

FILED

APR 15 2011

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

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABRAXIS BIOSCIENCE, LLC
11755 Wilshire Blvd, Suite 2000
Los Angeles, California 90025

Plaintiff,

v.

HONORABLE DAVID KAPPOS, in his official
capacity as UNDER SECRETARY OF
COMMERCE FOR INTELLECTUAL
PROPERTY AND DIRECTOR OF THE
UNITED STATES PATENT AND
TRADEMARK OFFICE,

United States Patent and Trademark Office
Office of the General Counsel
Madison Building East, Room 10B20
600 Dulany Street
Alexandria, Virginia 22314

Defendant.

Case: 1:11-cv-00730

Assigned To : Howell, Beryl A.

Assign. Date : 4/15/2011

Description: General Civil

COMPLAINT

Plaintiff, Abraxis Bioscience, LLC, for its Complaint against Defendant alleges as follows:

1. This civil action is brought by the assignee of United States Patent No. 7,820,788 (the "788 patent," attached as Exhibit A) seeking judgment pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '788 patent be changed from 85 days to at least 321 days.

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

JURISDICTION AND VENUE

3. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1338, and 1361, 35 U.S.C. § 154(b)(4)(A) and 5 U.S.C. §§ 701-706.

4. Venue is proper in this district pursuant to 35 U.S.C. § 154(b)(4)(A).

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

PARTIES

6. Plaintiff is a limited liability company organized under the laws of Delaware, having a principal place of business at 11755 Wilshire Blvd, Suite 2000, Los Angeles, California 90025.

7. Defendant the Honorable David Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (“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 under 35 U.S.C. § 154.

BACKGROUND

8. Neil P. Desai, Patrick Soon-Shiong, and Vuong Trieu are the inventors of the ’788 patent, entitled “Compositions and Methods of Delivery of Pharmacological Agents,” which issued on October 26, 2010, from U.S. Patent Application No. 11/553,339 (the “’339 application”). The ’339 application had been filed four years earlier on October 26, 2006

9. Plaintiff is the assignee of the ’788 patent.

10. 35 U.S.C. § 135 requires that the Director of the PTO grant a patent term adjustment in accordance with the provisions of Section 154(b). Specifically, 35 U.S.C. § 154(b)(3)(D) states that “[t]he Director shall proceed to grant the patent after completion of the Director’s determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination.”

11. In determining patent term adjustment, Defendant is required to extend the term of a patent for a period equal to the total number of days attributable to delay by the PTO under 35 U.S.C. § 154(b)(1), as limited by any overlapping periods of delay by the PTO as specified under 35 U.S.C. § 154(b)(2)(A), any disclaimer of patent term by the applicant under 35 U.S.C. § 154(b)(2)(B) and any delay attributable to the applicant under 35 U.S.C. § 154(b)(2)(C).

12. Under 35 U.S.C. § 154(b)(1)(A), Plaintiff is guaranteed prompt PTO responses. If the issuance of an original patent is delayed due to PTO delays, the term of the patent shall be extended in accordance with 37 C.F.R. § 1.703(a) (“Part A Delay”). Under 35 U.S.C. § 154(b)(1)(A), the term of a patent shall be extended due to the failure of the PTO to, for instance,

- (ii) respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken; or

- iv) issue a patent within 4 months after the date on which the issue fee was paid under section 151 and all outstanding requirements were satisfied.

13. Under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b), Plaintiff is guaranteed no more than a 3-year application pendency from the “actual filing date” of the application. Delay caused by the failure of the PTO to issue a patent within 3 years is assessed in accordance with 37 C.F.R. § 1.703(b) (“Part B Delay”). Under 35 U.S.C. § 154(b)(1)(B), the term of a patent shall be extended 1 day for each day after the end of that 3-year period until the patent is

issued, not including, for instance, any time consumed by continued examination of the application requested by the applicant under 35 U.S.C. § 132(b).

14. Defendant made a determination of patent term adjustment pursuant to U.S.C. § 154(b)(3) and issued the Notice of Allowance reflecting such determination on June 1, 2010.

