

FILED

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

2012 AUG -9 A 11: 52

CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

ARIAD PHARMACEUTICALS, INC.)
)
)
Plaintiff,)
)
)
v.)
)
)
DAVID J. KAPPOS,)
)
in his official capacity as Under Secretary of)
Commerce for Intellectual Property and Director)
of the United States Patent and Trademark Office)
)
Defendant.)

Civil Action No. 1:12CV886-TSE-TRJ

COMPLAINT

Plaintiff, ARIAD Pharmaceuticals, Inc. ("ARIAD"), for its Complaint against the Honorable David J. Kappos, states as follows:

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 8,114,874 ("the '874 patent," attached hereto as Exhibit 1) 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 ARIAD a patent term adjustment of 0 days. ARIAD asserts that it is entitled to a patent term adjustment of 400 days.

3. ARIAD has exhausted its administrative remedies by petitioning under 37 C.F.R. § 1.705(d) for the PTO to reconsider its patent term adjustment calculation. The PTO dismissed

the petition on May 14, 2012. On July 14, 2012, ARIAD filed a Petition to the Director Pursuant to 37 C.F.R. § 1.181 (“Petition to Director”) to request supervisory review of the PTO’s Decision on Patentee’s Request for Reconsideration of Patent Term Adjustment. The PTO has not yet issued a decision on the Petition to Director.

4. Pursuant to 35 U.S.C. § 154(b)(4)(A), ARIAD hereby seeks review of and a remedy for the PTO’s failure to award the proper amount of patent term adjustment. ARIAD furthermore seeks a judgment that 37 C.F.R. § 1.703(b)(1) is invalid, unconstitutional, and contrary to law.

5. This action arises under 35 U.S.C. § 154(b)(4)(A), the Fifth Amendment of the Constitution of the United States, and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

THE PARTIES

6. Plaintiff ARIAD is a corporation organized and existing under the laws of the state of Delaware, having its headquarters and principal place of business at 26 Landsdowne Street, Cambridge, Massachusetts 02139. ARIAD is the assignee with all right, title, and interest in the ’874 patent, as evidenced by the assignment documents recorded in the PTO and the face of the ’874 patent.

7. Defendant David J. Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the PTO (“Director”), 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

8. 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), 1361, 2201, & 2202; 35 U.S.C. § 154(b)(4)(A); and 5 U.S.C. §§ 701-706.

9. 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).

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

BACKGROUND

The Patent Term Adjustment Statute

11. 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.

12. 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.

13. 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.

14. At issue in this case is “B delay.” “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 three 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 three-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).

15. A request for continued examination under 35 U.S.C. § 132(b) is commonly referred to procedurally in the PTO as a request for continued examination (“RCE”). *See* 37 C.F.R. § 1.114.

16. The statute guarantees issuance of a patent from a pending patent application within three years after the actual filing date, not including time consumed during that three-year period by continued examination after the filing of an RCE. *See* 35 U.S.C. § 154(b)(1)(B)(i).

17. 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.

18. 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.

19. 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.”

20. These regulations do not include any reduction based on time consumed by examination after the filing of an RCE.

21. 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, the PTO has inappropriately promulgated and relied upon 37 C.F.R. § 1.703(b)(1).

Proceedings in the PTO with Respect to the '874 Patent

22. The proceedings in the PTO with respect to the '874 patent are reflected in the administrative record and summarized in-brief as follows:

23. Dong Zou, Wei-Sheng Huang, R. Mathew Thomas, Jan Antionette C. Romero, Jiwei Qi, Yihan Wang, Xiaotian Zhu, William C. Shakespeare, Rajeswari Sundaramoorthi, Chester A. Metcalf, III, David C. Dalgarno, and Tomi K. Sawyer are the inventors of U.S. patent application number 11/644,849 (“the '849 application”), filed on December 22, 2006.

24. On February 27, 2007, the PTO mailed a notice to file missing parts. On April 16, 2007, the applicant filed a response to the notice to file missing parts.

25. On April 23 and May 14, 2007, the applicant filed a first and second information disclosure statement.

26. On May 12, 2008, the PTO mailed a restriction requirement. On November 17, 2008, the applicant filed a response to the restriction requirement. The response to the restriction requirement included a certificate of mailing or transmission executed by applicant and dated November 12, 2008.

27. On December 11, 2008, the PTO mailed a first non-final action. On June 15, 2009, the applicant filed a response to the first non-final action. The response to the first non-final action included a certificate of mailing or transmission executed by applicant and dated June 11, 2009.

28. On August 3, 2009, the PTO mailed a final action. On February 12, 2010, the applicant filed a response to the final action and a request for continued examination under 35 U.S.C. § 132(b). The response to the final action included a certificate of mailing or transmission executed by applicant and dated February 3, 2010.

29. On February 19, 2010, the PTO mailed a notice of abandonment. On February 25, 2010, the applicant filed a petition to withdraw holding of abandonment.

