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

BAYER INTELLECTUAL PROPERTY GMBH)
)
Plaintiff,)
)
v.)
)
HON. TERESA STANEK REA,) C.A. No. 1:13CV274 AJT/JFA
Acting Under Secretary of Commerce for)
Intellectual Property and Acting Director of the)
United States Patent and Trademark Office)
Office of General Counsel)
United States Patent and Trademark Office)
Madison Building East, Room 10B20)
600 Dulany Street)
Alexandria, VA 22314)
)
Defendant.)

COMPLAINT

Bayer Intellectual Property GmbH ("Bayer"), by its attorneys, hereby alleges 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. 8,257,305 (herein, the "'305 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 Bayer a patent term adjustment of only 577 days, although Bayer is entitled to a patent term adjustment of 1837 days.

3. Pursuant to 35 U.S.C. § 154(b)(4)(A), Bayer 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 Bayer Intellectual Property GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 10, 40789 Monheim, Germany.

5. Bayer Intellectual Property GmbH is the assignee of the '305 patent. Bayer Pharma Akteingesellschaft, which is listed as the assignee of the '305 patent in the assignment documents recorded in the PTO and on the face of the '305 patent, transferred ownership of the '305 patent to Bayer Intellectual Property GmbH.

6. Defendant Teresa Stanek Rea is the Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the PTO, acting in her official capacity. The powers and duties of the PTO are vested in the Director, who is responsible for 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 id.* § 154(b)(4)(A).

JURISDICTION, VENUE, AND TIMING

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

8. This Court has subject matter jurisdiction 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.

9. Venue is proper in this Court under 35 U.S.C. § 154(b)(4)(A) and 5 U.S.C. § 703.

10. This Complaint is timely filed within 180 days after the grant of the '305 patent. *See* 35 U.S.C. § 154(b)(4)(A) (2006 & Supp. V 2011).[1]

BACKGROUND

The Patent Term Adjustment Statute

11. The American Inventors Protection Act of 1999 amended 35 U.S.C. § 154 to address concerns that delays by the PTO during prosecution of patent applications could result in a shortening of the effective life of the granted patent to less than seventeen years. The statute requires the PTO to adjust patent terms to compensate for three categories of processing delay. These categories are set forth in 35 U.S.C. §§ 154(b)(l)(A), (B), and (C), and are commonly known as "A delay," "B delay," and "C delay," respectively.

12. Under the "B delay" provision, applicants receive 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 "not including," among other things, "any time consumed by continued examination of the application requested by the applicant under section 132(b)," or "any time consumed by appellate review by the Board of Patent Appeals and Interferences." 35 U.S.C. § 154(b)(l)(B).

13. If the issuance of a patent is delayed beyond the 3-year period, the "B delay" provision requires 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." 35 U.S.C. § 154(b)(l)(B). A request for continued examination ("RCE") or a notice of appeal filed after the 3-year period has no impact

[1] Although § 154(b)(4)(A) was amended on January 14, 2013, *see* Pub. L. No. 112-274, § 1 (Jan. 3, 2013) (to be codified as amended at 35 U.S.C. § 154(b)(4)(A)) (*see* Enrolled Bill H.R. 6621), the amended statute does not apply retroactively to the '305 patent. The statute in force when the PTO issued its patent term adjustment calculation for the '305 patent and when the patent issued, 35 U.S.C. § 154(b)(4)(A) (2006 & Supp. V 2011), permits Bayer to file a civil action against the Director in this Court within 180 days after the grant of the patent.

on the calculation of the "B delay" period. While the patent term adjustment granted under the "B delay" provision is subject to certain limitations under 35 U.S.C. § 154(b)(2), none of the limitations identified in § 154(b)(2) reduces or limits the adjustment based on the filing of an RCE or a notice of appeal. *See Exelixis, Inc. v. Kappos*, No. 1:12-cv-0096, 2012 WL 5398876, at *7 (E.D. Va. Nov. 6, 2012), *appeal docketed*, No. 2013-1175 (Fed. Cir. filed Jan. 18, 2013).

Relevant Events in the Prosecution of the '305 patent

14. The following are the relevant dates during the prosecution of the '305 patent according to the "Patent Term Adjustments" page of the PTO's Patent Application Information Retrieval ("PAIR") database for the '305 patent, which is attached as Exhibit B:

15. U.S. Patent Application No. 10/528,577 (the "'577 application") was filed as PCT/DE03/02871 on August 26, 2003.

16. The '577 application commenced the U.S. National Stage under 35 U.S.C. § 371, and received a completion date of March 21, 2005 under 35 U.S.C. § 371(c).