15. Plaintiff filed a Request for Reconsideration of Patent Term Adjustment Under 37 C.F.R. § 1.705 on June 3, 2010 (attached as Exhibit B). In a decision rendered on September 20, 2010, the PTO dismissed Patentee's request based on Part A delay and dismissed the request based on Part B delay as being premature.

16. The '788 patent issued on October 26, 2010. The Issue Notification and the front page of the '788 patent indicate a patent term adjustment of 85 days.

17. Plaintiff filed another Request for Reconsideration of Patent Term Adjustment Under 37 C.F.R. § 1.705 on December 23, 2010 (attached as Exhibit C). The PTO has yet to issue a decision on this Request.

18. 35 U.S.C. § 154(b)(4)(A) provides that "[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after grant of the patent. Chapter 7 of Title 5 shall apply to such an action."

FIRST CLAIM FOR RELIEF

19. The allegations of paragraphs 1-18 are incorporated in this claim for relief as if fully set forth.

20. The patent term adjustment for the '788 patent, as determined by Defendant under 35 U.S.C. § 154(b) and indicated on the face of the '788 patent, is 85 days. (*See* Ex. A at 1.) The determination of this patent term adjustment should be adjusted because the PTO did not

properly account for the delays that occurred pursuant to statute. The correct patent term adjustment for the '788 patent is at least 321 days, as explained below.

I. PART A DELAY
(Patent Term Adjustment of 135 days)

21. Plaintiff filed a Response to Restriction Requirement on February 20, 2008. Under 35 U.S.C. § 154(b)(1)(A)(ii) and 37 C.F.R. § 1.703(a)(2), Plaintiff is entitled to a adjustment of patent term for any delay by the PTO longer than four months in responding to Plaintiff's filing. The PTO mailed a non-Final Office Action on May 12, 2008. This non-Final Office Action was subsequently withdrawn and replaced with a new non-Final Office Action mailed on October 10, 2008, in which the PTO explained that its May 12, 2008 Office Action "cited the wrong reference in the first paragraph of the 102(a) rejection. . . . The previous Office Action is withdrawn and is replaced by the instant action, which cites the correct reference."

22. Plaintiff filed a Request for Reconsideration of Patent Term Adjustment Under 37 C.F.R. § 1.705 on June 3, 2010, requesting a credit of 112 days – from four months after February 20, 2008 (*i.e.* June 20, 2008) to October 10, 2008 – to the Part A delay.

23. In its Decision mailed on September 20, 2010, the PTO dismissed Plaintiff's request to credit the 112 days to the Part A delay, reasoning that "[t]he mailing of a second Office Action withdrawing the first action does not negate the fact that the [PTO] took action in this application within the meaning of 1.702(a)(1) on May 12, 2008."

24. Consideration of a withdrawn Office Action as a response is contrary to the language and meaning of 35 U.S.C. § 154(b)(1)(A)(ii), which guarantees prompt PTO responses. Plaintiff could not meaningfully respond to the erroneously issued May 12, 2008 Office Action as it "cited the wrong reference" with respect to a prior art rejection. Had the PTO not issued the

erroneous May 12, 2008 Office Action in the first place, Plaintiff would have been similarly situated in not having an opportunity to respond to a rejection *and* would have been entitled to a 112 day credit to the Part A delay. Plaintiff therefore should be entitled to a 112 day patent term adjustment due to the PTO's delay in issuing the October 10, 2008 Office Action.

25. Moreover, under the PTO's reasoning in its September 20, 2010 Decision, the PTO can deprive a patentee of patent term adjustment by issuing erroneous Office Actions that are subsequently withdrawn. This is contrary to the intent of 35 U.S.C. § 154(b)(1)(A)(ii), which guarantees against PTO delays. Hence, the PTO erred when it deemed the withdrawn May 12, 2008 non-Final Office Action to be a response within the meaning of 35 U.S.C. § 154(b)(1)(A)(ii).

26. The PTO issued the Notice of Allowance of the '788 patent on June 1, 2010. The issue fee was paid on June 3, 2010. The patent was not issued by the PTO until October 26, 2010, however, 23 days after the four month period permitted for issuing a patent under 35 U.S.C. § 154(b)(1)(A)(iv).