30. On March 29, 2010, the applicant filed a third information disclosure statement.

31. On May 13, 2010, the PTO granted the petition to withdraw holding of abandonment. On June 10, 2010, the PTO issued a notice of rescinded abandonment and forwarded the case to the examiner.

32. On October 13, 2010, the PTO mailed a second non-final action. On April 18, 2011, the applicant filed a response to the second non-final action. The response to the second non-final action included a certificate of mailing or transmission executed by applicant and dated April 13, 2011.

33. On July 1, 2011, the PTO mailed an *ex parte* quayle action.

34. On August 19, 2011, the applicant filed a fourth information disclosure statement.

35. On September 6, 2011, the applicant filed a fifth information disclosure statement and response to the *ex parte* quayle action. The response to the *ex parte* quayle action included a certificate of mailing or transmission executed by applicant and dated September 1, 2011.

36. On October 13, 2011, the PTO mailed a notice of allowance.

37. On December 6, 2011, the applicant filed an amendment under 37 C.F.R. § 1.312. On January 3, 2012, the PTO mailed a response to Rule 312 communication and corrected notice of allowability.

38. On January 4, 2012, the applicant paid the issue fee.

39. On February 14, 2012, the PTO issued the '874 patent.

The Correct Calculation of Patent Term for the '874 Patent

40. The PTO admits that the "A delay" calculation for the '874 patent is 203 days.

41. The PTO failed to issue a patent within three years of the December 22, 2006, filing date of the application leading to the '874 patent, triggering the patent term adjustment provision of 35 U.S.C. § 154(b)(1)(B). The three-year period after the filing of the '849 application ended on December 22, 2009, without the PTO having issued a patent on the application. This three-year period did not include any time consumed by continued examination after the filing of an RCE. Accordingly, the three-year "trigger" condition of 35 U.S.C. § 154(b)(1)(B) was satisfied.

42. 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 ’874 patent is 783 days, which is the period of time between the three-year anniversary of the filing of the application leading to the ’874 patent and the date the patent issued.

43. Accordingly, the correct total patent term adjustment for the ’874 patent is 400 days, which is equal to the total of “A delay” of 203 days, plus “B delay” of 783 days, minus the “applicant delay” of 463 days, and minus 123 days 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).

The PTO’s Incorrect Calculation of Patent Term Adjustment for the ’874 Patent and ARIAD’s Request for Reconsideration

44. The patent term adjustment set forth on the face of the issued ’874 patent is 0 days. The same patent term adjustment is calculated and shown on the PTO’s Patent Application Information Retrieval (“PAIR”) database for the ’874 patent, which is attached hereto as Exhibit 2.

45. The PTO’s calculation shows an “A delay” of 203 days (80 days on line 24 and 123 days on line 69), a “B delay” of 51 days (shown as “PTA 36 months” on line 125.5), and “applicant delay” of 463 days (97 days on line 27, 96 days on line 39, 95 days on line 77, 29 days on line 107, 101 days on line 129, and 45 days on line 130). The “A delay” of 203 days plus the “B delay” of 51 days minus the “applicant delay” of 463 days yielded the PTO’s total adjustment of 0 days.

46. To arrive at its calculation of “B delay” of 51 days, the PTO omitted the 732-day period beginning on February 12, 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 ’874 patent issued).

47. As explained above, the PTO's exclusion of this 732-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 783-day period from December 23, 2009 through February 14, 2012.

48. On April 11, 2012, Plaintiff filed a Petition for Reconsideration of Patent Term Adjustment Pursuant to 37 C.F.R. § 1.705(d) ("Request for Reconsideration"). The Request for Reconsideration, which is attached hereto as Exhibit 3, challenged *inter alia* the PTO's calculation of "B delay" and indicated that the '874 patent is entitled to a total patent term adjustment of 56 days.

49. The PTO issued a Decision on Application for Reconsideration of Patent Term Adjustment ("Decision") on May 14, 2012, attached hereto as Exhibit 4. In the Decision, the PTO dismissed Plaintiff's Request for Reconsideration. Plaintiff had argued that the correct period of "B delay" should include an additional 120 days incurred as a consequence of the PTO incorrectly abandoning the '849 application after Plaintiff's RCE filing. The PTO disagreed, stating that "the entire period beginning on February 12, 2010 and [ending] on the date of issuance of the patent is considered time consumed by continued examination of an application under 35 U.S.C. 132(b) and [was] not included in the 'B delay.'" (Ex. D, May 14, 2012, Decision at 6.) In the Decision, the PTO also explained that it was entering an additional 146 days of "applicant delay" based on its review of the record.

50. 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 three-year period until the patent is issued," subject only to specific limits set forth at 35 U.S.C. § 154(b)(2). Once the three-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, that regulation is contrary to the statute and cannot support the PTO’s patent term adjustment calculation.

Alternative Grounds for PTO Error

51. 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 732-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.”

