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

ELI LILLY AND COMPANY)

Plaintiff,)

v.)

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)

Madison Building East, Rm. 10B20)
600 Dulany Street, Alexandria, VA 22314)

Defendant.)

Case No. 1:12cv1396
AJT/TCB

COMPLAINT

Plaintiff, Eli Lilly and Company ("Lilly"), 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. 8,114,901 ("the '901 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 Lilly a patent term adjustment of 848 days. Lilly asserts that it is entitled to a patent term adjustment of 1408 days.

3. Pursuant to 35 U.S.C. § 154(b)(4)(A), Lilly 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 Lilly is an Indiana corporation that has its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is the assignee with all right, title, and interest in the '901 patent, as evidenced by the assignment documents recorded in the PTO and the face of the '901 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 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).[1]

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 twenty 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

[1] This complaint is being filed within 180 days of the PTO's decision on Lilly's Request for Reconsideration of Patent Adjustment Indicated at Issuance (37 C.F.R. § 1.705). *See Bristol-Myers Squibb Co. v. Kappos*, No. 09-cv-1330, 2012 WL 4127636, at *6 (D.D.C. Sept. 20, 2012); *Novartis AG v. Kappos*, No. 10-cv-1138, 2012 WL 5564736, at *8 (D.D.C. Nov. 15, 2012). Alternatively, Lilly's action is timely filed because the 180-day limitation period in 35 U.S.C. § 154(b)(4)(A) is inapplicable to Lilly's claim herein. The 180-day limitation period in 35 U.S.C. § 154(b)(4)(A) applies to a re-determination of PTA by the PTO under "paragraph (3)," *i.e.*, 35 U.S.C. § 154(b)(3). 35 U.S.C. § 154(b)(3), by its plain terms, governs a PTA determination by the PTO only in conjunction with a notice of allowance of a patent application. 35 U.S.C. § 154(b)(3) does not cover a PTA determination by the PTO in conjunction with the issuance of a patent. The "B delay" determination by the PTO that is the subject of this complaint was not made by the PTO at the notice of allowance stage; such determination was first made by the PTO at the time the '901 patent issued. Due to the narrow scope of 35 U.S.C. § 154(b)(3), the limitation period in 35 U.S.C. § 154(b)(4)(A) does not restrict the time within which a patentee, through a civil action in this District, may appeal a PTA determination by the PTO made contemporaneous with the issuance of a patent.

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).

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 '901 Patent

19. Julie Kay Bush, Margaret Mary Faul, and Susan Marie Reutzel-Edens are the inventors of U.S. patent application number 10/520,360 ("the '360 application"), filed as PCT/US03/19548 on July 8, 2003.

20. On January 12, 2005, the application entered the U.S. National Stage under 35 U.S.C. § 371.

21. On June 29, 2006, the PTO mailed a first non-final action. On October 20, 2006, the applicants filed a response to the first non-final action.

22. On January 11, 2007, the PTO mailed a final action. On April 11, 2007, the applicants filed a reply and amendment.

23. On May 3, 2007, the PTO mailed an advisory action. On July 11, 2007, the applicants filed a response to the advisory action.

24. On August 16, 2007, the PTO mailed a non-final action.

25. On February 12, 2008, the applicant filed a response to the non-final action.

26. On April 30, 2008, the PTO mailed a final rejection.

27. On July 29, 2008, the applicants filed a notice of appeal.

28. On September 22, 2008, the applicants filed an appeal brief. On February 5, 2009, the PTO mailed the examiner's answering brief.

29. On January 28, 2010, the PTO mailed its decision reversing the examiner.

30. On May 4, 2010, the PTO mailed a notice of allowance.

31. On August 4, 2010, after the U.S. application had been pending for more than 5 years, the applicants filed a first request for continued examination under 35 U.S.C. § 132(b) and an accompanying information disclosure statement.

32. On November 30, 2010, the PTO mailed a non-final action. On January 31, 2011, the applicants filed a response to the non-final action. On February 9, 2011, the applicants filed a supplemental response to the non-final action.

33. On April 28, 2011, the PTO mailed a final action. On May 9, 2011, the applicants filed a response to the action.

34. On June 20, 2011, the applicants filed a notice of appeal. On July 15, 2011, the applicants filed an appeal brief.

35. On September 28, 2011, the PTO mailed a notice of allowance.

36. On October 18, 2011, the applicant paid the issue fee.

37. On February 14, 2012, the PTO issued the '901 patent.

The Correct Calculation of Patent Term for the '901 Patent

38. The PTO admits that the "A delay" calculation for the '901 patent is 123 days.

39. The PTO admits that the "C delay" calculation for the '901 patent is 549 days.

40. The PTO failed to issue a patent within three years of the January 12, 2005, filing date of the application leading to the '901 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 '360 application ended on January 12, 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.

