

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FILED

OCT 29 2010

Clerk, U.S. District & Bankruptcy
Courts for the District of Columbia

ABBOTT BIOTHERAPEUTICS CORP.
fka FACET BIOTECH CORPORATION

1500 Seaport Blvd.
Redwood City, CA 94063

Plaintiff,

v.

DAVID KAPPOS, in his official capacity as
Under Secretary of Commerce for Intellectual
Property and Director of the United States
Patent and Trademark Office

Office of the General Counsel
United States Patent and Trademark Office
P.O. Box 1450, Alexandria, VA 22313-1450

Madison Building East, Room 10B20
600 Dulany Street, Alexandria, VA 22314

Defendant.

Case: 1:10-cv-01853
Assigned To : Huvelle, Ellen S.
Assign. Date : 10/29/2010
Description: Admin. Agency Review

COMPLAINT

For its Complaint against David Kappos, Plaintiff Abbott Biotherapeutics Corp.

("Abbott") hereby alleges as follows:

Nature of 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. 7,709,610 (the "'610 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 Abbott a patent term adjustment of 675 days. Abbott asserts that it is entitled to a patent term adjustment of 1166 days.

3. Abbott 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 October 26, 2010, only days before Abbott’s statutory deadline for seeking relief from this Court under 35 U.S.C. § 154(b)(4)(A).

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

Parties

5. Plaintiff Abbott is a Delaware corporation with its principal place of business at 1500 Seaport Blvd., Redwood City, CA 94063. Abbott was formerly known as Facet Biotech Corporation (“Facet”). The ’610 patent was assigned to Facet by virtue of an assignment recorded in the PTO on February 27, 2009 at Reel 022326, Frame 0412. Facet changed its name to Abbott Biotherapeutics Corp. on September 7, 2010, which change was submitted for recordation in the PTO on October 29, 2010. Plaintiff Abbott is the assignee of the ’610 patent.

6. Defendant David Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the PTO. Under 35 U.S.C. § 3(a)(1), the powers and duties of the PTO are vested in the Director of the PTO. The Director of the PTO is designated by statute as the official responsible for determining the period of patent term adjustments, *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

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 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.

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

10. This Complaint is timely filed under 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 applicant’s effective 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. “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).

15. 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.

16. 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).

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.

Proceedings in the PTO with Respect to the '610 Patent

21. On November 5, 2004, the applicant filed United States patent Application No. 10/982,357 (the “’357 application”).

22. On May 18, 2007, the PTO mailed a restriction requirement.

23. On June 18, 2007, the applicant filed an election.

24. On September 10, 2007, the PTO mailed a non-final office action.

25. On March 10, 2008, the applicant filed a response to the non-final office action.

26. On July 2, 2008, the PTO mailed a final office action.

27. On August 27, 2008, the applicant filed an amendment after final rejection and affidavit.

28. On September 19, 2008, the PTO mailed an advisory action.

29. On December 18, 2008, the applicant filed a first request for continued examination under 35 U.S.C. § 132(b).
30. On March 3, 2009, the applicant filed a supplemental amendment.
31. On March 10, 2009, the PTO mailed a non-final office action.
32. On April 23, 2009, the applicant filed a response to the non-final office action.
33. On June 18, 2009, the applicant filed a supplemental information disclosure statement.
34. On August 17, 2009, the PTO mailed a notice of allowance.
35. On November 12, 2009, the applicant filed a second request for continued examination under 35 U.S.C. § 132(b).
36. On December 14, 2009, the PTO mailed a second notice of allowance.
37. On December 22, 2009, the applicant paid the issue fee.
38. On May 4, 2010, the PTO issued the '610 patent.

The Correct Calculation of Patent Term Adjustment for the '610 Patent

39. The PTO admits that the “A delay” calculation for the '610 patent is 510 days.
40. The PTO failed to issue a patent within three years of the November 5, 2004, filing date of the application leading to the '610 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 '357 application ended on November 5, 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.
41. Having satisfied the “trigger” condition, the “remedy” portion of the statute governs the amount of “B Delay” patent term adjustment to be awarded. The “remedy” portion

is the language which follows 35 U.S.C. § 154(b)(1)(B)(iii) (*i.e.*, “the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued”). The correct amount of “B delay” for the ’610 patent is 911 days, which is the period of time between the 3-year anniversary of the filing of the application leading to the ’610 patent and the date the patent issued.

42. Accordingly, the correct total patent term adjustment for the ’610 patent is 1166 days, which is equal to the total of the “A delay” of 510 days, plus “B delay” of 911 days, minus the “applicant delay” of 243 days, and minus 12 days during which the “A delay” and corrected “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.*, April 22, 2010 through May 4, 2010), for a total of 1166 days.

The PTO’s Incorrect Calculation of Patent Term Adjustment for the ’610 Patent, and Abbott’s Request for Reconsideration

43. The patent term adjustment set forth on the face of the issued ’610 patent is 675 days. The same adjustment is calculated and shown on the PTO’s Patent Application Information Retrieval (“PAIR”) database for the ’610 patent, which is attached as Exhibit B.

