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

OTSUKA PHARMACEUTICAL CO., LTD

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. 1:12cv357 AJT/TCB

COMPLAINT

Plaintiff, Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), 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. 8,030,312 ("the '312 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 Otsuka a patent term adjustment of 152 days. Otsuka asserts that it is entitled to a patent term adjustment of 1220 days.

3. Otsuka has exhausted its administrative remedies by petition under 37 C.F.R. § 1.705(d) for the PTO to reconsider its patent term adjustment calculation. The PTO denied Otsuka's petition that it is entitled to a patent term adjustment of 1220 days on December 14, 2011.

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

THE PARTIES

1. Plaintiff Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan. Otsuka is the assignee with all right, title, and interest in the '312 patent, as evidence by the assignment documents recorded in the PTO and the face of the '312 patent.

2. 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

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

4. 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.

5. 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).

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

BACKGROUND

The Patent Term Adjustment Statute

7. 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.

8. 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.

9. 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.

10. "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).

11. 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.

12. 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).

13. The statute also 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 appellate review by the Board of Patent Appeals and Interferences or by a Federal Court. *See* 35 U.S.C. § 154(b)(1)(B)(ii). The Board of Patent Appeals and Interferences does not assume jurisdiction over an appeal from the PTO until there is "transmittal of the file, including all briefs and examiner's answer, to the Board." 37 C.F.R. § 41.35.

14. 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.

15. The scope of the granted remedy is limited only by 35 U.S.C. § 154(b)(2)(A-C), which set 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 or time consumed after the filing of a notice of appeal but before the Board of Patent Appeals and Interferences assumes jurisdiction of the appeal.

16. 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."

17. These regulations do not include any reduction based on time consumed by examination after the filing of an RCE or time consumed after the filing of a notice of appeal but before the Board of Patent Appeals and Interferences assumes jurisdiction of the appeal.

Proceedings in the PTO with Respect to the '312 Patent

18. Shaun Jordan, Tetsuro Kikuchi, Katsura Tottori, Tsuyoshi Hirose, and Yasufumi Uwahodo are the inventors of U.S. patent application number 10/876,605 ("the '605 application"), filed on June 28, 2004.

19. On October 19, 2006, the PTO mailed a restriction requirement. On January 19, 2007, the applicant filed a response to the restriction requirement.

20. On May 16, 2007, the PTO mailed a first non-final action. On November 16, 2007, the applicant filed a response to the first non-final action.

21. On December 13, 2007, and January 18, 2008, the applicant filed a first and second information disclosure statement.

22. On March 3, 2008, the PTO mailed a second non-final action. On September 3, 2008, the applicant filed a notice of appeal. On January 30, 2009, the applicant filed a response to the second non-final action with a first request for continued examination under 35 U.S.C. § 132(b).

23. On April 10, 2009, the PTO mailed a third non-final action. On September 10, 2009, the applicant filed a response to the third non-final action.

24. On November 23, 2009, the applicant filed a third information disclosure statement.

25. On December 9, 2009, the PTO mailed a final action. On April 22, 2010, the applicant filed a response to the final action and a second request for continued examination under 35 U.S.C. § 132(b). On May 7, 2010, the applicant filed a supplemental response to the final action.

26. On June 9, 2010, June 30, 2010, and July 21, 2010, the applicant filed a fourth, fifth, and sixth information disclosure statement.

27. On August 23, 2010, the PTO mailed a fourth non-final action. On February 22, 2011, the applicant filed a response to the fourth non-final action.

28. On March 29, 2011, and May 2, 2011, the applicant filed a seventh and eight information disclosure statement.

29. On May 26, 2011, the PTO mailed a notice of allowance.

30. On June 16, 2011, the applicant filed a ninth information disclosure statement. On June 28, 2011, the Examiner considered the ninth information disclosure statement.

31. On August 25, 2011, the applicant paid the issue fee and filed an amendment pursuant to 37 C.F.R. § 1.312 with the issue fee payment. On September 1, 2011, the Examiner entered the amendment and issued a supplemental notice of allowability.

32. On October 4, 2011, the PTO issued the '312 patent.

The Correct Calculation of Patent Term for the '312 Patent

33. The PTO admits that the "A delay" calculation for the '312 patent is 418 days.

34. The PTO failed to issue a patent within three years of the June 28, 2004, filing date of the application leading to the '312 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 '605 application ended on June 28, 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 or appellate review by the Board of Patent Appeals and Interferences or by a Federal Court. Accordingly, the three year "trigger" condition of 35 U.S.C. § 154(b)(1)(B) was satisfied.

35. 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 '312 patent is 1559 days, which is the period of time between the 3-year anniversary of the filing of the application leading to the '312 patent and the date the patent issued.