17. On October 5, 2007, the PTO mailed a non-final rejection.

18. On November 3, 2008, the applicant filed a notice of appeal.

19. On June 3, 2009, the applicant filed an RCE.

20. On August 7, 2009, the PTO mailed a non-final rejection.

21. On December 7, 2009, the applicant filed a response to the non-final action.

22. On March 9, 2011, the applicant filed another RCE.

23. On November 28, 2011, the PTO mailed a notice of allowance.

24. On June 25, 2012, the PTO mailed another notice of allowance.

25. On September 4, 2012, the PTO issued the '305 patent.

The Correct Calculation of Patent Term Adjustment for the '305 patent

26. The PTO admits that the "A delay" calculation for the '305 patent is 644 days.

27. The PTO caused "B delay" by failing to issue a patent within three years of March 21, 2005, *i.e.*, by March 21, 2008. No RCE or notice of appeal was filed during that 3-year period. The correct amount of "B delay" for the '305 patent is 1628 days, which is the period of time between the 3-year anniversary of March 21, 2005 (*i.e.*, March 21, 2008) and the date the patent issued (*i.e.*, September 4, 2012).

28. The correct period of "overlap" of the "A delay" and corrected "B delay" periods is 142 days (July 9, 2011 through November 28, 2011). *See* 35 U.S.C. § 154(b)(2)(A); *see also Wyeth v. Kappos*, 591 F.3d 1364, 1369–70 (Fed. Cir. 2010).

29. Bayer and the PTO agree that no "C delay" occurred during pendency of the application that issued as the '305 patent.

30. The PTO calculated the total applicant delay throughout the entire prosecution of the '305 patent as 293 days.

31. Accordingly, the correct total patent term adjustment for the '305 patent is 1837 days, which is equal to the total of 644 days of "A delay," plus 1628 days of "B delay," minus 142 days of "overlap," minus 293 days of applicant delay.

The PTO's Incorrect Calculation of Patent Term Adjustment for the '305 Patent

32. The patent term adjustment set forth on the face of the issued '305 patent is 577 days. The same patent term adjustment is calculated and shown on the PTO's PAIR database for the '305 patent, which is attached as Exhibit B.

33. The PTO's calculation shows an "A delay" of 644 days (502 days on line 28, plus 142 days on line 135), a "B delay" of 226 days (shown as "PTA 36 Months" on line 170.5), an "overlap" of 0 days, and "applicant delay" of 293 days (31 days on line 31, plus 94 days on line

36, plus 57 days on line 51, plus 30 days on line 55, plus 37 days on line 66, plus 44 days on line 78).

34. To arrive at its calculation of only 226 days of "B delay," the PTO omitted the 1402-day period beginning on November 3, 2008 (*i.e.*, the date on which the notice of appeal was filed) and ending on September 4, 2012 (*i.e.*, the date the '305 patent issued). The PTO's exclusion of this 1402-day period of "B delay" is contrary to 35 U.S.C. § 154(b)(1)(B). 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.

35. The correct period of "B delay" is equal to the full 1628-day period from March 21, 2008 through September 4, 2012.

Alternative Grounds for PTO Error

36. Even if the PTO were correct that the "B delay" period excludes "any time consumed by continued examination of the application requested by the applicant under section 132(b)" or "any time consumed by appellate review by the Board of Patent Appeals and Interferences" that occurs after the 3-year period, the PTO's calculation is still incorrect.

a) Time after the Notice of Allowance

37. The PTO's "B-delay" calculation improperly left out the 71-day period between the mailing of the notice of allowance and the issuance of the '305 patent. The PTO improperly assumes that every day after the applicant's filing of an RCE constitutes "time consumed by continued examination." *See* 37 C.F.R. § 1.703(b)(1). However, no continued examination takes place after the PTO mails a notice of allowance, because that time would be consumed whether or not an RCE had been filed. As PTO itself stated in its notice of allowance on June 25, 2012, the application "Has Been Examined" and "Prosecution on the Merits Is Closed."

