter alia*, 35 U.S.C. § 154(b)(3)(B), of the Patent Term Adjustment of the '403 patent. Wyeth LLC and Janssen Alzheimer Immunotherapy seek a

judgment that the patent term adjustment for the '403 patent be changed from 890 days to 1129 days. In the alternative, Wyeth LLC and Janssen Alzheimer Immunotherapy seek a judgment that the patent term adjustment for the '403 patent be changed from 890 days to 912 days. Wyeth LLC and Janssen Alzheimer Immunotherapy further seek a judgment that 37 C.F.R. § 1.703(b)(1) and 37 C.F.R. § 1.703(b)(4) are invalid, unconstitutional and contrary to law, to the extent they conflict with the statutory provisions.

2. This action arises under 35 U.S.C. § 154, the Fifth Amendment of the Constitution of the United States, and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

THE PARTIES

3. Wyeth LLC ("Wyeth") is a Delaware company with its principal place of business at Madison, New Jersey.

4. Janssen Alzheimer Immunotherapy ("JAI") is a private unlimited company incorporated under the laws of Ireland with its principal place of business at Dublin, Ireland.

5. Director Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office ("PTO"), acting in his official capacity. The Director is the head of the PTO and is responsible for superintending or performing all duties required by law with respect to the granting and issuing of patents. As such, Director Kappos is designated by statute as the official responsible for determining the period of Patent Term Adjustments under 35 U.S.C. §154(b)(3)(B).

JURISDICTION AND VENUE

6. This Court has jurisdiction to hear this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a), 1361, 2201, & 2202; 35 U.S.C. § 154(b); and 5 U.S.C. §§ 701-706.

7. Venue is proper in this district by virtue of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 9, 125 Stat. 316 (2011).

8. This Complaint is being timely filed in accordance with 35 U.S.C. § 154(b)(4)(A).

BACKGROUND

The '403 Patent

9. Wyeth and JAI are the joint assignees of all right, title, and interest in the '403 patent, as evidenced by the assignments recorded with the USPTO. As such, Wyeth and JAI are the real parties in interest in this case.

10. Rasappa G. Arumugham, A. Krishna Prasad, and Michael Hagen, are inventors of the '503 application which is a US national stage application of PCT/US2004/044093 for which the national stage commenced on June 19, 2006 (the "Actual Filing Date") and which satisfied the §371(c) requirements on November 17, 2006.

11. On January 6, 2009, a Restriction Requirement was mailed by the USPTO as to the '503 application (the "Restriction Requirement"). A response to the Restriction Requirement was filed on March 5, 2009.

12. On April 13, 2009, an information disclosure statement (the "First IDS") was filed.

13. On June 19, 2009, the USPTO mailed a Notice to Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Disclosures as to the '503 application (the "First Sequence Notice"), and indicated that the response to the Restriction Requirement was non-compliant. A response to the First Sequence Notice was filed on June 25, 2009.

14. On September 11, 2009, the USPTO mailed a second Notice to Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Disclosures as to the '503 application (the "Second Sequence Notice"), and indicated that the response to the First Sequence Notice was non-compliant. A response to the Second Sequence Notice was filed on September 23, 2009 after a telephone interview with the patent examiner confirming that the '503 application complied with the sequence listing requirements.

15. On January 25, 2010, an information disclosure statement (the "Second IDS") was filed.

16. On May 19, 2010, the USPTO mailed a Non-Final Office Action as to the '503 application (the "Non-Final Office Action"). A response to the Non-Final Office Action was filed on November 19, 2010.

17. On November 30, 2010, an information disclosure statement (the "Third IDS") was filed.

18. On January 28, 2011, the USPTO mailed a Final Office Action as to the '503 application (the "Final Office Action").

19. On July 28, 2011, a Notice of Appeal was filed.

20. On February 14, 2012, a Terminal Disclaimer and a Request for Continued Examination (the "First RCE") were filed.

21. On February 29, 2012, the USPTO mailed a Notice of Allowance and Fees Due for the '503 application (the "First Notice of Allowance"). Included in the First Notice of Allowance was a Determination of Patent Term Adjustment in which the USPTO indicated that the Patent Term Adjustment to date for the '503 application was 122 days.