36. Accordingly, the correct total patent term adjustment for the '312 patent is 1220 days, which is equal to the total of "A delay" of 418 days, plus "B delay" of 1559 days, minus the "applicant delay" of 756 days, and minus 1 day during which the "A delay" and "B delay" "overlap[ped]" within the meaning of 35 U.S.C. § 154(b)(2)(A), *see Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), (*i.e.*, August 23, 2010), for a total of 1220 days.

The PTO's Incorrect Calculation of Patent Term Adjustment for the '312 Patent and Otsuka's Request for Reconsideration

37. The patent term adjustment set forth on the face of the issued '312 patent is 209 days. On March 6, 2012, the PTO issued a Certificate of Correction stating that the corrected patent term adjustment is 152 days. The same corrected patent term adjustment is calculated and shown on the PTO's Patent Application Information Retrieval ("PAIR") database for the '312 patent, which is attached hereto as Exhibit B.

38. The PTO's calculation shows an "A delay" of 418 days (417 days on line 25 and 1 day on line 115), a "B delay" of 432 days (shown as "PTA 36 months" on line 160.5), and "applicant delay" of 698 days (92 days on line 39, 63 days on line 47, 92 days on line 54, 62 days on line 74, 74 days on line 86, 44 days on line 91, 91 days on line 118, 69 days on line 133, 13 days on line 144, 41 days on line 150, and 57 days on line 164). The "A delay" of 418 days plus the "B delay" of 432 days minus the "applicant delay" of 698 days yielded the PTO's total adjustment of 152 days.

39. To arrive at its calculation of "B delay" of 432 days, the PTO omitted the 1127-day period beginning on September 3, 2008 (*i.e.*, the date on which the notice of appeal was filed), and ending on October 4, 2011 (*i.e.*, the date the '312 patent issued).

40. As explained above, the PTO's exclusion of this 1127-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 1559-day period from September 3, 2008 through October 4, 2011.

41. On December 2, 2011, Plaintiff filed an Application for Patent Term Adjustment–Post Grant including a request for reconsideration under 37 C.F.R. § 1.705(d) ("Request for Reconsideration"). The Request for Reconsideration, which is attached hereto as Exhibit C, raised *inter alia* the issues asserted in this Complaint and indicated that the '312 patent is entitled to a total patent term adjustment of 1220 days, or in the alternative, 836 days. In the Request for Reconsideration, Plaintiff also pointed out that the PTO's assessment of "applicant delay" was incorrect.

42. The PTO issued a Decision on Request for Reconsideration of Patent Term Adjustment and Notice of Intent to Issue Certificate of Correction ("Decision") on December 14, 2011, attached hereto as Exhibit D. In the Decision, the PTO granted Plaintiff's Request for Reconsideration to the extent that the Request for Reconsideration indicated that the PTO's assessment of "applicant delay" was incorrect. The PTO denied Plaintiff's Request for Reconsideration to the extent that Plaintiff argued that the correct period of "B delay" should be 1559 days, or in the alternative 1175 days. According to the PTO, "the period beginning on the date the RCE was filed up until the date of issuance of the patent was considered time consumed by examination of an application under 35 U.S.C. 132(b) and was not included in the 'B delay.'" (Ex. D, December 14, 2011, Decision at 3.) Likewise, the PTO stated that "the period consumed by appellate review, whether successful or not, is excluded from the calculation of B delay." (*Id.*) Consistent with its Decision, the PTO issued a Certificate of Correction on March 6, 2012, correcting the patent term extension of the '312 patent from 209 days to 152 days.

43. 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 or a notice of an appeal for purposes of calculating the "B delay" remedy. To the extent that 37 C.F.R. §§ 1.703(b)(1) and 1.703(b)(4) would require otherwise, these regulations are contrary to the statute and cannot support the PTO's patent term adjustment calculation.

Alternative Grounds for PTO Error

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)" and "any time consumed by appellate review by the Board of Patent Appeals and Interferences," the PTO's calculation is still incorrect. The 1127-day period excluded by the PTO included time that was not "time consumed by continued examination" or "time consumed by appellate review by the Board of Patent Appeals and Interferences."

