

FILED

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

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CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

VERTEX PHARMACEUTICALS
INCORPORATED., a Massachusetts
corporation,
130 Waverly Street
Cambridge, MA 02139

Civil Action No. 1:13cv653
LMB/TRJ

Plaintiff,

v.

TERESA STANEK REA,
Acting Under Secretary of Commerce for
Intellectual Property and Acting Director of
the United States Patent and Trademark
Office,
Office of the General Counsel
United States Patent and Trademark Office
P.O. Box 15667, Arlington, VA 22215
Madison Building East, Room 10B20
600 Dulany Street, Alexandria, VA 22314

Defendant.

_____ /

COMPLAINT

Plaintiff Vertex Pharmaceuticals Incorporated ("Vertex" or "Plaintiff"), for its complaint against Teresa Stanek Rea (hereinafter "Stanek Rea" or "Defendant"), states as follows:

NATURE OF THE ACTION

1. This is an action by Vertex, the owner and assignee of United States Patent No. 8,324,242 (the '242 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 '242 patent. Vertex seeks a judgment

that the patent term for the '242 patent be changed from 663 days to 772 days. Vertex furthermore seeks a judgment that 37 C.F.R. § 1.703(b)(1) is invalid, unconstitutional, and contrary to law.

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. Vertex is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, with its principal place of business at 130 Waverly Street, Cambridge, MA 02139.

4. Stanek Rea is the Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office ("PTO"), acting in her official capacity. The Acting 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, Stanek Rea 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

5. 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.

6. 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).

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

ALLEGATIONS COMMON TO ALL COUNTS

The '242 Patent

1. Vertex is the assignee of all right, title, and interest in the '242 patent, as evidenced by records on deposit with the PTO and the face of the '242 patent. As such, Vertex is the real party in interest in this case.
2. Sara Hadida Ruah, Anna Hazelwood, Peter D. J. Grootenhuis, Fredrick Van Goor, Ashvani Singh, Jinglan Zhou and Jason McCartney are the inventors of patent application number 12/351,447 ("the '447 application") which was filed on January 9, 2009 (the "Filing Date"). The '447 application is a division of U.S. application number 11/165,818, filed on June 24, 2005, now Patent No. 7,495,103, which claims priority to June 24, 2004 (the "Priority Date").
3. The '242 patent is subject to a terminal disclaimer to U.S. Pat. No. 7,553,855.
4. On June 27, 2011, the PTO mailed a Restriction/Election Requirement as to the '447 application (the "Restriction Requirement"). Vertex responded to the Restriction Requirement on September 27, 2011.
5. On December 7, 2011, the PTO mailed a Non-Final Action as to the '447 application (the "First Office Action"). Vertex responded to the First Office Action on February 6, 2012.
6. On April 16, 2012, the PTO mailed a Notice of Allowance and Fees Due for the '447 application (the "Notice of Allowance"). On July 16, 2012, Vertex filed amendments to the claims for the purpose of clarity and a Request for Continued Examination as to the '447 application (the "RCE").
7. On August 17, 2012, the PTO mailed a second Notice of Allowance and Fees Due for the '447 application (the "second Notice of Allowance"). Included in the Notice of Allowance was a Determination of Patent Term Adjustment wherein the PTO indicated that the Patent Term Adjustment to date for the '447 application was 475 days.
8. On October 8, 2012, Vertex paid the issue fee for the '447 application, thereby satisfying all outstanding requirements for issuance of a patent.

9. On November 14, 2012, the PTO mailed an Issue Notification for the '447 application. Included in the Issue Notification was a Determination of Patent Term Adjustment in which the PTO indicated that the Patent Term Adjustment for the '447 application was 663 days. The PTO calculated 475 days of "A Delay" and 188 days of "B Delay."

10. On December 4, 2012, the '447 application issued as the '242 patent, reflecting a Patent Term Adjustment of 663 days. A true and correct copy of the '242 patent is attached hereto as Exhibit A.

11. On February 1, 2013, Vertex filed with the PTO a Patent Term Adjustment Petition requesting that the PTO change its Patent Term Adjustment for the '242 patent (the "PTA Petition").

Patent Term Guarantee

12. 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.

13. 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").

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

15. 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).

16. 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").

17. 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)" ("B Delay").

18. 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."

19. On January 7, 2010, the Court of Appeals for the Federal Circuit in Wyeth v. Kappos, 591 F.3d 1364 (Fed. Cir. 2010) ("Wyeth"), 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 days twice.

20. 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" ("C Reduction").

21. 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

22. 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).

23. 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.

24. 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.

25. 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).

26. 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.

27. 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.

28. 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).

29. 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.

30. In the alternative, even if the remedy afforded under 35 U.S.C. § 154(b)(1)(B) somehow can be construed to be limited by "any time consumed by Continued Examination of the application requested by the applicant under section 132(b)," the PTO still has improperly calculated PTA in a manner that deprives patentees of B Delay due to its incorrect interpretation of the effect of filing an RCE.

31. The only time properly "consumed by Continued Examination" is the period from the date the applicant files an RCE through the date the PTO thereafter mails a Notice of Allowance, an event that concludes the Continued Examination. The period encompassed by mailing a Notice of Allowance to issuance of a patent occurs in all cases where a patent issues and is not unique to situations where an RCE was filed and thus should not properly be included in the limitation on time "consumed by Continued Examination". Accordingly, an applicant is entitled to accrue B Delay for the period from the date of the mailing of a Notice of Allowance through the date of issuance of the patent.