22. On May 25, 2012, a second Request for Continued Examination (the "Second RCE") and a Request to Correct Inventorship of the '503 application were filed.

23. On June 11, 2012, the USPTO mailed a second Notice of Allowance and Fees Due for the '503 application (the "Second Notice of Allowance"). Included in the Second Notice of Allowance was a Determination of Patent Term Adjustment in which the USPTO indicated that the Patent Term Adjustment to date for the '503 application was 122 days.

24. On June 21, 2012, the issue fee for the '503 application was paid, thereby satisfying all outstanding requirements for issuance of a patent.

25. On July 4, 2012, the USPTO mailed an Issue Notification for the '503 application. Included in the Issue Notification was a Determination of Patent Term Adjustment in which the USPTO indicated that the Patent Term Adjustment for the '503 application was 890 days. The USPTO calculated 355 days of "A delay", 768 days of "B delay", and 233 days of "Applicant Delay".

26. On July 24, 2012, the '503 application issued as the '403 patent reflecting a Patent Term Adjustment of 890 days. A true and correct copy of the '403 patent is attached hereto as Exhibit A.

Patent Term Guarantee

27. The Patent Term Guarantee Act of 1999, a part of the American Inventors Protection Act ("AIPA"), amended 35 U.S.C. § 154(b) to address concerns that delays by the PTO during the prosecution of patent applications could result in a shortening of the effective life of the resulting patents to less than seventeen years.

28. Amended 35 U.S.C. § 154(b) broadened the universe of cognizable administrative delays by the PTO that could retroactively yield an extension of the patent term to compensate for such prosecution delays ("Patent Term Adjustment" or "PTA").

29. Patent Term Adjustment applies to original utility patent applications (including continuations, divisionals, and continuations-in-part) filed on or after May 29, 2000.

30. In calculating PTA, Defendant must take into account PTO delays under 35 U.S.C. §154(b)(1), any overlapping periods in the PTO delays under 35 U.S.C. § 154(b)(2)(A), and any applicant delays under 35 U.S.C. § 154(b)(2)(C).

31. Under 35 U.S.C. § 154(b)(1)(A), an applicant is entitled to PTA for the PTO's failure to carry out certain acts during processing and examination within defined deadlines ("A Delay").

32. Under 35 U.S.C. § 154(b)(1)(B), an applicant is entitled to additional PTA attributable to the PTO's "failure .. . to issue a patent within 3 years after the actual Filing Date of the application in the United States," but not including "any time consumed by continued examination of the application requested by the applicant under section 132(b)" or "... any time consumed by appellate review by the Board of Patent Appeals and Interferences..." ("B Delay").

33. 35 U.S.C. § 154(b)(2)(A) provides that "to the extent that periods of delay attributable to grounds specified in paragraph [154(b)(1)] overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the

patent was delayed."

34. On January 7, 2010, the Court of Appeals for the Federal Circuit in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), affirmed the District Court ruling in *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008), that the correct method for calculating overlap of A Delay and B Delay is to aggregate A Delay and B Delay except to the extent that such aggregation would amount to counting the same calendar day twice.

35. 35 U.S.C. § 154(b)(2)(B) provides that "[n]o patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer."

36. 35 U.S.C. § 154(b)(2)(C)(i) also directs that "the period of adjustment of the term of a patent under paragraph [154(b)(1)] shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application" ("Applicant Delay").

37. Under 35 U.S.C. § 154(b)(4)(A), "an applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action."

Defendant's Abrogation of the Patent Term Guarantee

38. Defendant has improperly calculated PTA in a manner that deprives patentees of B Delay due to an incorrect interpretation of the effect of the continued examination procedure under 35 U.S.C. § 132(b) within the context of 35 U.S.C. § 154(b)(1)(B).

39. Defendant has inappropriately promulgated and relied upon 37 C.F.R. § 1.703(b)(1) to support its flawed interpretation of 35 U.S.C. § 154(b)(1)(B) that B Delay permanently ceases to accrue upon the filing of an RCE by an applicant.

