

FILED

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

337 12-6 P 10
COURT REPORTER
ALEXANDRIA, VA

ONCOTHYREON INC.,
2601 Fourth Avenue, Suite 500
Seattle, WA 98121

Plaintiff,

v.

HON. 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. 1:12cv1404

LMB/TRJ

COMPLAINT

Plaintiff Oncothyreon Inc. ("Oncothyreon" 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 Oncothyreon, the owner and assignee of United States Patent No. 8,198,400 ("the '400 patent"), entitled "Vaccine For Modulating Between T1 and T2 Immune Responses" 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 '400

patent. Oncothyreon seeks a judgment that the additional patent term for the '400 patent be changed from 427 days to 2316 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. Oncothyreon is a Delaware corporation with its principal place of business at 2601 Fourth Avenue, Suite 500, Seattle, Washington 98121.

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 '400 Patent

8. Oncothyreon is the assignee of all right, title, and interest in the '400 patent, as evidenced by records on deposit with the PTO and the face of the '400 patent.

9. Wladyslaw A. Budzynski, R. Rao Koganty, Mark J. Krantz, and Michael Longenecker are the inventors of patent application number 10/106,876 ("the '876 application") which was filed (*i.e.*, met all 35 U.S.C. § 111(a) requirements) on March 27, 2002

(the "Filing Date"). The '876 application claims priority to March 27, 2001 (the "Priority Date").

10. On March 24, 2004, the PTO mailed a Restriction/Election Requirement as to the '876 application (the "Restriction Requirement"). Oncothyreon responded to the Restriction Requirement on April 26, 2004.

11. On July 1, 2004, the PTO mailed a Non-Final Office Action as to the '876 application (the "First Office Action"). Oncothyreon responded to the First Office Action on October 1, 2004.

12. On September 26, 2005, Oncothyreon filed an Information Disclosure Statement for the '876 application.

13. On November 3, 2005, the PTO mailed a Non-Final Office Action as to the '876 application (the "Second Office Action"). Oncothyreon responded to the Second Office Action on February 3, 2006.

14. On April 18, 2006, the PTO mailed a Final Office Action as to the '876 application (the "Third Office Action").

15. On May 5, 2006, the PTO mailed a Supplemental Office Action as to the '876 application (the "Supplemental Office Action"). Oncothyreon responded to the Supplemental and Third Office Actions on November 3, 2006.

16. On January 3, 2007, Oncothyreon filed a Request for Continued Examination as to the '876 application (the "First RCE").

17. On February 23, 2007, the PTO mailed a Non-Final Office Action as to the '876 application (the "Fourth Office Action"). Oncothyreon responded to the Fourth Office Action on May 23, 2007.

18. On August 20, 2007, the PTO mailed a Final Office Action as to the '876 application (the "Fifth Office Action"). Oncothyreon responded to the Fifth Office Action on October 31, 2007.

19. On October 31, 2007, Oncothyreon filed a response to the Fourth Office Action and second Request for Continued Examination as to the '876 application (the "Second RCE").

20. On December 31, 2007, the PTO mailed a Final Office Action as to the '876 application (the "Sixth Office Action"). Oncothyreon responded to the Sixth Office Action on March 31, 2008 and filed a Notice of Appeal on June 2, 2008.

21. On October 2, 2008, Oncothyreon filed a response to the Fifth Office Action and second Request for Continued Examination as to the '876 application (the "Third RCE").

22. On December 13, 2008, the PTO mailed a Restriction/Election Requirement as to the '876 application (the "Second Restriction Requirement"). Oncothyreon responded to the Restriction Requirement on January 15, 2009.

23. On April 27, 2009, the PTO mailed a Non-Final Office Action as to the '876 application (the "Seventh Office Action"). Oncothyreon responded to the Seventh Office Action on July 20, 2009.

24. On November 9, 2009, the PTO mailed a Final Office Action as to the '876 application (the "Eighth Office Action"). Oncothyreon responded to the Eighth Office Action on March 9, 2010.

25. On April 8, 2010, Oncothyreon filed a Request for Continued Examination as to the '876 application (the "Fourth RCE").

26. On October 15, 2010, the PTO mailed a Non-Final Office Action as to the '876 application (the "Ninth Office Action"). Oncothyreon responded to the Ninth Office Action on March 14, 2011.

27. On May 27, 2011, the PTO mailed a Non-Final Office Action as to the '876 application (the "Tenth Office Action"). Oncothyreon responded to the Tenth Office Action on August 5, 2011.

28. On August 19, 2011, Oncothyreon filed an Information Disclosure Statement for the '876 application.

29. On October 31, 2011, the PTO mailed a Non-Final Office Action as to the '876 application (the "Eleventh Office Action"). Oncothyreon responded to the Eleventh Office Action on January 31, 2012.

30. On February 16, 2012, the PTO mailed a Notice of Allowance and Fees Due for the '876 application (the "First 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 '876 application was 2 days.

31. On April 2, 2012, the PTO mailed a Second Notice of Allowance and Fees Due for the '876 application (the "Second Notice of Allowance").