The Proper Calculation of PTA for the '242 Patent

32. Under 35 U.S.C. § 154(b)(1)(A)(i), Vertex is entitled to an adjustment of the term of the '242 patent for a period of 475 days. This A Delay period is attributable to the PTO's failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the actual Filing Date of the application. This period consists of the period from March 9, 2010 (14 months after the Filing Date) through June 27, 2011 (the mailing date of the Restriction Requirement).

33. Under 35 U.S.C. § 154(b)(1)(B), Vertex is entitled to an additional adjustment of the term of the '242 patent for a period of 330 days. This B Delay period consists of the period from January 9, 2012 (three years after the Filing Date) through December 4, 2012 (the issue date of the '242 patent). Under 35 U.S.C. § 154(b)(2)(C)(i), 33 days of delay is attributable to Vertex. This Applicant Delay is prescribed by the Director under 37 C.F.R. § 1.704(c)(10) for the submission of an amendment or other paper after a notice of allowance.

34. In the alternative, under 35 U.S.C. § 154(b)(1)(B), Vertex is entitled to an additional adjustment of the term of the '242 patent for a period of 297 days. This B Delay period consists of the period from January 9, 2012 (three years after the Filing Date) through July 16, 2012 (filing of the RCE) and the period from August 17, 2012 (mailing of the Notice of Allowance) through December 4, 2012 (the issue date of the '242 patent).

35. There is no overlap of A Delay and B Delay for the '242 patent pursuant to 35 U.S.C. § 154(b)(2)(A).

36. The correct PTA for the '242 patent is 772 days: the sum of the 475 days of A Delay and the 330 days of B Delay, minus the 33 days of Applicant Delay.

37. In the alternative, the correct PTA for the '242 patent is 772 days: the sum of the 475 days of A Delay and the 297 days of B Delay.

CLAIMS FOR RELIEF

COUNT ONE

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

38. The allegations of paragraphs 1-46 are incorporated in this claim for relief as if fully set forth herein.

39. The PTO's calculation of B Delay for the '242 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 Vertex filed the RCE.

40. Vertex filed an RCE during prosecution of the '447 application more than three years after the actual Filing Date of that application.

41. Vertex's filing of the RCE during prosecution of the '447 application has no effect upon the accrual of B Delay for the '242 patent.

42. In the alternative, the PTO's calculation of B Delay for the '242 patent was based upon an interpretation of 35 U.S.C. § 154(b)(1)(B) that improperly excluded PTO delay that was not "consumed by continuing examination."

43. Continued examination of the '447 application by the PTO concluded on the date the PTO mailed to Vertex the second Notice of Allowance.

44. The '242 patent accrued B Delay for the period from the date the PTO mailed to Vertex the Notice of Allowance through the date of issuance of that patent.

45. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation B Delay for the '242 patent that deprived Vertex of the appropriate PTA for this patent.

46. Vertex is entitled to additional patent term for the '242 patent such that the 663 days of PTA granted by the PTO should be changed to 772 days.

COUNT TWO

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

47. The allegations of paragraphs 1-55 are incorporated in this claim for relief as if fully set forth herein.

48. 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."

49. Vertex enjoys a substantial and cognizable private property right in the full and complete term of the '242 patent.

50. Vertex has not failed to pay any necessary maintenance fees to the PTO required to maintain its rights in the '242 patent.

51. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1), the regulatory subsection interpreting 35 U.S.C. § 154(b)(1)(B)(i), and reliance upon this regulatory subsection in improperly calculating B Delay when determining PTA for the '242 patent permanently deprived Vertex of patent term to which it was entitled under 35 U.S.C. § 154(b).

52. Defendant's purposeful and deliberate diminution of the patent term of the '242 patent constitutes a taking of Vertex's property without just compensation, in violation of the Fifth Amendment of the Constitution of the United States.

53. Vertex is entitled to additional patent term for the '242 patent such that the 663 days of PTA granted by the PTO should be changed to 772 days.

COUNT THREE

(Declaratory Judgment Under The Administrative Procedures Act,

5 U.S.C. § 702 et seq.)

54. The allegations of paragraphs 1-62 are incorporated in this claim for relief as if fully set forth herein.

55. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1), the regulatory subsection interpreting 35 U.S.C. § 154(b)(1)(B)(i), and its improper calculation of B Delay when determining PTA for the '242 patent were contrary to law.

56. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '242 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 Vertex'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).

57. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '242 patent were final agency actions that are reviewable by a district court in accordance with 5 U.S.C. § 704.

58. Vertex has adequately exhausted all of its available administrative remedies under 35 U.S.C. § 154 or, in the alternative, pursuit of any further administrative remedies is futile.

59. Vertex has been afforded no adequate remedy at law for Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '242 patent.

60. Vertex will suffer irreparable injury if 37 C.F.R. § 1.703(b)(1) is not invalidated and Defendant is not directed to recalculate PTA for the '242 patent.

61. An order invalidating 37 C.F.R. § 1.703(b)(1) and directing Defendant to recalculate PTA for the '242 patent would not substantially injure any other interested parties, and the public interest will be furthered by invalidation of a regulatory subsection and recalculation of PTA that is contrary to law.

62. Vertex is entitled to additional patent term for the '242 patent such that the 663 days of PTA granted by the PTO should be changed to 772 days.

WHEREFORE, Vertex respectfully prays that this Court:

A. Issue an Order changing the period of PTA for the '242 patent from 663 days to 772 days and requiring Defendant to alter the term of the '242 patent to reflect such additional PTA;

B. Declare pursuant to 28 U.S.C. § 2201 that 37 C.F.R. § 1.703(b)(1) is 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: May 31, 2013

Respectfully submitted,

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