

FILED

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

2013 JAN 14 P 2: 04
CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

BIOPROJET SCR
30, Rue Des Francs-Bourgeois
75003 Paris, FRANCE,
a French company,

Plaintiff,

v.

HON. DAVID J. KAPPOS
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
Madison Building East, Room 10B20
600 Dulany Street, Alexandria, VA 22314

Defendant.

Civil Action No.

1:13CV 55- LMB/TCB

COMPLAINT

Plaintiff Bioprojet SCR (herein "Plaintiff"), for its complaint against the Honorable David J. Kappos (herein "Kappos" or "Defendant"), states as follows:

NATURE OF THE ACTION

1. This is an action by Plaintiff, the owner and assignee of United States Patent No. 8,222,294 (the '294 patent"), for review of the determination by Defendant, pursuant to, inter alia, 35 U.S.C. § 154(b)(3)(B), of the Patent Term Adjustment of the '294 patent. Plaintiff seeks a judgment that the Patent Term Adjustment for the '294 patent be changed from 210 days to 1135 days.

2. This action arises under 35 U.S.C. § 154, the Fifth Amendment of the Constitution of the United States, and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

THE PARTIES

3. Plaintiff is a corporation organized and existing under the laws of France, with its principal place of business at 30, Rue des Francs-Bourgeois, 75003 Paris, France.

4. 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 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, 2201, & 2202; 35 U.S.C. § 154(b); and 5 U.S.C. §§ 701-706.

6. Venue is proper in this district by virtue of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 9, 125 Stat. 316 (2011).

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

ALLEGATIONS COMMON TO ALL COUNTS

The '294 Patent

8. Plaintiff is the assignee of all right, title, and interest in the '294 patent, as evidenced by records on deposit with the PTO and the face of the '294 patent. As such, Plaintiff is the real party in interest in this case.

9. Jean-Charles Schwartz and Jeanne-Marie Lecomte are the inventors of patent application number 10/587,899 ("the '899 application"), which commenced the National Stage under 35 U.S.C. 371(b) on July 28, 2006 (the "Commencement Date"), based on International application PCT/IS05/00351 filed February 14, 2005.

10. The '899 application claims priority to European application No. 04290384.9, filed February 12, 2004 (the "Priority Date").

11. On January 22, 2010, Plaintiff filed an Request for Continued Examination for the '899 application ("the RCE"). The RCE was filed more than three years after the Commencement Date of the '899 application under 37 C.F.R. § 1.703(b).

12. On June 24, 2011, Plaintiff filed a second Request for Continued Examination in the '899 application.

13. On March 30, 2012, the PTO mailed a Notice of Allowance and Fees Due for the '899 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 '899 application was 210 days.

13. On June 15, 2012, Plaintiff paid the issue fee for the '899 application, satisfying all outstanding requirements for issuance of a patent.

14. On June 27, 2012, the PTO mailed an Issue Notification for the ‘899 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 ‘899 application was 210 days.

15. On July 17, 2012, the ‘899 application issued as the ‘294 patent, reflecting a Patent Term Adjustment of 210 days. A true and correct copy of the ‘294 patent is attached hereto as Exhibit A.

16. On November 1, 2012, this Court issued a Memorandum Opinion in the case of *Exelixis, Inc. v. Kappos*, Civil Action No.: 1:12-CV-00096-TSE-TCB (“*Exelixis*”) which rejected the USPTO’s interpretation of B delay under 35 U.S.C. 154(b)(1)(B) as set forth in 37 CFR 1.703(b) as “not in accordance with law”, and ordered an extension of the patent term adjustment accordingly.

Patent Term Guarantee

17. The Patent Term Guarantee Act of 1999, a part of the American Inventors Protection Act (“AIPA”), amended 35 U.S.C. § 154(b) to address 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.

18. 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”).

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

20. 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).

21. 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").

22. Under 35 U.S.C. § 154(b)(1)(B), and 37 C.F.R. § 1.702(b), an applicant is entitled to additional PTA attributable to the PTO's failure to issue a patent within 3 years after the Filing Date or Commencement 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").

23. 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."

24. On January 7, 2010, the Court of Appeals for the Federal Circuit in *Wyeth v. Kappos*, 591 P.3d 1364 (Fed. Cir. 2010) ("Wyeth") 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.

25. Section 154(b)(2)(C)(i) of 35 U.S.C. 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”).

26. 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

27. Defendant has improperly calculated PTA in a manner that deprives patentees of B Delay Adjustment 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).

28. 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.

29. 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.

30. 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).

31. 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.

32. 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.

33. Accordingly, the plain language of 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.703(b) dictates that if an RCE is not filed within three years after the Commencement Date under 35 U.S.C. § 371(b), 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).

34. 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 '294 Patent

35. Under 35 U.S.C. § 154(b)(1)(A)(i), Plaintiff is entitled to an adjustment of the term of the '294 patent for a period of 255 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.

