FILED

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

2012 DEC 21 P 3:35

CERENIS THERAPEUTICS HOLDING SA,

Plaintiff,

v.

HON. DAVID J. KAPPOS, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office,

Defendant.

Civil Action No. 1:12cv1488 LO/TCB

COMPLAINT

Plaintiff Cerenis Therapeutics Holding SA ("Cerenis" or "Patentee") alleges as follows:

INTRODUCTION

1. This is an action under 35 U.S.C. § 154(b)(4)(A) seeking a change in the patent term adjustment ("PTA") conferred by the United States Patent and Trademark Office ("USPTO") on U.S. Patent No. 8,206,750 (the " '750 patent," attached hereto as Exhibit A).

2. The existing USPTO regulations in this area conflicted with the plain language of the statute. Both this Court and the U.S. District Court for the District of Columbia have ruled against the USPTO on this legal question just last month. *See Exelixis, Inc. v. Kappos*, No. 1:12-cv-96, 2012 WL 5398876, 2012 U.S. Dist. LEXIS 157762 (E.D. Va. Nov. 1, 2012) (Ellis, J.); *Novartis AG v. Kappos*, No. 1:10-cv-01138-ESH, 2012 WL 5564736, 2012 U.S. Dist. LEXIS 163237 (D.D.C. Nov. 15, 2012).

3. In determining the PTA for the '750 patent, the USPTO applied the calculation described in 37 CFR §§ 1.702(b)(1) and 1.703(b)(1) and conferred 92 days of PTA. However, the calculation described in those regulations is contrary to the plain language of 35 U.S.C. § 154(b)(1)(B)(i). Applying the calculation described in the statute, instead of the calculation in the regulations, changes the PTA for the '750 patent from 92 days to 888 days.

4. Alternatively, even if the reasoning in *Exelixis* and *Novartis* is not accepted, the PTA for the '750 patent should be changed from 92 to 333 days.

PARTIES

5. Plaintiff Cerenis Therapeutics Holding SA is a French corporation having a place of business at 265 Rue de la Découverte, 31670 LABEGE, France. Cerenis is the owner of all right, title, and interest in and to the '750 patent.

6. Defendant David J. Kappos (the "Director") is named in his official capacity as the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office ("USPTO"). The Director's addresses are P.O. Box 15667, Arlington, VA 22215 and Mason Building East, Room 10B20, 600 Dulany Street, Alexandria, VA 22314. Under 35 U.S.C. § 3(a)(1), the powers and duties of the USPTO are vested in the Director.

JURISDICTION, VENUE, AND TIMING

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

2. This Court has subject matter jurisdiction under 5 U.S.C. §§ 701-706, 28 U.S.C. §§ 1331, 1338(a), and 1361, and 35 U.S.C. § 154(b)(4)(A).

3. Venue is proper in this District under 35 U.S.C. § 154(b)(4)(A) as amended by the Leahy-Smith American Invents Act, Pub. L. No. 112-29, § 9(a), 125 Stat. 284, 316 (2011).

4. This Complaint is timely under 35 U.S.C. § 154(b)(4)(A) because it is being filed within 180 days of the issuance of the '750 patent.

THE PATENT TERM ADJUSTMENT STATUTE

5. The American Inventors Protection Act of 1999 included changes to the patent laws granting inventors additional patent term under specified conditions. These changes were codified within 35 U.S.C. § 154.

6. 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 USPTO's processing of an application reduces the duration of the patent term.

7. To prevent such delays from decreasing patent term, Congress directed the USPTO to grant successful applicants upward adjustments of their patent terms to compensate for three categories of processing delay by the USPTO. 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.

8. B Delay is based on a statutory "Guarantee of No More Than 3-Year Application Pendency." 35 U.S.C. § 154(b)(1)(B). Under this guarantee, applicants are granted additional patent term "if the issue of an original patent is delayed due to the failure of the [USPTO] to issue a patent within 3 years after the actual filing date of the application in the United States."

Id. In calculating whether the USPTO 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).

9. The continued examination procedure under 35 U.S.C. § 132(b) is referred to as a request for continued examination ("RCE"). *See* 37 CFR § 1.114.

10. If the USPTO fails to meet the B Delay 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).

11. The USPTO 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 CFR § 1.704 under the heading "Reduction of period of adjustment of patent term." These regulations do not include any reduction based on time consumed by examination after the filing of an RCE.

