

FILED

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

2012 DEC 14 P 3:10

CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

Theranos, Inc.
1601 S California Avenue
Palo Alto, CA 94304

Plaintiff,

v.

Honorable David J. Kappos
Under Secretary of Commerce for Intellectual
Property and Director of the United States
Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313
401 Dulany Street
Alexandria, VA 22314

Office of the General Counsel
United States Patent and Trademark Office
P.O. Box 15667, Arlington, VA 22215
Madison Building East, Room 10B20
600 Dulany Street, Alexandria, VA 22314

Defendant.

Civil Action No. 1:12cv1445
AJT/TRJ

COMPLAINT

Plaintiff Theranos, Inc. (“Theranos” or “Plaintiff”), for its complaint against the Honorable David J. Kappos, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, (hereinafter “Kappos” or “Defendant”), states as follows:

NATURE OF THE ACTION

1. This is an action by Theranos, the owner and assignee of United States Patent No. 8,202,697 (“the ‘697 patent”), entitled “Medical Device for Analyte Monitoring and Drug Delivery” for review of the determination by Defendant, pursuant to, *inter alia*, 35 U.S.C. § 154(b)(3)(B) and 5 U.S.C. §§ 701-706, of the Patent Term Adjustment of the ‘697 patent.

Theranos seeks a judgment that the additional patent term for the '697 patent be changed from 78 days to 1218 days.

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

THE PARTIES

3. Theranos is a Delaware corporation with its principal place of business at 1601 S California Avenue, Palo Alto, California 94304.

4. Defendant 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 PTO and is responsible for superintending or performing all duties required by law with respect to the granting and issuing of patents. As such, Kappos is designated by statute as the official responsible for determining the period of Patent Term Adjustments under 35 U.S.C. § 154(b)(3)(B).

JURISDICTION AND VENUE

5. This Court has jurisdiction to hear this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a), 1361; 35 U.S.C. § 154(b); and 5 U.S.C. §§ 701-706.

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

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

BACKGROUND AND COMMON ALLEGATIONS

The '697 Patent

8. Theranos is the assignee of all right, title, and interest in the '697 patent, as evidenced by records on deposit with the PTO and the face of the '697 patent.

9. Elizabeth A. Holmes is the sole inventor of patent application number 11/202,231 ("the '231 application") which was filed (*i.e.*, met all 35 U.S.C. § 111(a) requirements) on August 12, 2005 (the "Filing Date"). The '231 application claims priority to

patent application number 10/937,872 filed on September 10, 2004 which claims priority to provisional application number 60/501,847 filed on September 11, 2003.

10. On June 21, 2007, the PTO mailed a Non-Final Office Action as to the '231 application (the "First Office Action"). Theranos responded to the First Office Action on December 21, 2007.

11. On February 22, 2008, the PTO mailed a Final Office Action as to the '231 application (the "Second Office Action"). Theranos responded to the Second Office Action on April 22, 2008 and filed a Notice of Appeal on August 21, 2008.

12. On September 29, 2008, Theranos filed an Amendment after Notice of Appeal for the '231 application and on November 21, 2008 filed a Request for Continued Examination (the "First RCE").

13. On February 9, 2009, Theranos filed an Information Disclosure Statement for the '231 application.

14. On February 17, 2009, the PTO mailed a Non-Final Office Action as to the '231 application (the "Third Office Action"). Theranos responded to the Third Office Action on July 17, 2009.

15. On November 5, 2009, the PTO mailed a Final Office Action as to the '231 application (the "Fourth Office Action"). Theranos responded to the Fourth Office Action and filed a Request for Continued Examination (the "Second RCE") on March 1, 2010.

16. On March 16, 2011, the PTO mailed a Non-Final Office Action as to the '231 application (the "Fifth Office Action"). Theranos responded to the Fifth Office Action on September 16, 2011.

17. On November 22, 2011, the PTO mailed a Non-Final Office Action as to the '231 application (the "Sixth Office Action"). Theranos responded to the Sixth Office Action and filed a Terminal Disclaimer over Application No. 11/202,206 on January 17, 2012.

18. On January 18, 2012, Theranos filed an Information Disclosure Statement for the '231 application.

19. On March 1, 2012, the PTO mailed a Notice of Allowance and Fees Due for the '231 application (the "Notice of Allowance"). Included in the Notice of Allowance was a Determination of Patent Term Adjustment wherein the PTO indicated that the Patent Term Adjustment to date for the '231 application was 70 days.

20. On April 12, 2012, Theranos paid the issue fee for the '231 application, thereby satisfying all outstanding requirements for issuance of a patent.

21. On May 30, 2012, the PTO mailed an Issue Notification for the '231 application. Included in the Issue Notification was a Determination of Patent Term Adjustment in which the PTO indicated that the Patent Term Adjustment for the '231 application was 78 days.