36. Under 35 U.S.C. § 154(b)(1)(B), Plaintiff is entitled to an additional adjustment of the term of the '294 patent for a period of 1085 days. This B delay period consists of the period from July 28, 2009 (three years after the Commencement Date) through July 17, 2012 (the issue date of the '294 patent). This differs from the B delay period of 160 days as incorrectly determined by Kappos PTA using the rationale rejected by this Court in *Exelixis* by 925 days

37. Under 37 CFR 1.704(c)(10), there were 205 days of delay attributable to Plaintiff.

38. Accordingly, because of the increase of 925 days attributed to B delay due to the PTO's improper calculations, calculating the correct PTA gives a total of 1135 days, including 255 days of A delay, 1085 days of B delay, minus 205 days of Applicant delay. Thus, the total PTA on the '294 patent, originally stated as 210 days, should be revised upwardly by 925 days to 1135 days.

CLAIMS FOR RELIEF

COUNT ONE

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

39. The allegations of paragraphs 1-38 are incorporated in this claim for relief as if set forth fully herein.

40. The PTO's calculation of 210 days of B Delay for the '294 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 Plaintiff filed the RCE.

41. Plaintiff filed an RCE during prosecution of the '899 application more than three years after the Commencement Date of that application pursuant to 37 C.F.R. § 1.703(b).

42. In light of the opinion in *Exelixis*, Plaintiff's filing of the RCE during prosecution of the '225 application should have had no effect upon the accrual of B Delay for the '294 patent, and the proper calculation of accrued B Delay was for the period from three years from the Filing Date to the Issue Date of the '294 patent.

43. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation B Delay for the '294 patent that deprived Plaintiff of the appropriate PTA for this patent.

44. Plaintiff is entitled to additional patent term of 925 days for the '294 patent such that the 210 days of PTA granted by the PTO should be changed to 1135 days.

COUNT TWO

(Violation of the Fifth Amendment of the Constitution of the United States)

45. The allegations of paragraphs 1-44 are incorporated in this claim for relief as if set forth fully herein.

46. The Fifth Amendment of the Constitution of the United States provides in relevant part, “[N]or shall private property be taken for public use, without just compensation.”

47. Plaintiff enjoys a substantial and cognizable private property right in the full and complete term of the ‘294 patent.

48. Plaintiff has not failed to pay any necessary maintenance fees to the PTO required to maintain its rights in the ‘294 patent.

49. Defendant’s promulgation of 37 C.F.R. § 1.703(b)(1), the regulatory subsection interpreting 35 U.S.C. § 154(b)(1)(B)(i), and reliance upon this regulatory subsection in improperly calculating B Delay when determining PTA for the ‘294 patent permanently deprived Plaintiff of patent term to which it was entitled under 35 U.S.C. § 154(b).

50. Defendant’s purposeful and deliberate diminution of the patent term of the ‘294 patent constitutes a taking of Plaintiff’s property without just compensation, in violation of the Fifth Amendment of the Constitution of the United States.

51. Plaintiff is entitled to additional patent term of 925 days for the '294 patent such that the 210 days of PTA granted by the PTO should be changed to 1135 days.

COUNT THREE

(Declaratory Judgment Under The Administrative Procedures Act,

5 U.S.C. § 702 et seq.)

52. The allegations of paragraphs 1-51 are incorporated in this claim for relief as if set forth fully herein.

53. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1), the regulatory subsection interpreting 35 U.S.C. § 154(b)(1)(13)(i), and its improper calculation of B Delay when determining PTA for the '294 patent were contrary to law as set forth in this Court's opinion in *Exelixis*.

54. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '294 patent are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A); contrary to Plaintiff's constitutional rights within the meaning of 5 U.S.C. § 706(2)(B); and in excess of statutory authority within the meaning of 5 U.S.C. § 706(2)(C).

55. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '294 patent were final agency actions that are reviewable by a district court in accordance with 5 U.S.C. § 704.

56. Plaintiff has adequately exhausted all of its available administrative remedies under 35 U.S.C. § 154 or, in the alternative, pursuit of any further administrative remedies is futile.

57. Plaintiff has been afforded no adequate remedy at law for Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '294 patent.

58. Plaintiff will suffer irreparable injury if Defendant is not directed to recalculate PTA for the '294 patent.

59. There is an actual controversy between the parties within this Court's jurisdiction.

60. An order directing Defendant to recalculate PTA for the '294 patent would not substantially injure any other interested parties, and the public interest will be furthered by recalculation of PTA that is contrary to law.

61. Plaintiff is entitled to additional patent term of 925 days for the '294 patent such that the 210 days of PTA granted by the PTO should be changed to 1135 days.

WHEREFORE, Plaintiff respectfully prays that this Court:

A. Issue an Order changing the period of PTA for the '294 patent from 210 days to 1135 days and requiring Defendant to alter the term of the '294 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: January 14, 2013

Respectfully submitted,

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