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; and

UNITED STATES PATENT AND TRADEMARK OFFICE

Defendants.

Case No. 1:12CV1491-AJT/JFA

COMPLAINT

Plaintiff, Eli Lilly and Company ("Lilly"), for its complaint against Defendants, 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 Nos. 7,498,414 ("the '414 patent") (attached hereto as Exhibit A) seeking correction 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 5 days for the '414 patent. Lilly asserts that it is entitled to a patent term adjustment of 551 days.

3. Lilly hereby seeks review of and a remedy for the PTO's failure to award the proper amount of patent term adjustment for this patent.

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 '414 patent, as evidenced by the assignment documents recorded in the PTO.

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), and is a proper defendant in a suit seeking review of such determinations.

6. Defendant the PTO is a federal agency within the United States Department of Commerce. The PTO is located at 600 Dulany St., Alexandria, Virginia 22314.

JURISDICTION, VENUE, AND TIMING

A. JURISDICTION

7. This action arises under 35 U.S.C. § 154 and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 because it arises under the Constitution and laws of the United States. This Court otherwise has subject-matter jurisdiction over this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a), 1361, 35 U.S.C. § 154, and/or 5 U.S.C. §§ 701-706.

9. This Court has personal jurisdiction over Defendants because they are domiciled in this district and/or engaged in the acts at issue in this district.

10. The agency action challenged herein constitutes a final agency action reviewable in this Court under the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

B. VENUE

11. Venue is proper in this district pursuant to 28 U.S.C. § 1391 (b), (e), and 35 U.S.C. § 1(b), because this is a civil action against an agency of the United States and an officer of that agency acting in his official capacity, and a substantial part of the events or omissions giving rise to the claim occurred in this district.

C. TIMELINESS

12. This Complaint has been filed within six years of the issuance of the '414 patent and the assignment of "B" delay by the Director that is the subject of this complaint and is thus timely filed in accordance with 28 U.S.C. § 2401(a).

13. The 180-day limitation period in 35 U.S.C. § 154(b)(4)(A) is inapplicable to Lilly's claims herein.

14. The 180-day limitation period in 35 U.S.C. § 154(b)(4)(A) expressly applies to a determination of patent term adjustment by the PTO under "paragraph (3)," *i.e.*, 35 U.S.C. § 154(b)(3).

15. 35 U.S.C. § 154(b)(3), by its plain terms, only governs a patent term adjustment determination by the PTO to the patent applicant with the written notice of allowance of a patent application. The PTO could and should under the statute provide a fully updated patent term adjustment determination, including both "A" and "B" delay, in conjunction with the notice of allowance. Considerable "B" delay often accrues by the time the PTO provides the applicant the written notice of allowance. The only delay the PTO cannot definitively determine at the notice of allowance stage are delays occurring from the relatively short period of time from the notice of allowance until patent issuance. The PTO, however, under its current rules and practice, does not provide *any* notice of "B" delay at the time of the notice of allowance, but instead *only* provides notification of "B" delay when the patent issues.

16. The PTO's rules and practice of not calculating any "B" delay with the notice of allowance means that patent applicants cannot address disputes regarding patent term adjustment determinations by the PTO until after the patent issues, which is the first time the PTO provides notice to the applicants of its calculation of "B" delay. This PTO practice has significantly complicated the patent term adjustment process, results in patent term adjustment determinations at multiple times in the patent process, and has resulted in the PTO engaging in activity not contemplated by Congress.

17. Indeed, and consistent with the statutory framework of having the PTO determine patent term adjustment at the time of allowance, the language of 35 U.S.C. § 154(b)(3) expressly

does not cover a patent term adjustment determination by the PTO in conjunction with the issuance of a patent.

18. The "B delay" determination by the PTO for the '414 patent, which is the subject of this complaint, was not made by the PTO at the notice of allowance stage, but was instead first made by the PTO at the time the '414 patent issued.

19. Accordingly, and due to the expressed language and the limited scope of 35 U.S.C. § 154(b)(3) discussed above, the 180-day 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 patent term adjustment determination by the PTO made for the first time contemporaneous with the issuance of a patent.