52. 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.” In this case, because the PTO improperly abandoned the ’849 application, no continued examination took place during the period of time after the filing of the RCE until at least four months before the mailing date of the first substantive action after the filing of the RCE. At a minimum, the PTO did not conduct any continued examination until it issued the notice of rescinded abandonment and forwarded the case to the Examiner.

53. Additionally, 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. And in the case where an applicant files an amendment under 37 C.F.R. § 1.312 after a notice of allowance has been mailed, as Plaintiff did here, 37 C.F.R. § 1.704(c)(10) already provides for a reduction of the period of patent term adjustment available to applicant. The period of patent term adjustment available is reduced by the lesser of (i) the number of days beginning on the date the amendment under § 1.312 was filed and ending on the

mailing date of the Office Action or notice in response to the amendment or (ii) four months. 37 C.F.R. § 1.704(c)(10).

54. Thus, no continued examination took place during the 120-day period from February 12, 2010 (when the applicant filed the RCE) until June 12, 2010 (the day before the four-month period preceding the mailing date of the first substantive action after the filing of the RCE) and during the 124-day period from October 13, 2011 (when the Notice of Allowance was issued) to February 14, 2012 (when the patent issued). In total, those delays result in “B delay” of 244 days.

55. Thus, the total “B delay” that was not “time consumed by continued examination” is 295 days (i.e., 51 days + 244 days). Therefore, even following the PTO’s improper statutory interpretation, the correct patent term adjustment is 35 days (i.e., 203 “A delay” days + 295 “B delay” days - 463 “applicant delay” days).

CLAIMS FOR RELIEF

COUNT ONE

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

56. Plaintiff incorporates paragraphs 1-55 as if fully set forth herein.

57. The PTO’s calculation of the “B delay” adjustment for the ’874 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).”

58. The PTO’s calculation of the “B delay” adjustment for the ’874 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.”

59. The PTO's incorrect calculation of the "B delay" adjustment for the '874 patent led to an incorrect calculation of the total patent term adjustment for the '874 patent. The PTO's calculation of the total term adjustment for the '874 patent was based on improper interpretations of 35 U.S.C. § 154(b)(1)(B).

60. The PTO's patent term adjustment calculation of 0 days for the '874 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).

COUNT TWO

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

61. Plaintiff incorporates paragraphs 1-60 as if fully set forth herein.

62. 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."

63. ARIAD enjoys a substantial and cognizable private property right in the full and complete term of the '874 patent.

64. ARIAD has not failed to pay any necessary maintenance fees to the PTO required to maintain its rights in the '874 patent.

65. The PTO'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 '874 patent permanently deprived ARIAD of patent term to which it was entitled under the Patent Act, including 35 U.S.C. § 154(b).

66. The PTO's purposeful and deliberate diminution of the patent term of the '874 patent constitutes a taking of ARIAD's property without just compensation, in violation of the Fifth Amendment of the Constitution of the United States.

67. ARIAD is entitled to additional patent term for the '874 patent such that the 0 days of PTA granted by the PTO should be changed to 400 days or, in the alternative, to at least 35 days.

COUNT THREE

(Declaratory Judgment Under the Administrative Procedures Act, 5 U.S.C. § 702 et seq.)

68. Plaintiff incorporates paragraphs 1-67 as if fully set forth herein.

69. The PTO'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 '874 patent were contrary to law.

70. The PTO's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '874 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 ARIAD'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).

71. The PTO's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '874 patent were final agency actions that are reviewable by a district court in accordance with 5 U.S.C. § 704.

72. ARIAD 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.

73. ARIAD has been afforded no adequate remedy at law for the PTO's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '874 patent.

74. ARIAD will suffer irreparable injury if 37 C.F.R. § 1.703(b)(1) is not invalidated and the PTO is not directed to recalculate PTA for the '874 patent.

75. An order invalidating 37 C.F.R. § 1.703(b)(1) and directing the PTO to recalculate PTA for the '874 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.

76. ARIAD is entitled to additional patent term for the '874 patent such that 0 days of PTA granted by the PTO should be changed to 400 days or, in the alternative, to at least 35 days.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that this Court:

A. Vacate the PTO's patent term adjustment calculation of 0 days for the '874 patent, order the PTO to correct the patent term adjustment for the '874 patent to 400 days and alter the term of the '874 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 0 days for the '874 patent, order the PTO to correct the patent term adjustment for the '874 patent to 35 days and alter the term of the '874 patent to reflect the corrected adjustment, and to issue a certificate of correction reflecting the corrected adjustment and term.

C. Declare pursuant to 28 U.S.C. § 2201 that 37 C.F.R. § 1.703(b)(1) is invalid, unconstitutional, and contrary to law.

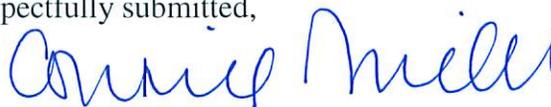
D. Grant such further and other relief as this Court deems just and proper.

Dated: August 9, 2012

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