

FILED

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

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U.S. DISTRICT COURT
ALEXANDRIA, VIRGINIA

ABBVIE BIOTECHNOLOGY, LTD.)
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Plaintiff,)
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v.)
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)
HON. DAVID J. KAPPOS)
)
Under Secretary of Commerce for Intellectual)
Property and Director of the United States Patent)
and Trademark Office)
)
)
Office of General Counsel,)
United States Patent and Trademark Office)
P.O. Box 1450, Alexandria, VA 22313-1450)
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)
Madison Building East, Rm. 10B20)
600 Dulany Street, Alexandria, VA 22314)
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)
Defendant.)

Case No. 1:12CV1511 AJT/TRS

COMPLAINT

Plaintiff, AbbVie Biotechnology, Ltd. ("AbbVie"), for its complaint against the Honorable David J. Kappos, states as follows:

NATURE OF THE ACTION

1. This is an action under 35 U.S.C. § 154 and the Administrative Procedure Act, 5 U.S.C. §§ 701-706, by the assignee of United States Patent No. 8,216,583 ("the '583 patent," attached hereto as Exhibit A) seeking review of the patent term adjustment granted by the Director of the United States Patent and Trademark Office ("PTO") pursuant to 35 U.S.C. § 154(b).

2. The PTO, acting contrary to its statutory jurisdiction and authority, arbitrarily, and capriciously granted AbbVie a patent term adjustment of 989 days. AbbVie asserts that it is entitled to a patent term adjustment of 1206 days.

3. Pursuant to 35 U.S.C. § 154(b)(4)(A), AbbVie hereby seeks review of and a remedy for the PTO's failure to award the proper amount of patent term adjustment.

THE PARTIES

4. Plaintiff AbbVie is a corporation organized under the laws of Bermuda, with a place of business at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda. AbbVie is the assignee with all right, title, and interest in the '583 patent.

5. Defendant David J. Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the PTO, acting in his official capacity. The Director is the head of the agency, charged by statute with providing management supervision for the PTO and for the issuance of patents. The Director is the official responsible for determining the period of patent term adjustment, *see* 35 U.S.C. § 154(b)(3), and is the proper defendant in a suit seeking review of such determinations, *see* § 154(b)(4)(A).

JURISDICTION, VENUE, AND TIMING

6. This action arises under 35 U.S.C. § 154(b)(4)(A) and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

7. This Court has subject-matter jurisdiction over this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1361; 35 U.S.C. § 154(b)(4)(A); and/or 5 U.S.C. §§ 701-706.

8. 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).

9. This Complaint is timely filed in accordance with 35 U.S.C. § 154(b)(4)(A), as it is being filed within 180 days of the issuance of the '583 patent.

BACKGROUND

The Patent Term Adjustment Statute

10. The American Inventors Protection Act of 1999 ("AIPA") included changes to the patent laws granting inventors additional patent term under specified conditions. These changes were codified within 35 U.S.C. § 154.

11. Under 35 U.S.C. § 154(a)(2), the grant of a patent is for a term ending 20 years from the date on which the underlying application was filed in the United States, or from certain other dates specifically referenced in the application. Because this 20-year period begins to run even before a patent is issued, any delay in the PTO's processing of an application reduces the duration of the patent term.

12. To prevent such delays from decreasing patent term, Congress directed the PTO to grant successful applicants upward adjustments of their patent terms to compensate for three categories of processing delay by the PTO. The categories of delay that are compensated are grounded in three "Guarantees" to applicants contained in § 154(b). These categories of delay set forth in 35 U.S.C. §§ 154(b)(1)(A), (B), and (C), are commonly known as "A delay," "B delay," and "C delay," respectively.

13. "B delay" is based on a statutory "Guarantee of No More Than 3-Year Application Pendency." Under this guarantee, applicants are granted additional patent term "if the issue of an original patent is delayed due to the failure of the [PTO] to issue a patent within 3 years after the actual filing date of the application in the United States." 35 U.S.C. § 154(b)(1)(B). In calculating whether the PTO has met its 3-year pendency guarantee or if,

instead, the applicant's right to patent term adjustment is triggered, the statute excludes three categories of time: 1) time consumed by continued examination of the application requested by the applicant under 35 U.S.C. § 132(b); 2) time consumed by interferences, appeals, or secrecy orders; and 3) time consumed by processing delays requested by the applicant. *See* 35 U.S.C. § 154(b)(1)(B)(i)-(iii).