20. As such, Lilly is not barred by 35 U.S.C. § 154(b)(4)(A) in appealing the patent term adjustment determination as to the '414 patent.

D. EQUITABLE TOLLING

21. Even if the 180-day limitation period set forth in 35 U.S.C. § 154(b)(4)(A) is applicable to Lilly's claims herein, it is a non-jurisdictional statute of limitations.

22. The equitable tolling doctrine is a creation of common law that has been read into every statute of limitations.

23. Lilly lacked and continues to lack knowledge and adequate notice of the potential viability of its claim in Count I, *infra*, concerning the '414 patent and, thus, the appropriate patent term of the this patent, until the action entitled *Novartis AG v. Kappos*, 2012 WL 5564736, Civil Action No. 10-CV-1138 (D.D.C. Nov. 15, 2012), including any appeal from that case, is finally resolved.

24. Lilly justifiably relied to its detriment upon Defendants' consistent and long standing, yet flawed, interpretation of 35 U.S.C. § 154(b)(1)(B) to determine patent term

adjustment in failing to raise its claim under Court I, *infra*, as to the '414 patent at any earlier date.

25. Accordingly, the 180-day limitation period set forth in 35 U.S.C. § 154(b)(4)(A) should be equitably tolled from the date the *Novartis AG v. Kappos* litigation is finally resolved.

E. DISCOVERY RULE

26. The discovery rule, which governs a claim's accrual date for statute of limitations purposes, is distinct from equitable tolling.

27. The discovery rule is to be applied in all federal question cases in the absence of a contrary directive from Congress.

28. The deprivation of patent term for the '414 patent resulting from Defendants' failure to properly determine PTA under of 35 U.S.C. § 154(b)(1)(B) was not the sort of injury that could readily have been discovered by Lilly at the time of the deprivation due to Defendants' consistent policy and practice of incorrectly interpreting and implementing this statutory provision.

29. Lilly, with due diligence, could not have discovered the deprivation of patent term for the '414 patent resulting from Defendants' failure to properly determine patent term adjustment under of 35 U.S.C. § 154(b)(1)(B) until the decision of United States District Court for the District of Columbia in *Novartis AG v. Kappos*, 2012 WL 5564736, Civil Action No. 10-cv-1138 (D.D.C. Nov. 15, 2012), and/or any appeal of that decision.

30. Accordingly, the 180-day limitation period set forth in 35 U.S.C. § 154(b)(4)(A) should not run until, at the earliest, the November 15, 2012, date of the *Novartis AG v. Kappos* decision.

BACKGROUND

The Patent Term Adjustment Statute

31. 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.

32. 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.

33. 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.

34. "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).

35. 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.

36. 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).

37. 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.

38. 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.

39. 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.

40. Moreover, the relevant statutes and regulations require that when calculating "B delay" for a national stage filing under 35 U.S.C. § 371, application pendency must be measured from the date that is 30 months from the priority date of the international application (*i.e.*, not from the date on which the application fulfilled the requirements of 35 U.S.C. § 371).

41. The term of a patent shall, under certain circumstances, be extended if the PTO fails to issue a patent within three years after the "actual filing date" of the application. *See* 35 U.S.C. § 154(b)(1)(B). 37 C.F.R. § 1.702(b) explains the meaning of the term "actual filing date" as used in this subsection of the statute. PTO delay for a national stage application begins if the PTO fails to issue a patent within three years after the date the national stage "commenced under 35 U.S.C. § 371(b) or (f)." 37 C.F.R. § 1.702(b); *see also* MPEP § 2730.

42. 35 U.S.C. § 371(b) and (f) refer to the time when a national stage application "commences." Specifically, under § 371(b), the national stage "shall commence with the expiration of the applicable time limit under article 22(1) or (2), or under article 39(1)(a) of the treaty."

43. Under § 371(f), "[a]t the express request of the applicant, the national stage of processing may be commenced at any time at which the application is in order for such purpose and the applicable requirements of subsection (c) of this section have been complied with." 35 U.S.C. § 371(f) relates to the situation where an applicant files an express request for early processing of an international application.