41. 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 '901 patent is 945 days, which is the period of time between the 3-year anniversary of the filing of the application leading to the '901 patent and the date the patent issued.

42. Accordingly, the correct total patent term adjustment for the '901 patent is 1408 days, which is equal to the total of "A delay" of 123 days, plus "B delay" of 945 days, plus "C delay" of 549 days, minus the "applicant delay" of 209 days for a total of 1408 days.

The PTO's Incorrect Calculation of Patent Term Adjustment for the '901 Patent and Lilly's Request for Reconsideration

43. The patent term adjustment set forth on the face of the issued '901 patent is 848 days. The same patent term adjustment is calculated and shown on the PTO's Patent Application Information Retrieval ("PAIR") database for the '901 patent, which is attached hereto as Exhibit B.

44. The PTO's calculation shows an "A delay" of 123 days (109 days on line 17 and 14 days of PTO Manual Adjustments), a "B delay" of 385 days (shown as "PTA 36 months" on line 181.5), and "applicant delay" of 209 days (21 days on line 19, 91 days on line 34, 88 days on line 45, and 9 days on line 124). The "A delay" of 123 days plus the "B delay" of 385 days plus the "C delay" of 549 days minus the "applicant delay" of 209 days yielded the PTO's total adjustment of 848 days.

45. To arrive at its calculation of "B delay" of 385 days, the PTO omitted the 560-day period beginning on August 4, 2010 (*i.e.*, the date on which the request for continued examination was filed), and ending on February 14, 2012 (*i.e.*, the date the '901 patent issued).

46. As explained above, the PTO's exclusion of this 560-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 945-day period from August 4, 2010 through February 14, 2012.

47. On March 14, 2012, Plaintiff filed a Request for Reconsideration of Patent Term Adjustment Indicated at Issuance (37 C.F.R. § 1.705(d)) ("Request for Reconsideration").

48. On June 12, 2012, the PTO issued a Decision on Request for Reconsideration of Patent Term Adjustment. In the Decision, the PTO dismissed Plaintiff's Request for Reconsideration.

49. 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. To the extent that 37 C.F.R.

§ 1.703(b)(1) would require otherwise, the regulation is contrary to the statute and cannot support the PTO's patent term adjustment calculation.

Alternative Grounds for PTO Error

50. 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 560-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."

51. 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 139-day period from September 29, 2011 (the day after the Notice of Allowance was issued when the applicant filed the RCE) until February 14, 2012 (when the patent issued), which results in "B delay" of 524 days.

52. Thus, the total "B delay" that was not "time consumed by continued examination" is 139 days. Therefore, even following the PTO's improper statutory interpretation, the correct patent term adjustment is 987 days (*i.e.*, 123 "A delay" days + 524 "B delay" days + 549 "C delay" days - 209 "applicant delay" days).

COUNT I

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

53. Plaintiff incorporates paragraphs 1-52 as if fully set forth herein.

54. The PTO's calculation of the "B delay" adjustment for the '901 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)."

55. 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.

56. The PTO's calculation of the "B delay" adjustment for the '901 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."

57. The PTO's incorrect calculation of the "B delay" adjustment for the '901 patent led to an incorrect calculation of the total patent term adjustment for the '901 patent. The PTO's calculation of the total term adjustment for the '901 patent was based on improper interpretations of 35 U.S.C. § 154(b)(1)(B).

58. The PTO's patent term adjustment calculation of 848 days for the '901 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 848 days for the '901 patent, order the PTO to correct the patent term adjustment for the '901 patent to 1408 days and

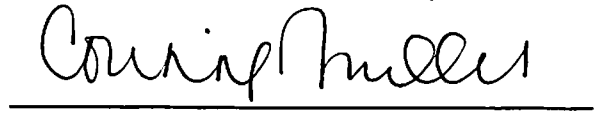
alter the term of the '901 patent to reflect the corrected adjustment, and to issue a certificate of correction reflecting the corrected adjustment and term.

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 "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 848 days for the '901 patent, order the PTO to correct the patent term adjustment for the '901 patent to 987 days and alter the term of the '901 patent to reflect the corrected adjustment, and to issue a certificate of correction reflecting the corrected adjustment and term.

C. Grant such further and other relief as this Court deems just and proper.

Dated: December 6, 2012

Respectfully submitted,



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