22. On June 19, 2012, the '231 application issued as the '697 patent, reflecting a Patent Term Adjustment of 78 days. A true and correct copy of the '697 patent is attached hereto as Exhibit A.

Patent Term Guarantee

23. The Patent Term Guarantee Act of 1999, a part of the American Inventors Protection Act ("AIPA"), amended 35 U.S.C. § 154(b), addressed concerns that delays by the PTO during the prosecution of patent applications could result in a shortening of the effective life of the resulting patents to less than seventeen years.

24. Amended 35 U.S.C. § 154(b) broadened the universe of cognizable administrative delays by the PTO that could retroactively yield an extension of the patent term to compensate for such prosecution delays ("Patent Term Adjustment" or "PTA").

25. Patent Term Adjustment applies to original utility patent applications (including continuations, divisionals, and continuations-in-part) filed on or after May 29, 2000.

26. In calculating PTA, Defendant must take into account PTO delays under 35 U.S.C. § 154(b)(1), any overlapping periods in the PTO delays under 35 U.S.C. § 154(b)(2)(A), and any applicant delays under 35 U.S.C. § 154(b)(2)(C).

27. Under 35 U.S.C. § 154(b)(1)(A), an applicant is entitled to PTA for the PTO's failure to carry out certain acts during processing and examination within defined deadlines ("A Delay").

28. Under 35 U.S.C. § 154(b)(1)(B), an applicant is entitled to additional PTA attributable to the PTO's "failure ... to issue a patent within 3 years after the actual Filing Date of the application in the United States," but not including "any time consumed by Continued Examination of the application requested by the applicant under section 132(b)" ("B Delay").

29. 35 U.S.C. § 154(b)(2)(A) provides that "to the extent that periods of delay attributable to grounds specified in paragraph [154(b)(1)] overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed."

30. On January 7, 2010, the Court of Appeals for the Federal Circuit in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), affirmed the District Court ruling in *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008), that the correct method for calculating overlap of A Delay and B Delay is to aggregate A Delay and B Delay except to the extent that such aggregation would amount to counting the same calendar days twice.

31. 35 U.S.C. § 154(b)(2)(C)(i) also directs that "the 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" ("Applicant Delay Reduction").

32. On November 1, 2012, *Exelixis, Inc. v. Kappos*, No. 1:12-cv-00096, 2012 U.S. Dist. LEXIS 157762, at *8 (E.D. Va. Nov. 1, 2012) held that Patent Term Adjustment awards arising from the failure of the PTO to grant a patent within three (3) years of the filing date (known as "B delays") are not necessarily reduced by the filing of a Request for Continuation ("RCE") if the RCE is filed more than three (3) years after the filing date for that patent application. Therefore, the "B delay" should be calculated from the date three years after filing to the date the patent is issued, whether or not an RCE was filed. *Id.*

33. Under 35 U.S.C. § 154(b)(4)(A), “an 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 Eastern District of Virginia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action.”

Defendant’s Abrogation of the Patent Term Guarantee for the ‘697 Patent

34. Defendant has improperly calculated the PTA for the ‘697 patent in a manner that deprives patentees of B Delay due to an incorrect interpretation of the effect of the Continued Examination procedure under 35 U.S.C. § 132(b) within the context of 35 U.S.C. § 154(b)(1)(B).

35. Defendant has inappropriately promulgated and relied upon 37 C.F.R. § 1.703(b)(1) 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.

36. Instead, 35 U.S.C. § 154(b)(1)(B)(i) merely requires the exclusion of “any time consumed by Continued Examination of the application requested by the applicant under 35 U.S.C. § 132(b)” when calculating whether the PTO has satisfied the three-year pendency guarantee.

37. When properly construed, if the PTO fails to meet this three-year pendency guarantee, the applicant is entitled to the full remedy afforded by 35 U.S.C. § 154(b)(1)(B): “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 the specific limitations set forth in 35 U.S.C. § 154(b)(2).

38. None of the limitations included within 35 U.S.C. § 154(b)(2) reduce or otherwise affect the PTA remedy in 35 U.S.C. § 154(b)(1)(B) on the basis of time consumed by examination after filing of an RCE.

39. The PTO also 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, set forth at 37 C.F.R. § 1.704, likewise do not include

any reduction or limitation based upon time consumed by examination after the filing of an RCE.

40. Accordingly, the plain language of 35 U.S.C. § 154(b)(1)(B) dictates that if an RCE is not filed within three years after the actual filing date of a patent application, the filing of the RCE has no effect upon the accrual of B Delay for that patent. Under such circumstances, the applicant is entitled to B Delay from the day after the three-year pendency period through the date of issuance of the patent, the explicit remedy set forth in 35 U.S.C. § 154(b)(1)(B), subject only to the specific limitations set forth at 35 U.S.C. § 154(b)(2). *See Exelixis, Inc. v. Kappos*, No. 1:12-cv-00096, 2012 U.S. Dist. LEXIS 157762 (E.D. Va. Nov. 1, 2012).