44. In the absence of filing such a request, the U.S. national stage commences under the provisions of 35 U.S.C. § 371(b), *i.e.* with the expiration of the applicable time limit under article 22(1) or (2), or under article 39(1)(a) of the treaty. The "applicable time limit" referred to in Patent Cooperation Treaty articles 22(1), 22(2), and 39(1)(a) is "the expiration of 30 months

from the priority date." As a result, the "expiration of 30 months from the priority date" is the time at which the U.S. national stage commences under the provisions of 35 U.S.C. § 371(b). *See also* MPEP § 1893.01.

45. In view of the foregoing, the "actual filing date" of a U.S. national stage application filed under 35 U.S.C. § 371, for purposes of calculating "B delay" under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b), is the date that is 30 months from the priority date of the international application (absent meeting the requirements to enter earlier). *See* PTO Notice Concerning Calculation of the Patent Term Adjustment under 35 U.S.C. § 154(b)(1)(B) involving International Applications Entering the National Stage Pursuant to 35 U.SC. § 371 (September 9, 2009).

Proceedings in the PTO with Respect to the '414 Patent

46. Zhenping Zhu is the inventor of U.S. patent application number 10/506,997 ("the '997 application"), filed as PCT/US03/06459 on March 4, 2003.

47. On September 4, 2004, the application entered the U.S. National Stage under 35 U.S.C. § 371. This date is 30 months from the March 4, 2002, priority date of the international application.

48. On January 19, 2007, the PTO mailed a restriction requirement. On July 9, 2007, the applicant filed a response to the restriction requirement.

49. On August 31, 2007, the PTO mailed a non-final action. On March 3, 2008, the applicant filed a response to the non-final action.

50. On September 4, 2007, the application leading to the '414 patent had been pending for three years.

51. On June 12, 2008, the PTO mailed a notice of allowance.

52. On August 15, 2008, after the U.S. application had been pending for more than 3 years, the applicant filed a first request for continued examination under 35 U.S.C. § 132(b) and an accompanying information disclosure statement.

53. On November 13, 2008, the PTO mailed a notice of allowance.

54. On January 21, 2009, the applicant paid the issue fee.

55. On March 3, 2009, the PTO issued the '414 patent.

The Correct Calculation of Patent Term for the '414 Patent

56. The PTO admits that the "A delay" calculation for the '414 patent is 180 days.

57. The PTO admits that the "C delay" calculation for the '414 patent is 0 days.

58. The PTO failed to issue a patent within three years of the September 4, 2004, filing date of the application leading to the '414 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 '997 application ended on September 4, 2007, 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.

59. 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 '414 patent is 546 days, which is the period of time between the 3-year anniversary of the filing of the application leading to the '414 patent and the date the patent issued.

60. Accordingly, the correct total patent term adjustment for the '414 patent is 551 days, which is equal to the total of "A delay" of 180 days, plus "B delay" of 546 days, plus "C delay" of 0 days, minus the "applicant delay" of 175 days for a total of 551 days.

The PTO's Incorrect Calculation of Patent Term Adjustment for the '414 Patent

61. The patent term adjustment set forth on the face of the issued '414 patent is 5 days. The same patent term adjustment is calculated and shown on the PTO's Patent Application Information Retrieval ("PAIR") database for the '414 patent, which is attached hereto as Exhibit B.

62. The PTO's calculation shows an "A delay" of 180 days (180 days on line 22), a "B delay" of 0 days (shown as "PTA 36 months" on line 83.5), and "applicant delay" of 175 days (94 days on line 38 and 81 days on line 32). The "A delay" of 180 days plus the "B delay" of 0 days plus the "C delay" of 0 days minus the "applicant delay" of 175 days yielded the PTO's total adjustment of 5 days.

63. To arrive at its calculation of "B delay" of 0 days, the PTO improperly used the May 23, 2005, § 371(c) completion date, rather than the September 4, 2004, national stage entry date, as the basis for the calculation of the three-year pendency deadline. In addition, the PTO omitted the period beginning on August 15, 2008 (*i.e.*, the date on which the request for continued examination was filed), and ending on March 3, 2009 (*i.e.*, the date the '414 patent issued).