40. Instead, 35 U.S.C. § 154(b)(1)(B)(i) merely requires the exclusion of "any time consumed by continued examination of the application requested by the applicant under 35 U.S.C. §132(b)" when calculating whether the PTO has satisfied the three-year pendency

guarantee.

41. When properly construed, if the PTO fails to meet this three-year pendency guarantee, the applicant is entitled to the full remedy afforded by 35 U.S.C. § 154(b)(1)(B): "the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued," subject only to the specific limitations set forth in 35 U.S.C. § 154(b)(2).

42. None of the limitations included within 35 U.S.C. § 154(b)(2) reduce or otherwise affect the PTA remedy in 35 U.S.C. § 154(b)(1)(B) on the basis of time consumed by examination after filing of an RCE.

43. The PTO also promulgated regulations pursuant to 35 U.S.C. § 154(b)(2)(C) specifying applicant actions that will result in a reduction of the additional patent term available under § 154(b)(1)(B). These regulations, set forth at 37 C.F.R. § 1.704, likewise do not include any reduction or limitation based upon time consumed by examination after the filing of an RCE.

44. Accordingly, the plain language of 35 U.S.C. § 154(b)(1)(B) dictates that if an RCE is not filed within three years after the Actual Filing Date of a patent application, the filing of the RCE has no effect upon the accrual of B Delay for that patent. Under such circumstances, the applicant is entitled to B Delay from the day after the three-year pendency period through the date of issuance of the patent, the explicit remedy set forth in 35 U.S.C. § 154(b)(1)(B), subject only to the specific limitations set forth at 35 U.S.C. § 154(b)(2).

45. To the extent that 37 C.F.R. § 1.703(b)(1) conflicts with the straightforward and unambiguous language of 35 U.S.C. § 154(b)(1)(B), this subsection of the regulation is invalid.

46. Defendant has improperly calculated PTA in a manner that deprives patentees of B Delay due to an incorrect interpretation of the effect of appellate review by the Board of Patent Appeals and Interferences within the context of 35 U.S.C. § 154(b)(1)(B).

47. Defendant has inappropriately promulgated and relied upon 37 C.F.R. § 1.703(b)(4) to support its flawed interpretation of 35 U.S.C. § 154(b)(1)(B) that B Delay ceases to accrue during appellate review that occurs after expiration of the three-year pendency guarantee.

48. Instead, 35 U.S.C. § 154(b)(1)(B)(ii) merely requires the exclusion of "any time consumed by appellate review by the Board of Patent Appeals and Interferences" when calculating whether the PTO has satisfied the three-year pendency guarantee.

49. When properly construed, if the PTO fails to meet this three-year pendency guarantee, the applicant is entitled to the full remedy afforded by 35 U.S.C. § 154(b)(1)(B): "the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued," subject only to the specific limitations set forth in 35 U.S.C. § 154(b)(2).

50. None of the limitations included within 35 U.S.C. § 154(b)(2) reduce or otherwise affect the PTA remedy in 35 U.S.C. § 154(b)(1)(B) on the basis of time consumed by appellate review.

51. The PTO also promulgated regulations pursuant to 35 U.S.C. § 154(b)(2)(C) specifying applicant actions that will result in a reduction of the additional patent term available under § 154(b)(1)(B). These regulations, set forth at 37 C.F.R. § 1.704, likewise do not include any reduction or limitation based upon time consumed by appellate review by the Board of Patent Appeals and Interferences.

52. Accordingly, the plain language of 35 U.S.C. § 154(b)(1)(B) dictates that if a notice of appeal is not filed within three years after the Actual Filing Date of a patent application, the filing of the notice of appeal has no effect upon the accrual of B Delay for that patent. Under such circumstances, the applicant is entitled to B Delay from the day after the three-year pendency period through the date of issuance of the patent, the explicit remedy set forth in 35 U.S.C. § 154(b)(1)(B), subject only to the specific limitations set forth at 35 U.S.C. § 154(b)(2).

53. To the extent that 37 C.F.R. § 1.703(b)(4) conflicts with the straightforward and unambiguous language of 35 U.S.C. § 154(b)(1)(B), this subsection of the regulation is invalid.