14. The continued examination procedure under 35 U.S.C. § 132(b) is referred to as a request for continued examination ("RCE"). *See* 37 C.F.R. § 1.114. The current practice regarding continued examination procedure remains the same as it was at the time the AIPA was enacted.

15. The statute guarantees issuance of a patent from a pending patent application within 3 years after the actual filing date, not including time consumed during that 3-year period by RCE examination. *See* 35 U.S.C. § 154(b)(1)(B)(i); *see also Exelixis, Inc. v. Kappos*, No. 12-cv-96, 2012 WL 5398876 (E.D. Va. Nov. 1, 2012).

16. If the PTO fails to meet this guarantee, the statute grants the applicant a remedy by requiring that "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 to specific limits set forth at 35 U.S.C. § 154(b)(2). The remedy granted by the statute is separate from the events giving rise to it.

17. The scope of the granted remedy is limited only by 35 U.S.C. § 154(b)(2)(A-C), which sets forth certain conditions under which the period of additional patent term granted to an applicant may be limited or reduced. These conditions do not purport to reduce or limit patent term adjustment on the basis of time consumed by examination after filing of an RCE.

18. The PTO 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 are set forth at 37 C.F.R. § 1.704 under the heading “Reduction of period of adjustment of patent term.” These regulations do not include any reduction based on time consumed by examination after the filing of an RCE.

Proceedings in the PTO with Respect to the '583 Patent

19. Hans-Juergen Krause, Lisa Baust, and Michael Dickes are the inventors of U.S. patent application number 10/525,292 (“the '292 application”), filed as PCT/IB03/04502 on August 15, 2003.

20. On February 16, 2005, the application entered the U.S. National Stage under 35 U.S.C. § 371.

21. On November 17, 2008, the PTO mailed a restriction requirement. On December 17, 2008, the applicants filed a response to the restriction requirements.

22. On March 3, 2009, the PTO mailed a non-final action. On June 3, 2009, the applicants filed a response to the non-final action.

23. On October 1, 2009, the PTO mailed a final action.

24. On February 1, 2010, after the U.S. application had been pending for more than 3 years, the applicants filed a first request for continued examination under 35 U.S.C. § 132(b) and an accompanying amendment.

25. On February 13, 2012 and March 15, 2012, the applicants filed supplemental responses.

26. On April 5, 2012, the PTO mailed a notice of allowance.

27. On April 19, 2012, the applicants filed a second request for continued examination under 35 U.S.C. § 132(b) and an accompanying information disclosure statement.

28. On May 4, 2012, the PTO mailed a notice of allowance.

29. On May 15, 2012, the applicants paid the issue fee.

30. On July 10, 2012, the PTO issued the '583 patent.

The Correct Calculation of Patent Term for the '583 Patent

31. The PTO admits that the "A delay" calculation for the '583 patent is 1365 days.

32. The PTO admits that the "C delay" calculation for the '583 patent is 0 days.

33. The PTO failed to issue a patent within three years of the February 16, 2005, national stage commencement date of the application leading to the '583 patent, triggering the patent term adjustment provision of 35 U.S.C. § 154(b)(1)(B). The 3-year period after the filing of the '292 application ended on February 16, 2008, without the PTO having issued a patent on the application. This 3-year period did not include any time consumed by RCE continued examination. Accordingly, the three year "trigger" condition of 35 U.S.C. § 154(b)(1)(B) was satisfied.

34. Having satisfied the "trigger" condition, the "remedy" portion of the statute governs the amount of "B delay" patent term adjustment to be awarded. The "remedy" portion is the language which follows 35 U.S.C. § 154(b)(1)(B)(iii) (*i.e.*, "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"). The correct amount of "B delay" for the '583 patent is 1606 days, which is the period of time between the 3-year anniversary of the filing of the application leading to the '583 patent and the date the patent issued.