64. As explained above, the PTO's exclusion of this 546-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 546-day period from September 4, 2007 through March 3, 2009.

65. As discussed above, the "actual filing date" of a U.S. national stage application filed under 35 U.S.C. § 371, for purposes of calculating "B delay" under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b), is the date that is 30 months from the priority date of the international application—not the § 371(c) completion date.

66. Moreover, 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.

First Alternative Grounds for PTO Error

67. 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 546-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."

68. 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 110-day period from November 14, 2008 (the day

after the Notice of Allowance was issued) until March 3, 2009 (when the patent issued), which results in "B delay" of 456 days.

69. Thus, the total "B delay" that was not "time consumed by continued examination" is 110 days. Therefore, even following the PTO's improper statutory interpretation, the correct patent term adjustment is 461 days (*i.e.*, 180 "A delay" days + 456 "B delay" days + 0 "C delay" days - 175 "applicant delay" days).

Second Alternative Grounds for PTO Error

70. Even if the '414 patent is not entitled to any additional patent term adjustment under the theories above, the '414 patent should be awarded total patent term adjustment of 351 days, which corrects the PTO's admittedly improper calculation of the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) in this international application.

71. As explained in the PTO's Notice Concerning Calculation of the Patent Term Adjustment under 35 U.S.C. § 154(b)(1)(B) involving International Applications Entering the National Stage Pursuant to 35 U.SC. § 371 (September 9, 2009), the date for calculation the '414 patent application's three-year pendency should have been September 4, 2007, which is the date that the application entered the national stage. The PTO, however, used the § 371(c) completion date of May 23, 2005, as the date for calculating the application's three-year pendency.

72. Under the proper interpretation of the statute, the total "B delay," calculated beginning with the September 4, 2004, national stage commencement date for the three-year pendency deadline, and ending with the filing of a request for continued examination on August 15, 2008, is 346 days. Thus, the correct patent term adjustment is 351 days (*i.e.*, 180 "A delay" days + 346 "B delay" days + 0 "C delay" days - 175 "applicant delay" days).

COUNT I

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

73. Plaintiff incorporates paragraphs 1-72 as if fully set forth herein.

74. The PTO's calculation of the "B delay" adjustment for the '414 patent was based on an improper date for entry of the national phase of the international application.

75. The PTO's calculation of the "B delay" adjustment for the '414 patent was also 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)."

76. 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.

77. The PTO's calculation of the "B delay" adjustment for the '414 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."

78. The PTO's incorrect calculation of the "B delay" adjustment for the '414 patent led to an incorrect calculation of the total patent term adjustment for the '414 patent. The PTO's calculation of the total term adjustment for the '414 patent was based on improper interpretations of 35 U.S.C. § 154(b)(1)(B).

79. The PTO's patent term adjustment calculation of 5 days for the '414 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 5 days for the '414 patent, order the PTO to correct the patent term adjustment for the '414 patent to 551 days and alter the term of the '414 patent to reflect the corrected adjustment, and to issue a certificate of correction reflecting the corrected adjustment and term.

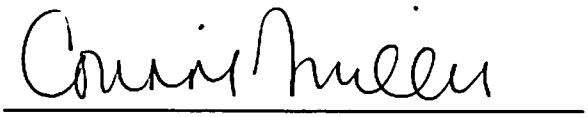
B. In the alternative—and only if the Court rejects Plaintiff's primary contention that the PTO improperly excluded from its calculation of the length of the "B delay" adjustment "time consumed by continued examination of the application requested by the applicant under section 132(b)"—vacate the PTO's patent term adjustment calculation of 5 days for the '414 patent, order the PTO to correct the patent term adjustment for the '414 patent to 461 days and alter the term of the '414 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 and secondary contentions 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 5 days for the '414 patent, order the PTO to correct the patent term adjustment for the '414 patent to 351 days and alter the term of the '414 patent to reflect the corrected adjustment, and to issue a certificate of correction reflecting the corrected adjustment and term.

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

Dated: December 26, 2012

Respectfully submitted,



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