27. Accordingly, under 35 U.S.C. § 154(b)(1)(A), the following periods of time are properly attributable to the Part A delay:

- a. A period of 112 days under 35 U.S.C. § 154(b)(1)(A)(ii) and 37 C.F.R. § 1.703(a)(2) due to the failure of the PTO to mail an action under 35 U.S.C. § 132 not later than four months after Plaintiff's February 20, 2008 Response to Restriction Requirement.
- b. A period of 23 days under 35 U.S.C. § 154(b)(1)(A)(iv) due to the failure of the PTO to issue the '788 patent not later than four months after the payment of the issue fee.

c. Thus, the total number of days attributable to the Part A delay is 135 days (112 days + 23 days = 135 days).

II. PART B DELAY
(Patent Term Adjustment of 316 days)

28. Plaintiff filed the '339 application on October 26, 2006. On April 14, 2010, Plaintiff filed a Request for Continued Examination ("RCE") under 35 U.S.C. § 132(b). The PTO issued the Notice of Allowance on June 1, 2010. The issue fee was paid on June 3, 2010. The patent issued on October 26, 2010, more than the three years after the actual filing date as guaranteed under 35 U.S.C. § 154(b)(1)(B).

29. 35 U.S.C. § 154(b)(3) directs the PTO to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments under this subsection."

30. Pursuant to 35 U.S.C. § 154(b)(3), the PTO promulgated 37 C.F.R. § 1.703(b)(1). Section 1.703(b)(1) provides that the Part B delay does not include

The number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date the patent was issued.

31. The promulgation of 37 C.F.R. § 1.703(b)(1) is an incorrect interpretation of patent law. The "time consumed by continued examination" provided by 35 U.S.C. § 154(b)(1)(B)(i) does not extend from "the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and end[] on the date the patent was issued," as set forth in the rule promulgated by the PTO. Properly construed, the "time consumed by continued examination" provided for by 35 U.S.C. § 154(b)(1)(B)(i) extends from the date on

which a request for continued examination of the application under 35 U.S.C. § 132(b) was filed and ends on the date the PTO issues a Notice of Allowance.

32. The period from the date immediately after the issuance of the Notice of Allowance to the issue date of the patent is not time consumed by continued examination of the application under 35 U.S.C. § 154(b)(1)(B)(i). The patent statute distinguishes between the examination period and the post-examination period of patent procurement. *Compare, e.g.,* 35 U.S.C. § 131 (describing procedures related to “Examination of Application”) and 35 U.S.C. § 151 (specifying that notice of allowance is issued “[i]f it appears that applicant is entitled to a patent under the law”).

33. Further, 37 C.F.R. § 1.703(b)(1) is inconsistent with other PTO rules and patent statutes that address patent term extension.

34. For instance, 37 C.F.R. § 1.703(b)(4) states that the number of days consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal Court under 35 U.S.C. § 154(b)(1)(B)(ii) is calculated from the day on which a notice of appeal was filed and ending on the date of mailing of either an action under 35 U.S.C. § 132 or a Notice of Allowance under 35 U.S.C. § 151, whichever occurs first. This provision does not include post-allowance processing as time deducted from the total days of patent term adjustment guaranteed by 35 U.S.C. § 154(b)(1)(B).

35. Moreover, 35 U.S.C. § 154(b)(1)(B) is a guarantee of patent term that is provided independent of 35 U.S.C. § 154(b)(1)(A). *See Wyeth v. Kappos*, 591 F.3d 1364, 1369-70 (Fed. Cir. 2010) (“Each ‘period of delay’ has its own discrete time span whose boundaries are defined in section 154(b)(1).”). 35 U.S.C. § 154(b)(1)(A)(iv) already provides an independent basis for patent term adjustment due to the PTO’s post-examination delay in issuing a patent within four

months after the payment of issue fee. There is no statutory basis for deducting the post-examination period in processing an allowed patent application for issuance from the patent term adjustment guaranteed by 35 U.S.C. § 154(b)(1)(B).

36. A patent term adjustment for Part B delay is part of the guarantee provided by the PTO to issue a patent within three years. Under 37 C.F.R. § 1.703(b)(1), a patentee who has filed an RCE would effectively be punished for doing so by being deprived of any credit for Part B delay for the time that falls within the post-examination period when the PTO delays issuance of the patent. This is contrary to the intent of 35 U.S.C. § 154(b)(1)(B)(i).