32. On May 14, 2012, Oncothyreon paid the issue fee for the '876 application, thereby satisfying all outstanding requirements for issuance of a patent.

33. On May 23, 2012, the PTO mailed an Issue Notification for the '876 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 '876 application was 427 days.

34. On June 12, 2012, the '876 application issued as the '400 patent, reflecting a Patent Term Adjustment of 427 days. A true and correct copy of the '400 patent is attached hereto as Exhibit A.

Patent Term Guarantee

35. 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.

36. 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").

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

38. 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).

39. 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").

40. 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").

41. 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."

42. 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.

43. 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" ("C Reduction").

44. 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.*

45. 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 '400 Patent

46. Defendant has improperly calculated the PTA for the '400 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).

47. 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.

48. 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.

49. 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).

50. 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.

51. 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.

52. 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).

53. 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 '400 Patent

54. Under 35 U.S.C. § 154(b)(1)(A)(i), Oncothyreon is entitled to an adjustment of the term of the '400 patent for a period of 302 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 May 27, 2003 (14 months after the Filing Date) through March 24, 2004 (the mailing date of the Restriction Requirement).

55. Under 35 U.S.C. § 154(b)(1)(A)(ii), Oncothyreon is entitled to an additional adjustment of the term of the '400 patent for a period of 343 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 February 1, 2005 (4 months after the mailing date of the reply to the First Office Action) through November 3, 2005 (the mailing date of the Second Office Action), *i.e.*, 275 days, and the period from August 8, 2010 (4 months after the mailing date of the reply to the Seventh Office Action) through October 15, 2010 (the mailing date of the Eighth Office Action), *i.e.*, 68 days.

56. Under 35 U.S.C. § 154(b)(1)(B), Oncothyreon is entitled to an additional adjustment of the term of the '400 patent for a period of 2633 days. This B Delay period consists of the period from March 28, 2005 (three years after the Filing Date) through June 12, 2012 (the issue date of the '400 patent).

57. There is overlap of A Delay and B Delay of 289 days for the '400 patent pursuant to 35 U.S.C. § 154(b)(2)(A). The overlap period consists of the period from March 27, 2005 (three years after the Filing Date) through November 3, 2005 (the mailing date of the Second Office Action), *i.e.*, 221 days, and the period from August 8, 2010 (4 months after the mailing date of the reply to the Eighth Office Action) through October 15, 2010 (the mailing date of the Ninth Office Action), *i.e.*, 68 days.

58. Under 35 U.S.C. § 154(b)(2)(C)(i), 673 days of delay is attributable to Oncothyreon. This Applicant Delay Reduction is the sum total of Oncothyreon's delay in filing an Information Disclosure Statement to the reply to the First Office Action on September 26, 2005, a delay of 360 days; Oncothyreon's delay in filing a response to the Supplemental Office Action on November 3, 2006, a date in excess of three months by 90 days; Oncothyreon's delay in filing a Notice of Appeal to the Sixth Office Action on June 2, 2008, a date in excess of three months by 63 days; Oncothyreon's delay in filing the Third RCE on October 2, 2008, a date in excess of three months by 30 days; Oncothyreon's delay in filing the Fourth RCE to the Eighth Office Action on April 8, 2010, a date in excess of three months by 58 days, Oncothyreon's delay in filing a response to the Ninth Office Action on March 14, 2011, a date in excess of three months by 58 days, and Oncothyreon's delay in filing an

Information Disclosure Statement to the reply to the Tenth Office Action on August 19, 2011, a delay of 14 days.

59. The correct PTA for the '400 patent is 2316 days: the sum of the 645 days of A Delay and the 2633 days of B Delay, minus the overlap of A Delay and B Delay of 289 days and 673 days of Applicant Delay.

CLAIMS FOR RELIEF

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

60. The allegations of paragraphs 1-59 are incorporated in this claim for relief as if fully set forth herein.

61. The PTO's calculation of B Delay for the '400 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 Oncothyreon filed the RCE.

62. Oncothyreon filed four RCEs during prosecution of the '876 application, all of which were filed more than three years after the actual Filing Date of that application.

63. Oncothyreon's filing of the RCEs during prosecution of the '876 application has no effect upon the accrual of B Delay for the '400 patent.

64. Continued examination of the '876 application by the PTO concluded on the date the PTO mailed to Oncothyreon the Notice of Allowance.

65. The '400 patent accrued B Delay for the period from the March 27, 2005 (three (3) years after the Filing Date) through June 12, 2012 (the issue date of the '400 patent) for a total of 2633 days of B delay.


66. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation B Delay for the '400 patent that deprived Oncothyreon is of the appropriate PTA for this patent.

67. Oncothyreon is entitled to additional patent term for the '400 patent such that the 427 days of PTA granted by the PTO should be changed to 2316 days.

WHEREFORE, Oncothyreon respectfully prays that this Court:

- A. Issue an Order changing the period of PTA for the '400 patent from 427 days to 2316 days and requiring Defendant to alter the term of the '400 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 6, 2012

By: 
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