35. Accordingly, the correct total patent term adjustment for the '583 patent is 1206 days, which is equal to the total of "A delay" of 1365 days, plus "B delay" of 1606 days, plus "C delay" of 0 days, minus the "applicant delay" of 816 days, and minus 949 overlapping days for a total of 1206 days.

The PTO's Incorrect Calculation of Patent Term Adjustment for the '583 Patent

36. The patent term adjustment set forth on the face of the issued '583 patent is 989 days. The same patent term adjustment is calculated and shown on the PTO's Patent Application Information Retrieval ("PAIR") database for the '583 patent, which is attached hereto as Exhibit B.

37. The PTO's calculation shows an "A delay" of 1365 days (691 days on line 25 and 674 days on line 90), a "B delay" of 715 days (adopted in petition decision), and "applicant delay" of 816 days (adopted in petition decision). The "A delay" of 1365 days plus the "B delay" of 715 days, plus the "C delay" of 0 days, minus the "applicant delay" of 816 days, minus "overlapping days" of 275 days, yielded the PTO's total adjustment of 989 days.

38. To arrive at its calculation of "B delay" of 715 days, the PTO, as it consistently does in application of its regulation 37 C.F.R. § 1.703(b)(1), omitted the period beginning when the first RCE was filed (even though the application had already been pending three years) and ending when the patent issued. Specifically, the PTO omitted the 891-day period beginning on February 1, 2010 (*i.e.*, the date on which the first request for continued examination was filed), and ending on July 10, 2012 (*i.e.*, the date the '583 patent issued).

39. As explained above, the PTO's exclusion of this 891-day period of "B delay" is contrary to 35 U.S.C. § 154(b)(1)(B). The correct period of "B delay" is equal to the full 1606-day period from February 1, 2010 through July 10, 2012.

40. As discussed above, the patent term adjustment statute, 35 U.S.C. § 154(b)(1) provides that, once "B delay" is triggered, "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 specific limits set forth at 35 U.S.C. § 154(b)(2). Once the 3-year period has ended and the "B delay"

provision is triggered, the statute does not allow the PTO to ignore days occurring after the filing of an RCE for purposes of calculating the “B delay” remedy. Since 37 C.F.R. § 1.703(b)(1) requires otherwise, the regulation is contrary to the statute and cannot support the PTO’s patent term adjustment calculation.

First Alternative Grounds for PTO Error of the ’583 Patent Term Adjustment

41. Even under the PTO’s improper statutory interpretation, which excludes from the calculation of the length of the “B delay” adjustment “any time consumed by continued examination of the application requested by the applicant under section 132(b),” the PTO’s calculation is still incorrect. The 891-day period excluded by the PTO included time that even under the PTO’s reading of the statute was not “time consumed by continued examination.”

42. The PTO, as set forth in 37 C.F.R. § 1.703(b)(1), improperly assumes that every day after an RCE is filed constitutes “time consumed by continued examination.” No continued examination takes place after a notice of allowance is mailed until either a request for continued examination is filed or a patent is issued since prosecution on the merits has closed and no examination is taking place. Thus, no continued examination took place during the 14-day period from April 5, 2012 (the day after the first Notice of Allowance was issued) until April 19, 2012 (when a request for continued examination was filed) and during the 67-day period from May 4, 2012 (the day after the second Notice of Allowance was issued) until July 10, 2012 (when the patent issued). Thus, the total “B delay” after the first RCE was filed that was not “time consumed by continued examination” is 81 days. When added to the 715 day period of “B delay” that occurred from the day after the 3-year date to the filing date of the first RCE, the total “B delay” is 796 days.

43. Therefore, even following the PTO's improper statutory interpretation, the correct patent term adjustment is 1070 days (*i.e.*, 1365 "A delay" days + 796 "B delay" days + 0 "C delay" days - 816 "applicant delay" days - 275 "overlapping days").