44. The PTO’s calculation shows an “A delay” of 510 days (498 days on line 42 and 12 days on line 125), a “B delay” of 408 days (shown as “PTA 36 Months” on line 125.5), and “applicant delay” of 243 days (91 days on line 51, 77 days on line 68, and 75 days on line 74). The “A delay” of 510 days plus the “B delay” of 408 days minus the “applicant delay” of 243 days yielded the PTO’s total adjustment of 675 days.

45. To arrive at its calculation of “B delay” of 408 days, the PTO omitted the 503-day period beginning on December 18, 2008 (*i.e.*, the date on which the first request for continued examination was filed), and ending on May 4, 2010 (*i.e.*, the date the ’610 patent issued).

46. As explained above, the PTO's exclusion of this 503-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 911 day period from November 6, 2007 through May 4, 2010.

47. On July 2, 2010, Plaintiff filed an Application for Patent Term Adjustment Including Request for Reconsideration Under 37 C.F.R. § 1.705(d) (the "Request for Reconsideration"). The Request for Reconsideration, which is attached as Exhibit C, raised *inter alia* the issues asserted in this Complaint, which included a request for a corrected patent term adjustment of 1166 days.

48. The PTO issued a Decision dismissing the Request for Reconsideration on October 26, 2010. In that decision, the PTO cited 37 C.F.R. § 1.703(b)(1) for the proposition that the period of adjustment added to an applicant's patent term when the PTO fails to live up to its guarantee of a maximum of 3-years of application pendency *does not include* the period of time from the filing of an RCE under 35 U.S.C. 132(b) to the issuance of the patent. According to the PTO, "any days that occurred subsequent to the filing of the RCE are not considered." (October 26, 2010 Decision on Request for Reconsideration at 3).

49. As discussed above, the patent term adjustment statute, 35 U.S.C. § 154(b)(1) provides that, once "B delay" is triggered, "the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued," subject only to specific limits set forth at 35 U.S.C. § 154(b)(2). Once the 3-year period has ended and the "B delay" provision is triggered, the statute does not allow the PTO to ignore days occurring after the filing of an RCE for purposes of calculating the "B delay" remedy. To the extent that 37 C.F.R. § 1.703(b)(1) would require otherwise, that regulation is contrary to the statute and cannot support the PTO's patent term adjustment calculation.

Alternative Grounds for PTO Error

50. Even under the PTO's improper statutory interpretation, which excludes from the calculation of the length of the "B delay" adjustment "any time consumed by continued examination of the application requested by the applicant under section 132(b)," the PTO's calculation is still incorrect. The 503-day period excluded by the PTO included time that was not "consumed by continued examination of the application." The PTO mailed a Notice of Allowance, thereby closing examination of the application on December 14, 2009. Thus, no continued examination took place during the 141-day period from December 15, 2009 (the day after the PTO mailed the Notice of Allowance) until May 4, 2010 (the day the '610 patent issued). Thus, even following the PTO's improper statutory interpretation, the correct patent term adjustment would be 816 days.

COUNT I

51. Plaintiff incorporates the foregoing paragraphs as if fully set forth herein.

52. The PTO's calculation of the "B delay" adjustment for the '610 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)."

53. 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.

54. The PTO's calculation of the "B delay" adjustment for the '610 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.”

55. The PTO’s incorrect calculation of the “B delay” adjustment for the ’610 patent led to an incorrect calculation of the total patent term adjustment for the ’610 patent. The PTO’s calculation of the total patent term adjustment for the ’610 patent therefore was based on improper interpretations of 35 U.S.C. § 154(b)(1)(B).

56. The PTO’s patent term adjustment calculation of 675 days for the ’610 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:

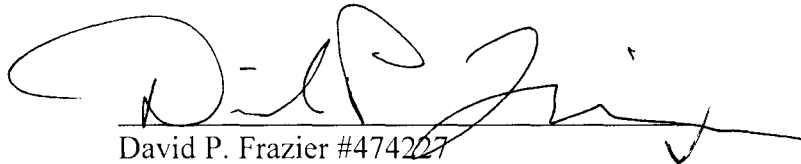
1. Vacate the PTO’s patent term adjustment calculation of 675 days for the ’610 patent, order the PTO to correct the patent term adjustment for the ’610 patent to 1166 days and alter the term of the ’610 patent to reflect the corrected adjustment, and to issue a certificate of correction reflecting the corrected adjustment and term.

2. 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 675 days for the ’610 patent, order the PTO to correct the patent term adjustment for the ’610 patent to 816 days and alter the term of the ’610 patent to reflect the corrected adjustment and to issue a certificate of correction reflecting the corrected adjustment and term.

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

Dated: October 29, 2010

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'D. P. Frazier', written over a horizontal line.

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