37. Hence, the PTO erred in considering this post-examination period as time being consumed by continued examination.

38. The promulgation of 37 C.F.R. § 1.703(b)(1) is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority, or limitation.

39. Accordingly, under 35 U.S.C. § 154(b)(1)(B), the following periods of time are properly attributable to the Part B delay:

- a. The addition of a period of 365 days under 35 U.S.C. § 154(b)(1)(B) due to the PTO's failure to issue the patent within three years after the filing date of the application – the '788 patent issued October 26, 2010, which is four years after the Plaintiff filed the '339 application on October 26, 2006.
- b. The deduction of a period of 49 days under 35 U.S.C. § 154(b)(1)(B)(i) due to the total number days consumed by the continued examination of the application, *i.e.*, from the day on which the RCE was filed – April 24, 2010 – until the day when a Notice of Allowance was issued – June 1, 2010.

- c. Thus, the total number of days attributable to the Part B delay is 316 days (365 days – 49 days = 316 days).

**III. TOTAL PATENT TERM ADJUSTMENT
(Additional Term Extension of 321 days)**

40. Under 35 U.S.C. § 154(b)(2)(A) and *Wyeth*, Plaintiff is entitled to adjustment of patent term for all non-overlapping days of PTO delay under both 35 § U.S.C. 154(b)(1)(A) (Part A delay) and 35 § U.S.C. 154(b)(1)(B) (Part B delay). *See Wyeth*, 591 F.3d at 1371 (“[T]he actual number of days the issuance of the patent was delayed’ therefore refers to each day covered by a ‘period of delay’ in the first clause with no such day counted twice.”).

41. Under *Wyeth*, the only days of the Part A delay and the Part B delay that fall on the same calendar dates are from the day immediately after four months from the payment of issue fee to the date of issuance (23 days). Thus, the sum of the Part A delay and Part B delay minus the overlap is 428 days (135 days + 316 days – 23 days = 428 days).

42. Under 35 U.S.C. § 154(b)(2)(C), the following periods of time are attributable to the Applicant delay:

- a. A period of 2 days as Plaintiff filed a response on January 12, 2009 to the PTO’s October 10, 2008 Non-Final Rejection.
- b. A period of 91 days as Plaintiff filed a response on October 27, 2009 to the PTO’s April 28, 2009 Non-Final Rejection.
- c. A period of 14 days as Plaintiff filed a Request for Continued Examination on April 14, 2010 after the PTO’s December 31, 2009 Final Rejection.
- d. Thus, the total period of applicant delay is 107 days (2 days + 91 days + 14 days = 107 days).

43. Under 35 U.S.C. § 154(b), the '788 patent is entitled to a patent term adjustment of 321 days (428 days of Part A Delay and Part B Delay – 107 days of Applicant Delay = 321 days), which is 236 days more than the 85 days provided by Defendant.

44. The Defendant's determination that the '788 patent is entitled to only 85 days of patent term adjustment is arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority or limitation.

SECOND (ALTERNATIVE) CLAIM FOR RELIEF

45. The allegations of paragraphs 1-18, and 20 are incorporated in this claim for relief as if fully set forth.

46. If the Court does not find that the correct patent term adjustment for the '788 patent is at least 321 days, the correct patent term adjustment for the '788 patent is at least 319 days, as explained below.

I. PART A DELAY (Patent Term Adjustment of 135 days)

47. The allegations of paragraphs 21-27 are incorporated in this section as if fully set forth. As described in paragraphs 21-27 above, the total number of days attributable to the Part A delay is 135 days.

II. PART B DELAY – ALTERNATIVE CALCULATION (Patent Term Adjustment of 314 days)

48. The allegations of paragraphs 28-30 and 33-38 are incorporated in this section as if fully set forth.

49. The promulgation of 37 C.F.R. § 1.703(b)(1) is an incorrect interpretation of patent law. The “time consumed by continued examination” provided by 35 U.S.C. § 154(b)(1)(B)(i) does not extend from “the date on which a request for continued examination

of the application under 35 U.S.C. 132(b) was filed and end[] on the date the patent was issued,” as set forth in the rule promulgated by the PTO. Properly construed, the “time consumed by continued examination” provided for by 35 U.S.C. § 154(b)(1)(B)(i) extends from the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ends on the date of payment of the issue fee.