PROSECUTION HISTORY OF THE '750 PATENT

12. U.S. patent application no. 11/388,135 (the " '135 application") was filed in the USPTO on March 22, 2006 naming Jean-Louis Dasseux as inventor and assigned to Cerenis.

13. On April 20, 2006, the USPTO mailed a notice to file missing parts.

14. On June 6, 2006, the applicant filed a response to the notice to file missing parts.

15. On August 28, 2006, the applicant filed a first information disclosure statement.

16. On November 26, 2007, the USPTO mailed a restriction requirement.

17. On May 27, 2008, the applicant filed a response to the restriction requirement and first amendment.

18. On October 1, 2008, the USPTO mailed a non-final office action.

19. On April 1, 2009, the applicant filed a response to the non-final office action and second amendment.

20. On July 14, 2009, the applicant filed a second information disclosure statement was filed.

21. On August 10, 2009, the USPTO mailed a final office action.

22. On November 13, 2009, the applicant filed a response to the final office action, with a request for continued examination under 35 U.S.C. § 132(b) and 37 CFR § 1.114 (an "RCE") with a third amendment.

23. On February 8, 2010, the USPTO mailed a second restriction requirement.

24. On March 8, 2010, the applicant filed a response to the restriction requirement.

25. On June 15, 2010, the USPTO mailed a non-final office action.

26. On November 15, 2012, the applicant filed a response to the non-final office action and fourth amendment.

27. On March 15, 2011, the applicant filed a third information disclosure statement.

28. On April 11, 2011, the applicant filed a corrected third information disclosure statement.

29. On August 23, 2011, the USPTO mailed a non-final office action.

30. On September 28, 2011, the applicant filed a response to the non-final office action and fifth amendment.

31. On December 20, 2011, the USPTO mailed a notice of allowance.

32. Also on December 20, 2011, the USPTO mailed a "Determination of Patent Term Adjustment under 35 U.S.C. § 154(b)" calculating a PTA of 0 days.

33. On March 20, 2012, the applicant paid the issue fee.

34. Also on March 20, 2012, an application under 37 CFR § 1.705(b) (denominated "Petition" by the USPTO) was timely filed seeking a PTA of 888 days or, in the alternative, 92 days, provided the patent were to issue as anticipated by the Office on June 26, 2012.

35. On May 21, 2012, the USPTO mailed a decision dismissing the application under 37 CFR § 1.705(b) filed on March 20, 2011.

36. On June 26, 2012, the '135 application issued as the '750 patent. The first page of the patent states that "the term of this patent is extended or adjusted under 35 U.S.C. § 154(b) by 92 days." *See* Exhibit A.

37. On August 24, 2012, the patentee timely filed an application under 37 CFR § 1.705(d) (denominated "Petition" by the USPTO) seeking a PTA of 888 days or, in the alternative, 333 days. The August 24, 2012 application sought the same correction that is being sought in this Complaint.

38. On October 11, 2012, the USPTO dismissed the August 24, 2012 application.

39. No terminal disclaimer was filed during the prosecution of the '135 application.

THE USPTO'S DETERMINATION OF PTA FOR THE '750 PATENT

40. 35 U.S.C. § 154(b)(3)(B) requires the Director to determine PTA for the '750 patent.

41. The correct amount of PTA due the ' 750 patent is described at 35 U.S.C. § 154(b) and is properly determined by the following steps, numbered in conformity with the relevant subsections of § 154(b):

(1)(A) adding 1 day for each day that the USPTO fails to meet certain deadlines during examination of the application ("A Delay"), including:

(i)(II) providing a initial response to the application within 14 months after an international application enters the United States national stage; and

(iv) issuing the patent within 4 months after payment of the issue fee; and

(1)(B) adding 1 day for each day after 3 years that the patent has not yet issued, subject to certain conditions ("B Delay"); and

(2)(A) subtracting any overlap of the A Delay and the B Delay above, as interpreted by *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010) ("Overlap");

(2)(C) subtracting any time during which the Applicant fails to take reasonable efforts to conclude prosecution of the application ("Applicant Delay").

42. Exhibit B is a printout of the USPTO's determination of PTA for the '750 patent, as shown on the PAIR section of the USPTO's website.