Exhibit C, at 1. Moreover, the PTO's rules explain that "[p]rosecution in an application is closed" if "the last Office action is . . . a notice of allowance." *See* 37 C.F.R. § 1.114. Thus, between the PTO's mailing of the notice of allowance on June 25, 2012, thereby closing examination of the application, and the issuance of the patent on September 4, 2012, an additional 71 days of "B delay" accrued.

b) Time between the Filing of the Notice of Appeal and the RCE

38. In addition, the PTO's "B-delay" calculation also improperly left out the 212-day period between the applicant's filing of a notice of appeal on November 3, 2008 and the applicant's filing of an RCE on June 3, 2009. That 212-day period does not fall under any of the exceptions in 35 U.S.C. § 154(b)(l)(B). Jurisdiction over this application never passed to the Board of Patent Appeals and Interferences. No appeal was docketed with the Board, and the Board never reviewed the application that issued as the '305 patent. Under a plain reading of the statute, therefore, this 212-day period does not constitute "time consumed by appellate review by the Board of Patent Appeals and Interferences." 35 U.S.C. § 154(b)(l)(B)(ii). Thus, the PTO's "B-delay" calculation should have included the 212-day period between the filing of the notice of appeal on November 3, 2008 and the filing of the RCE on June 3, 2009.

c) Improper Subtraction of "Applicant Delay"

39. The PTO also improperly subtracted periods of time as "applicant delay" that did not occur during any periods of "A," "B," or "C delay."

40. The PTO subtracted 30 days as "applicant delay" in connection with a response to a non-final action filed on December 7, 2009. *See* Exhibit B (30 days on line 55). That subtraction was improper, because § 154(b)(2)(C)(ii), pertaining to such "applicant delay," only applies "[w]ith respect to adjustments to patent term made under the authority of paragraph

[§ 154(b)](1)(B)," and the PTO has not adjusted the term of the '305 patent to account for B-delay during this time period. Therefore, any extensions of time taken to respond to the non-final rejection mailed on August 7, 2009 should not be counted as applicant delay, because no adjustment was made under 35 U.S.C. § 154(b)(1)(b) for that time period. Accordingly, the PTA determination should be increased by 30 days under the PTO's own interpretation of what constitutes "B delay."

41. The PTO also subtracted 138 days as "applicant delay" in connection with information disclosure statements filed on July 30, 2009, January 13, 2010, and July 2, 2010. *See* Exhibit B (57 days on line 51, plus 37 days on line 66, plus 44 on line 78). That subtraction was also improper. Under § 154(b)(2)(C)(i), "*[t]he period of adjustment of the term of a patent under paragraph [§ 154(b)](1)* shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." 35 U.S.C. § 154(b)(2)(C)(i) (emphasis added). If the PTO were correct that there should be no period of "B-delay" adjustment following the filing of an RCE on June 3, 2009, then it was improper for the PTO to count 138 days during that period as "applicant delay." There is, therefore, no period of adjustment to reduce by the filings of the information disclosure statements. Accordingly, if the PTO's interpretation of what constitutes "B delay" is maintained, then the PTA should also be increased by 138 days.

42. As explained above, Bayer contends that the '305 patent is entitled to a patent term adjustment of 1837 days. However, if this calculation is rejected, the '305 patent is entitled in the alternative to a PTA that includes not only the 577 days of the PTO's original calculation, but also the 71-day, 212-day, 30-day, and 138-day periods identified above for a total of 1028 days (*i.e.*, 644 days of "A delay," plus 509 days of "B delay," minus 0 days of "overlap," minus

125 days of "applicant delay"). To the extent that the '305 patent is not entitled to one of the additional 71-day, 212-day, 30-day, or 138-day periods identified above, the PTA determination should include the remaining periods.

CLAIM FOR RELIEF

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

43. Bayer incorporates the foregoing paragraphs as if fully set forth herein.

44. The PTO's calculation of the "B delay" adjustment for the '305 patent was based on a flawed interpretation of 35 U.S.C. § 154(b).

45. The PTO's erroneous interpretation of 35 U.S.C. § 154(b) resulted in an incorrect calculation of patent term adjustment and deprived Bayer of the correct patent term for the '305 patent.

46. The PTO's patent term adjustment calculation of only 577 days for the '305 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, Bayer requests the following relief:

(a) A judgment ordering the PTO to correct the patent term adjustment for the '305 patent to 1837 days thereby correcting the term of the '305 patent, and to issue a certificate of correction reflecting the corrected adjustment;

(b) In the alternative—and only if the Court rejects Bayer'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)"—a judgment ordering the PTO to correct the patent term adjustment for the '305 patent to 1028 days (or, as set forth above, to an additional appropriate

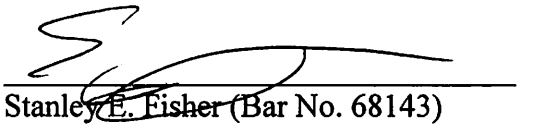
period above 577 days) thereby correcting the term of the '305 patent, and to issue a certificate of correction reflecting the corrected adjustment; and

(c) Such further and other relief as this Court deems just and proper.

Dated: March 1, 2013

Respectfully submitted,

WILLIAMS & CONNOLLY LLP



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