The Proper Calculation of PTA for the '403 Patent

54. Under 35 U.S.C. § 154(b)(1)(A)(i), Wyeth and JAI are entitled to an adjustment of the term of the '403 patent for a period of 561 days of A Delay. This A Delay is attributable to the USPTO's failure to mail an action under 35 U.S.C. § 132 not later than 14 months from

the date the application fulfilled the requirements under 35 U.S.C. § 371, plus the USPTO's failure to respond to a reply under 35 U.S.C. § 132 after the date on which the reply was filed. The period consists of the period from January 18, 2008 (the day after the date that is 14 months after the completion of requirements under section 371) through January 6, 2009 (the mailing date of the Restriction Requirement), and the period from October 26, 2009 (the day after the date that is 4 months after the filing of a compliant response to the Restriction Requirement) through May 19, 2010 (the mailing date of the Non-Final Office Action).

55. Under 35 U.S.C. § 154(b)(1)(B), Wyeth and JAI are entitled to an additional adjustment of the term of the '403 patent for a period of 1,131 days of B Delay. This B Delay period consists of the period from June 20, 2009 (the day after the date that is three years after the Actual Filing Date of the application) through July 24, 2012 (the issue date of the '403 patent).

56. In the alternative, under 35 U.S.C. § 154(b)(1)(B), Wyeth and JAI are entitled to an additional adjustment of the term of the '403 patent for a period of 914 days of B Delay. This B Delay period consists of the period from June 20, 2009 (the day after the date that is three years after the Actual Filing Date of the application) through July 27, 2011 (the day before the filing of the Notice of Appeal), and the period from March 1, 2012 (the day after the mailing of the First Notice of Allowance) through July 24, 2012 (the issue date of the '403 patent).

57. Taken together, the A Delay and B Delay periods equate to 1,692 days of delay, or alternatively, 1,475 days of delay. The periods of A Delay and B Delay overlap by 206 days, however, leaving 1,486 days of delay, or alternatively, 1,269 days of delay.

58. Under 35 U.S.C. § 154(b)(2)(C)(i), 357 days of that delay is attributable to Wyeth and JAI. This Applicant Delay resulted from Wyeth's and JAI's delay in filing a response to the Non-Final Office Action (92 days of delay); delay in filing a response to the Final Office Action (91 days of delay); and delay in submitting the First IDS (39 days of delay), the Second IDS (124 days of delay), and the Third IDS (11 days of delay).

59. As a result, the correct PTA for the '403 patent is 1,129 days: the sum of 561 days

of A Delay and 1,131 days of B Delay, minus the 206 days of overlap and the 357 days of Applicant Delay.

60. In the alternative, the correct PTA for the '403 patent is 912 days: the sum of 561 days of A Delay and 914 days of B Delay, minus the 206 days of overlap and the 357 days of Applicant Delay.

CLAIM I

(Patent Term Adjustment Under 35 U.S.C. § 154)

61. The allegations of the paragraphs above are incorporated in this claim for relief as if fully set forth herein.

62. The PTO's calculation of B Delay for the '403 patent was based upon a flawed interpretation of 35 U.S.C. § 154(b)(1)(B) that wrongly excluded all otherwise compensable PTO delay that accrued after Wyeth and JAI filed the Notice of Appeal and the RCE.

63. Wyeth and JAI filed a Notice of Appeal and an RCE during prosecution more than three years after the Actual Filing Date of the '503 application.

64. Wyeth's and JAI's filing of the Notice of Appeal and the RCE during prosecution has no effect upon the accrual of B Delay for the '403 patent.

65. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation of B Delay for the '403 patent that deprived Wyeth and JAI of the appropriate PTA for this patent.

66. Wyeth and JAI are entitled to additional patent term for the '403 patent such that the 890 days of PTA granted by the PTO should be changed to 1,129 days.

67. In the alternative, the PTO's calculation of B Delay for the '403 patent was based upon a flawed interpretation of 35 U.S.C. § 154(b)(1)(B) that wrongly excluded all otherwise compensable PTO delay that accrued after Wyeth and JAI filed the RCE.