43. The USPTO correctly determined determination that the so-called A Delay is 362 days. *See* Exhibit B.

44. Patentee is entitled to a period of patent term adjustment pursuant to 35 U.S.C. § 154(b)(1)(A)(i) and 37 CFR §§ 1.702(a)(1) and 1.703(a)(1) because of the Office's failure to mail an action under 35 U.S.C. § 132 not later than 14 months after Patentee's actual filing date of March 22, 2006 (*i.e.*, by May 22, 2007). Since the Office failed to mail an action under 35 U.S.C. § 132 until November 26, 2007, Patentee is entitled to a day-for-day adjustment to the patent term beginning on the day after May 22, 2007 (*i.e.*, May 23, 2007), and ending on the date of mailing of an action under 35 U.S.C. § 132 (*i.e.*, November 26, 2007), for a total of 188 days.

45. Patentee is also entitled to a period of patent adjustment pursuant to 35 U.S.C. § 154(b)(1)(A)(ii) and 37 CFR §§ 1.702(a)(2) and 1.703(a)(2) because of the Office's failure to respond to replies under 35 U.S.C. § 132 not later than 4 months after the filing of a response by Patentee. Patentee is entitled to an adjustment of patent term of: (a) 4 days for the response filed on May 27, 2008 (reply due by September 27, 2008 but action mailed October 1, 2008); (b) 9 days for the response filed by Patentee on April 1, 2009 (reply due by August 1, 2009 but action mailed August 10, 2009); (c) 161 days for the response filed by Patentee on November 15, 2010 (reply due by March 15, 2011 but action mailed August 23, 2011).

46. Thus, the total A Delay is 188 days plus 4 days plus 9 days plus 161 days, or a total of 362 days.

47. The USPTO determined that '750 patent was due 235 days of so-called B Delay PTA (indicated in Exhibit B as "PTA 36 Months").

48. Upon information and belief, the USPTO performed that determination as follows using the method described in 37 CFR §§ 1.702(b)(1) and 1.703(b)(1) for determining B Delay. Because the USPTO failed to issue the '750 patent within 3 years of the actual filing date of the application (*i.e.* by March 22, 2009), the USPTO determined that the '750 patent was due one day of PTA for each day after March 22, 2009 until the earlier of either the day that the '750 patent issued or the day before the Applicant filed an RCE. An RCE was filed on November 13, 2009 and the '750 patent issued on June 26, 2012. Thus, on information and belief, the USPTO determined the amount of B Delay to be the number of days from March 23, 2006 through November 12, 2009, which is 235 days.

49. The USPTO determined the amount of Overlap, as interpreted in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), to be 9 days. *See* Exhibit B.

50. The USPTO correctly determined the amount of Applicant Delay under 35 U.S.C. § 154(b)(2)(C) and 37 CFR § 1.704 is 496 days. *See* Exhibit B.

51. Pursuant to 37 CFR § 1.704(b), the Applicant Delay is the number of days beginning on the day after the date that is three months after the date of mailing of an office action by the USPTO and ending on the date a reply is filed. The USPTO determined that the Applicant Delay is: (a) 91 days with respect to the response by Patentee filed on May 27, 2008; (b) 90 days with respect to the response filed by Patentee on April 1, 2009; (c) 104 days with respect to a second information disclosure statement filed by Patentee on July 14, 2009; (d) 3 days with respect to the request for continued examination filed by Patentee on November 13, 2009; (e) 61 days with respect to the response filed by Patentee on November 15, 2010, response was filed on November 15, 2010); and (f) 147 days with respect to the supplemental response filed by Patentee on April 11, 2011.

52. Thus, the total period of Applicant Delay under 37 CFR § 1.704 is 91 days plus 90 days plus 104 days plus 3 days plus 61 days plus 147 days, for a total of 496 days.

53. The total amount of PTA determined by the USPTO for the '750 patent was as follows (numbered in conformity with the relevant subsections of 35 U.S.C. § 154(b)):

(1)(A) taking 362 days of A Delay,

(1)(B) adding 235 days of B Delay,

(2)(A) subtracting 9 days of Overlap,

(2)(C) subtracting 496 days of Applicant Delay,

for a net total of 92 days.