Second Alternative Grounds for PTO Error of the '583 Patent Term Adjustment

44. Even under the PTO's improper statutory interpretation, which excludes from the calculation of the length of the "B delay" adjustment "any time consumed by continued examination of the application requested by the applicant under section 132(b)," the PTO's calculation is still incorrect. The 891-day period excluded by the PTO included time that even under the PTO's reading of the statute was not "time consumed by continued examination."

45. The PTO, as set forth in 37 C.F.R. § 1.703(b)(1), improperly assumes that every day after an RCE is filed constitutes "time consumed by continued examination." No continued examination takes place after a notice of allowance is mailed until a patent is issued since this time would be consumed regardless of whether a patent issued after an RCE or not. Thus, no continued examination took place during the 67-day period from May 5, 2012 (the day after the Notice of Allowance was issued) until July 10, 2012 (when the patent issued), which results in "B delay" of 782 days.

46. Thus, the total "B delay" that was not "time consumed by continued examination" is 782 days. Therefore, even following the PTO's improper statutory interpretation, the correct patent term adjustment is 1056 days (*i.e.*, 1365 "A delay" days + 782 "B delay" days + 0 "C delay" days - 816 "applicant delay" days - 275 "overlapping days").

COUNT I

(Patent Term Adjustment Under 35 U.S.C. § 154 Concerning Filing of an RCE)

47. Plaintiff incorporates paragraphs 1-46 as if fully set forth herein.

48. The PTO's calculation of the "B delay" adjustment for the '583 patent was based on an improper interpretation of 35 U.S.C. § 154(b)(1)(B) that improperly excluded "time consumed by continued examination of the application requested by the applicant under section 132(b)."

49. The PTO's regulation interpreting 35 U.S.C. § 154(b)(1)(B)—37 C.F.R. § 1.703(b)(1)—is contrary to that statute and cannot support the PTO's patent term adjustment calculation.

50. The PTO's calculation of the "B delay" adjustment for the '583 patent was also based on an interpretation of 35 U.S.C. § 154(b)(1)(B) that improperly construed the phrase "time consumed by continued examination" to include time during which there was no "continued examination."

51. The PTO's incorrect calculation of the "B delay" adjustment for the '583 patent led to an incorrect calculation of the total patent term adjustment for the '583 patent. The PTO's calculation of the total term adjustment for the '583 patent was based on improper interpretations of 35 U.S.C. § 154(b)(1)(B).

52. The PTO's patent term adjustment calculation of 989 days for the '583 patent is contrary to its statutory jurisdiction and authority, and arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that this Court:

A. Vacate the PTO's patent term adjustment calculation of 989 days for the '583 patent, order the PTO to correct the patent term adjustment for the '583 patent to 1206 days and

alter the term of the '583 patent to reflect the corrected adjustment, and to issue a certificate of correction reflecting the corrected adjustment and term.

B. In the alternative—and only if the Court rejects Plaintiff's primary contention that the PTO improperly excluded from its calculation of the length of the "B delay" adjustment all time from the filing of the first RCE until the grant of the patent—vacate the PTO's patent term adjustment calculation of 989 days for the '583 patent, order the PTO to correct the patent term adjustment for the '583 patent to 1070 days and alter the term of the '583 patent to reflect the corrected adjustment, and to issue a certificate of correction reflecting the corrected adjustment and term.

C. Further in the alternative—and only if the Court rejects Plaintiff's primary contention that the PTO improperly excluded from its calculation of the length of the "B delay" adjustment all time from the filing of the first RCE until the grant of the patent and the Court also rejects Plaintiffs' first alternative contention that the PTO improperly excluded from its calculation of the length of the "B delay" adjustment all time after the filing of the first RCE that was not, in fact, "time consumed by continued examination of the application requested by the applicant under section 132(b)"— vacate the PTO's patent term adjustment calculation of 989 days for the '583 patent, order the PTO to correct the patent term adjustment for the '583 patent to 1056 days and alter the term of the '583 patent to reflect the corrected adjustment, and to issue a certificate of correction reflecting the corrected adjustment and term..

Dated: December 28, 2012

Respectfully submitted,



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