45. First, 37 C.F.R. § 1.703(b)(1) improperly assumes that every day after an RCE is filed constitutes "time consumed by continued examination." The time from when an Office Action is mailed to the time that a response is filed is not "time consumed by continued examination" because no examination is taking place during this time. Additionally, after a notice of allowance is mailed until either a patent is issued or a paper is filed by applicant, no continued examination is normally taking place 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 153-day period from April 10, 2009 (when the third non-final action issued after the first RCE was filed) until September 10, 2009 (when the response was filed), during the 134-day period from December 9, 2009 (when the final action issued) until April 22, 2010 (when the first response was filed), during the 183-day period from August 23, 2010 (when the fourth non-final action issued) until February 22, 2011 (when the response was filed), during the 91-day period from May 26, 2011 (when the Notice of Allowance was issued) to August 25, 2011 (when the issue fee was paid and an amendment pursuant to 37 C.F.R. § 1.312 was filed), and during the 33-day period from September 1, 2011 (when the supplemental notice of allowance was issued) until October 4, 2011 (when the patent issued). In total, those delays result in "B delay" of 594 days.

46. Second, 37 C.F.R. § 1.703(b)(4) counts the days "beginning on the date on which a notice of appeal to the Board of Patent Appeals and Interferences was filed." The statute, however, excludes "time consumed by *appellate review* by the Board of Patent Appeals and Interferences or by a Federal court." 35 U.S.C. § 154(b)(1)(B)(ii) (emphasis added). No appellate review occurs upon filing of a notice of appeal until the Board assumes jurisdiction of the appeal from the PTO. As the PTO's own regulations clearly state, the Board does not have jurisdiction until there is "transmittal of the file, *including all briefs and examiner's answer,* to the Board." 37 C.F.R. § 41.35 (emphasis added).[1] In this case, the '605 application never fell under "appellate review" because an RCE was filed prior to any briefs being filed and prior to the file being transferred to the Board. Accordingly, the "B delay" includes the 581-day period between the expiration of the three-year pendency (i.e., June 28, 2007) and the filing of the RCE

[1] The PTO has made a formal proposal to change "its interpretation of the appellate review language of the 'B' provision (35 U.S.C. 154(b)(1)(B)(ii)), and provide that appellate review begins on the date on which jurisdiction over the application passes to the Board of Patent Appeals and Interferences under 37 CFR 41.35." 76 Fed. Reg. 81432-33 (Dec. 28, 2011).

(i.e., January 30, 2009) and does not simply terminate at the date the notice of appeal was filed (i.e., September 3, 2008).

47. Thus, the total "B delays" that was not "time consumed by continued examination" or "time consumed by appellate review by the Board of Patent Appeals and Interferences" is 1175 days (i.e., 594 days + 581 days). Therefore, even following the PTO's improper statutory interpretation, the correct patent term adjustment is 836 days (i.e., 418 "A delay" days + 1175 "B delay" days - 1 "overlap" day - 756 "applicant delay" days).

COUNT I

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

49. The PTO's calculation of the "B delay" adjustment for the '312 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)" and "time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal Court."

50. The PTO's regulations interpreting 35 U.S.C. § 154(b)(1)(B)—37 C.F.R. §§ 1.703(b)(1) and (b)(4)—are contrary to that statute and cannot support the PTO's patent term adjustment calculation.

51. The PTO's calculation of the "B delay" adjustment for the '312 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" and the phrase "time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal court" to include time during which there was no "appellate review."

52. The PTO's incorrect calculation of the "B delay" adjustment for the '312 patent led to an incorrect calculation of the total patent term adjustment for the '312 patent. The PTO's calculation of the total term adjustment for the '312 patent was based on improper interpretations of 35 U.S.C. § 154(b)(1)(B).

53. The PTO's patent term adjustment calculation of 152 days for the '312 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:

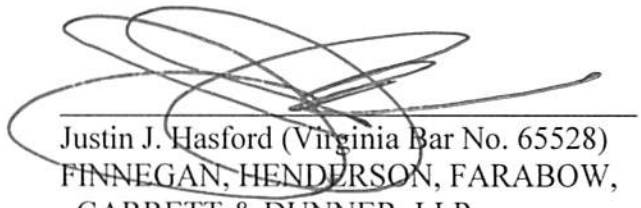
A. Vacate the PTO's patent term adjustment calculation of 152 days for the '312 patent, order the PTO to correct the patent term adjustment for the '312 patent to 1220 days and alter the term of the '312 patent to reflect the corrected adjustment, and to issue a certificate of correction reflecting the 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)" and "time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal Court"—vacate the PTO's patent term adjustment calculation of 152 days for the '312 patent, order the PTO to correct the patent term adjustment for the '312 patent to 836 days and alter the term of the '312 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: March 30, 2012

Respectfully submitted,



Justin J. Hasford (Virginia Bar No. 65528)
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000
(202) 408-4400 (fax)
justin.hasford@finnegan.com

Attorney for Plaintiff

Of Counsel:
Charles E. Van Horn
Krista E. Bianco
FINNEGAN, HENDERSON,
FARABOW, GARRETT &
DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000