CLAIM I
Award of an Additional 796 Days of Patent Term Adjustment per 35 U.S.C. § 154(b)(1)(B)(i)

54. All previous paragraphs are incorporated into this claim for relief.

55. The USPTO erred by failing to correctly apply 35 U.S.C. § 154(b)(1)(B)(i) after the applicant filed an RCE. Pursuant to and in accordance with its rules, the USPTO determined that the amount of B Delay for the '750 patent was 235 days. *See* 37 CFR §§ 1.702(b)(1) and 1.703(b)(1). However, the governing statute dictates that the B Delay is instead 1192 days.

56. 35 U.S.C. § 154(b)(1)(B) states, in relevant part:

> (B) Guarantee of no more than 3-year application pendency.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including—
>
> (i) any time consumed by continued examination of the application requested by the applicant under section 132(b);
>
> (ii) . . . ; or
>
> (iii) . . . ,
>
> 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.

57. The plain language of 35 U.S.C. § 154(b)(1)(B) sets up a "trigger" condition which denotes when B Delay applies, and a "remedy" of how much B Delay PTA will be granted if and when the "trigger" condition is satisfied.

58. The "trigger" condition consists of the first phrase of 35 U.S.C. § 154(b)(1)(B) (up to the second dash) plus the three exclusions denoted (i), (ii), and (iii). Only exclusion (i) is applicable in this case. This exclusion states that when determining if the "trigger" condition is met, *i.e.*, whether USPTO issued a patent within 3 years, one does not count any time consumed by an RCE.

59. In the case of the '750 patent, the "trigger" condition is satisfied. Even excluding the entire period after the filing of an RCE on November 13, 2009, the USPTO still took more than 3 years to issue the '750 patent, as the 3-year period ended on March 22, 2009.

60. Having satisfied the "trigger" condition, the "remedy" portion of the statute governs the amount of B Delay PTA to be awarded. The "remedy" portion is the flush 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").

61. The correct amount of B Delay PTA to be awarded to the '750 patent is 1 day for each day after the end of that 3-year period (*i.e.*, after March 22, 2006) until the patent was issued (*i.e.*, June 26, 2012), or 1192 days.

62. Because the amount of B Delay PTA includes an overlap in A Delay and B Delay of 161 days from March 20, 2012 to June 26, 2012, the amount of Overlap must also be increased by 161 days, changing it from 9 days to 170 days.

63. The USPTO's misinterpretation of 35 U.S.C. § 154(b)(1)(B)(i) is manifested at 37 CFR §§ 1.702(b)(1) and 1.703(b)(1). In accordance with 37 CFR § 1.703(b)(1), the USPTO declined to attribute any B Delay to the '750 patent for the period beginning on the date on which an RCE was filed and ending on the date the '750 patent issued. In effect, under the USPTO's rules, the filing of an RCE immediately cuts off accrual of any future B Delay.

64. The USPTO's interpretation of 35 U.S.C. § 154(b)(1)(B)(i), as articulated in 37 CFR §§ 1.702(b)(1) and 1.703(b)(1), is contrary to the plain language of that statute. Instead of applying the exception of 35 U.S.C. § 154(b)(1)(B)(i) (concerning RCEs) to only the "trigger" portion of the statute, as required by the plain language of that statute, these regulations

erroneously apply the exception of 35 U.S.C. § 154(b)(1)(B)(i) to both the "trigger" portion and to the "remedy" portion.

65. Correctly interpreted, the plain language of 35 U.S.C. § 154(b)(1)(B) makes the filing of an RCE relevant only to whether or not B Delay is triggered, but not to how long the term of the patent is adjusted if and when B Delay is triggered, as has been held in the Eastern District of Virginia and in the District of Columbia. *See Exelixis, Inc. v. Kappos*, No. 1:12-cv-96, 2012 WL 5398876, 2012 U.S. Dist. LEXIS 157762 (E.D. Va. Nov. 1, 2012); *Novartis AG v. Kappos*, No. 1:10-cv-01138-ESH, 2012 WL 5564736, 2012 U.S. Dist. LEXIS 163237 (D.D.C. Nov. 15, 2012). In both *Exelixis* and *Novartis*, the patentee had been denied patent term adjustment by the USPTO for the period beginning on the date on which an RCE was filed and ending on the date a patent issued. The district courts ruled in each case that the USPTO's interpretation of subparagraph (B) be set aside as not in accordance with the law. *See Exelixis v. Kappos*, at *8; *Novartis v. Kappos*, at *22. The present case presents the same issue of law and, consistent with the holdings in *Exelixis* and *Novartis*, should be resolved in Cerenis' favor.