50. The period from the date of payment of the issue fee to the issue date of the patent is not time consumed by continued examination of the application under 35 U.S.C. § 154(b)(1)(B)(i). This period involves only administrative processing by the PTO. *See* 35 U.S.C. § 151 (“Upon payment of [issue fee] the patent shall issue....”). Thus, the continued examination of a patent application concludes at the time the issue fee is paid.

51. Accordingly, to the extent that the Court considers only the period from the date immediately after the payment of the issue fee to the issue date of the patent not to be time consumed by continued examination under 35 U.S.C. § 154(b)(1)(B)(i), the following periods of time are attributable to the Part B delay:

- a. The addition of a period of 365 days under 35 U.S.C. § 154(b)(1)(B) due to the PTO’s failure to issue the patent within three years after the filing date of the application – the ’788 patent issued October 26, 2010, which is four years after the Plaintiff filed the ’339 application on October 26, 2006.
- b. The deduction of a period of 51 days under 35 U.S.C. § 154(b)(1)(B)(i) due to the total number days consumed by the continued examination of the application, *i.e.*, from the day on which the RCE was filed – April 24, 2010 – until the day when the issue fee was paid – June 3, 2010.

c. Thus, the total number of days attributable to the Part B delay under this theory is 314 days (365 days – 51 days = 314 days).

**III. TOTAL PATENT TERM ADJUSTMENT – ALTERNATIVE CALCULATION
(Additional Term Extension of 319 days)**

52. The allegations of paragraphs 40 and 42 are incorporated in this section as if fully set forth.

53. Under *Wyeth*, the only days of the Part A delay and Part B delay that fall on the same calendar dates are from the day immediately after four months from the payment of issue fee to the date of issuance (23 days). Thus, the sum of the Part A delay and Part B delay minus the overlap is 426 days (135 days + 314 days – 23 days = 426 days).

54. To the extent that the Court considers only the period from the date immediately after the payment of the issue fee to the issue date of the patent not to be time consumed by continued examination under 35 U.S.C. § 154(b)(1)(B)(i), the '788 patent is entitled to a patent term adjustment of 319 days (426 days of Part A Delay and Part B Delay – 107 days of Applicant Delay = 319 days), which is 234 days more than the 85 days provided by Defendant.

55. The Defendant's determination that the '788 patent is entitled to only 85 days of patent term adjustment is arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority or limitation.

PRAYER FOR RELIEF

56. Wherefore, Plaintiff demands judgment against Defendant and respectfully request that this Court enter Orders:

A. Declaring that 37 C.F.R. § 1.703(b)(1) is unlawful and legally void and promulgated in excess of the PTO's statutory authority insofar as this regulation is inconsistent with 35 U.S.C. 35 U.S.C. § 154(b)(1)(B)(i);

B. Issuing preliminary and permanent injunctions against Defendant's enforcement or maintenance of 37 C.F.R. § 1.703(b)(1) insofar as this regulation is inconsistent with the 35 U.S.C. 35 U.S.C. § 154(b)(1)(B)(i);

C. Changing the period of the Part A delay for the '788 patent term to 135 days of patent term adjustment and requiring Defendant to extend the term of the '788 patent to reflect that change;

D. Changing the period of the Part B delay for the '788 patent term to 316 days of patent term adjustment and requiring Defendant to extend the term of the '788 patent to reflect that change;

E. Changing the period of patent term adjustment for the '788 patent term from 85 days to 321 days and requiring Defendant to extend the term of the '788 patent to reflect the 321 day patent term adjustment;

F. Alternatively, if the relief sought in paragraphs D and E above is not granted, then:

1. Changing the period of the Part B delay for the '788 patent term to 314 days of patent term adjustment and requiring Defendant to extend the term of the '788 patent to reflect that change;

2. Changing the period of patent term adjustment for the '788 patent term from 85 days to 319 days and requiring Defendant to extend the term of the '788 patent to reflect the 319 day patent term adjustment;

G. Granting such other and future relief as the nature of the case may admit or require and as may be just and equitable.

Dated: April 15, 2011

Respectfully submitted,

By: 

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