68. Wyeth and JAI filed an RCE during prosecution more than three years after the Actual Filing Date of the '503 application.

69. Wyeth's and JAI's filing of the RCE during prosecution has no effect upon the

accrual of B Delay for the '403 patent.

70. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation of B Delay for the '403 patent that deprived Wyeth and JAI of the appropriate PTA for this patent.

71. Wyeth and JAI are entitled to additional patent term for the '403 patent such that the 890 days of PTA granted by the PTO should be changed to 912 days.

CLAIM II

(Violation of the Fifth Amendment of the Constitution of the United States)

72. The allegations of the paragraphs above are incorporated in this claim for relief as if fully set forth herein.

73. The Fifth Amendment of the Constitution of the United States provides in relevant part, "[N]or shall private property be taken for public use, without just compensation."

74. Wyeth and JAI enjoy a substantial and cognizable private property right in the full and complete term of the '403 patent.

75. Wyeth and JAI have not failed to pay any necessary maintenance fees to the PTO required to maintain their rights in the '403 patent.

76. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and § 1.703(b)(4), the regulatory subsections interpreting 35 U.S.C. § 154(b)(1)(B)(i) and (ii), and reliance upon these regulatory subsections in improperly calculating B Delay when determining PTA for the '403 patent permanently deprived Wyeth and JAI of patent term to which they were entitled under 35 U.S.C. § 154(b).

77. Defendant's purposeful and deliberate diminution of the patent term of the '403 patent constitutes a taking of Wyeth's and JAI's property without just compensation, in violation of the Fifth Amendment of the Constitution of the United States.

78. Wyeth and JAI are entitled to additional patent term for the '403 patent such that the 890 days of PTA granted by the PTO should be changed to 1,129 days or, in the alternative,

to at least 912 days.

CLAIM III

(Declaratory Judgment Under The Administrative Procedures Act, 5 U.S.C. § 702 et seq.)

79. The allegations of the paragraphs above are incorporated in this claim for relief as if fully set forth herein.

80. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and § 1.703(b)(4), the regulatory subsections interpreting 35 U.S.C. § 154(b)(1)(B)(i) and (ii), and its improper calculation of B Delay when determining PTA for the '403 patent were contrary to law.

81. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and § 1.703(b)(4) and determination of PTA for the '403 patent are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A); contrary to Wyeth's and JAI's constitutional rights within the meaning of 5 U.S.C. § 706(2)(B); and in excess of statutory authority within the meaning of 5 U.S.C. § 706(2)(C).

82. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and § 1.703(b)(4) and determination of PTA for the '403 patent were final agency actions that are reviewable by a district court in accordance with 5 U.S.C. § 704.

83. Wyeth and JAI have adequately exhausted all of their available administrative remedies under 35 U.S.C. § 154 or, in the alternative, pursuit of any further administrative remedies is futile.

84. Wyeth and JAI have been afforded no adequate remedy at law for Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and § 1.703(b)(4) and determination of PTA for the '403 patent.

85. Wyeth and JAI will suffer irreparable injury if 37 C.F.R. § 1.703(b)(1) and § 1.703(b)(4) are not invalidated and Defendant is not directed to recalculate PTA for the '403 patent.

86. An order invalidating 37 C.F.R. § 1.703(b)(1) and § 1.703(b)(4) and directing Defendant to recalculate PTA for the '403 patent would not substantially injure any other interested parties, and the public.

PRAYER FOR RELIEF

WHEREFORE, Wyeth and JAI respectfully pray that this Court:

A. Issue an Order changing the period of PTA for the '403 patent from 890 days to 1,129 days or, in the alternative, to at least 912 days, and requiring Defendant to alter the term of the '403 patent to reflect such additional PTA;

B. Declare pursuant to 28 U.S.C. § 2201 that 37 C.F.R. § 1.703(b)(1) and § 1.703(b)(4) are invalid, unconstitutional and contrary to law; and

C. Grant such other and further relief as the nature of the case may admit or require and as may be just and equitable.

Dated: January 10, 2013

Respectfully submitted,

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