66. The amount of PTA that would be due the '750 patent had the USPTO correctly applied 35 U.S.C. § 154(b)(1)(B)(i) after the applicant filed an RCE is (numbering conforms to the subsections of § 154(b)):

(1)(A) taking the sum of all A Delay, namely,

(1)(A) taking 362 days of A Delay and

(1)(B) adding 1192 days of B Delay;

(2)(A) subtracting 170 days of Overlap;

(2)(C) subtracting 496 days of Applicant Delay;

for a net total of 888 days.

67. The USPTO's use of 37 CFR § 1.703(b)(1) in determining the for '750 patent, and the failure to determine 888 days of PTA for the '750 patent, was arbitrary, capricious, an abuse of discretion, not according to law, and in excess of the Director's statutory authority.

CLAIM II
Award of an Additional 241 Days of Patent Term Adjustment per 35 U.S.C. § 154(b)(1)(B)(i)

68. Paragraphs 1-53 are incorporated into this claim for relief, which is made in the alternative to Count I.

69. Even under the USPTO's improper statutory interpretation excluding from the calculation of the length of B Delay adjustment any after the filing of an RCE, 37 CFR § 1.703(b)(1) is still contrary to the plain language of the statute because it excludes *all* periods following the filing of an RCE from B Delay rather than merely "any time consumed by continued examination of the application." 35 U.S.C. § 154(b)(1)(B)(i). After an RCE is filed, only a portion of the time is consumed by continued examination; other portions are consumed, for example, by the applicant or by the USPTO's administrative functions other than examination.

70. No continued examination of the '135 application took place during the following periods: (1) from February 9, 2010 (the day after a restriction requirement was mailed by the Office) until March 8, 2010 (the day a response was filed), which is 27 days; (2) from June 15, 2010 (the day after a non-final office action was mailed by the Office) until November 15, 2010 (the day a response was filed), which is 152 days; (3) from August 24, 2011 (the day after a non-final office action was mailed by the Office) until September 28, 2011 (the day a response was filed), which is 35 days; and from December 21, 2011 (the day after a notice of allowance was mailed by the Office) until March 26, 2012 (the day the '750 patent issued), which is 188 days.

Accordingly, in the alternative, the correct amount of B Delay PTA to be awarded to the '750 patent is 27 days plus 152 days plus 35 days plus 188 days, in addition to the 235 days calculated by the USPTO, or a total of 637 days.

71. As the amount of B Delay PTA includes an overlap in A Delay and B Delay of 161 days from March 20, 2012 to June 26, 2012, the amount of Overlap is also increased by 161 days, changing it from 9 days to 170 days.

72. The amount of PTA that would be due the '750 patent had the USPTO correctly applied 35 U.S.C. § 154(b)(1)(B)(i) after the applicant filed an RCE is (numbering conforms to the subsections of § 154(b)):

(1)(A) taking the sum of all A Delay, namely,

(1)(A) taking 362 days of A Delay and

(1)(B) adding 637 days of B Delay;

(2)(A) subtracting 170 days of Overlap;

(2)(C) subtracting 496 days of Applicant Delay;

for a net total of 333 days.

73. The USPTO's use of 37 CFR § 1.703(b)(1) in determining the PTA for '750 patent, and the failure to determine at least 333 days of PTA for the '750 patent, was arbitrary, capricious, an abuse of discretion, not according to law, and in excess of the Director's statutory authority.

Relief Sought

74. Wherefore, Cerenis seeks a judgment:

(a) declaring that the correct period of patent term adjustment for the '750 patent is 888 days, or in the alternative, 333 days;

(b) ordering the Director to change the amount of patent term adjustment for the '750 patent from 92 to 888 days, or in the alternative, 333 days, and to issue an appropriate Certificate of Correction for the '750 patent; and

(c) such other relief as is just and proper.

Dated: Dec. 21, 2012

Respectfully submitted,

Craig G. Falls (VSB No. 72926)
Dechert LLP
1775 I Street, NW
Washington, DC 20006-2401
craig.falls@dechert.com
Ph: (202) 261-3373
Fax: (202) 261-3333
Attorney for Plaintiff

Steven Engel
Dechert LLP
1775 I Street, N.W.
Washington, DC 20006-2401
steven.engel@dechert.com
Ph : (202) 261-3403
Fax: (202) 261-3143
Of Counsel