41. To the extent that 37 C.F.R. § 1.703(b)(1) conflicts with the straightforward and unambiguous language of 35 U.S.C. § 154(b)(1)(B), this subsection of the regulation is invalid.

The Proper Calculation of PTA for the '697 Patent

42. Under 35 U.S.C. § 154(b)(1)(A)(i), Theranos is entitled to an adjustment of the term of the '697 patent for a period of 252 days. This A Delay period is attributable to the PTO's failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the actual Filing Date of the application. This period consists of the period from October 12, 2006 (14 months after the Filing Date) through June 21, 2007 (the mailing date of the First Office Action).

43. Under 35 U.S.C. § 154(b)(1)(A)(ii), Theranos is entitled to an additional adjustment of the term of the '697 patent for a period of 258 days. This A Delay period is attributable to the PTO's failure to respond to a reply under 35 U.S.C. § 132 within 4 months after the date a reply was filed. This period consists of the period from July 1, 2010 (4 months after the mailing date of the reply to the Fourth Office Action) through March 16, 2011 (the mailing date of the Fifth Office Action).

44. Under 35 U.S.C. § 154(b)(1)(B), Theranos is entitled to an additional adjustment of the term of the '697 patent for a period of 1406 days. This B Delay period consists of the

period from August 12, 2008 (three years after the Filing Date) through June 19, 2012 (the issue date of the '697 patent).

45. There is overlap of A Delay and B Delay of 258 days for the '697 patent pursuant to 35 U.S.C. § 154(b)(2)(A). The overlap period consists of the period from July 1, 2010 (4 months after the mailing date of the reply to the Fourth Office Action) through March 16, 2011 (the mailing date of the Fifth Action).

46. Under 35 U.S.C. § 154(b)(2)(C)(i), 440 days of delay is attributable to Theranos. This Applicant Delay Reduction is the sum total of Theranos' delay in filing a response to the First Office Action on December 21, 2007, a date in excess of three months by 91 days; Theranos' delay in filing a Notice of Appeal to the Second Office Action on August 21, 2008, a date in excess of three months by 91 days; Theranos' delay in filing an Information Disclosure Statement to the reply to the Second Office Action on February 9, 2009, a delay of 80 days; Theranos' delay in filing a response to the Third Office Action on July 17, 2009, a date in excess of three months by 61 days; Theranos' delay in filing a response to the Fourth Office Action on March 1, 2010, a date in excess of three months by 24 days; Theranos' delay in filing a response to the Fifth Office Action on September 16, 2011, a date in excess of three months by 92 days; and Theranos' delay in filing an Information Disclosure Statement to the reply to the Sixth Office Action on January 18, 2012, a delay of 1 day.

47. The correct PTA for the '697 patent is 1218 days: the sum of the 510 days of A Delay and the 1406 days of B Delay, minus the overlap of A Delay and B Delay of 258 days and 440 days of Applicant Delay Reduction.

CLAIMS FOR RELIEF

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

48. The allegations of paragraphs 1-47 are incorporated in this claim for relief as if fully and expressly set forth herein.

49. The PTO's calculation of B Delay for the '697 patent was based upon a flawed interpretation of 35 U.S.C. § 154(b)(1)(B) that wrongly excluded all otherwise compensable PTO delay that accrued after Theranos filed the RCE.

50. Theranos filed two RCEs during prosecution of the '231 application, all of which were filed more than three years after the actual Filing Date of that application.

51. Theranos' filing of the RCEs during prosecution of the '231 application has no effect upon the accrual of B Delay for the '697 patent.

52. Continued examination of the '231 application by the PTO concluded on the date the PTO mailed to Theranos the Notice of Allowance.

53. The '697 patent accrued B Delay for the period from the August 12, 2008 (three (3) years after the Filing Date) through June 19, 2012 (the issue date of the '697 patent) for a total of 1406 days of B delay.

54. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation of B Delay for the '697 patent that deprived Theranos of the appropriate PTA for this patent.

55. Theranos is entitled to additional patent term for the '697 patent such that the 78 days of PTA granted by the PTO should be changed to 1218 days.

WHEREFORE, Theranos respectfully prays that this Court:

A. Issue an Order changing the period of PTA for the '697 patent from 78 days to 1218 days and requiring Defendant to alter the term of the '697 patent to reflect such additional PTA; and

B. Grant such other and further relief as the nature of the case may admit or require and as may be just and equitable.

Dated: December 14, 2012

By: 

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