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

BioGeneriX GmbH,

Plaintiff,

v.

DAVID J. KAPPOS, in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

Defendant.

Case No.: 1:12CV1484-GBL/TCB

COMPLAINT

Plaintiff, BioGeneriX GmbH ("BioGeneriX"), for its complaint against the Honorable David J. Kappos ("Defendant"), states as follows:

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 8,207,112 ("the '112 patent") seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '112 patent be changed from zero days to 152 days.

JURISDICTION AND VENUE

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

3. 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), and 1361, 35 U.S.C. § 154(b)(4)(A), and 5 U.S.C. §§ 701-706.

4. Venue is proper in this district by virtue of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 9, 125 Stat. 315 (2011).

5. This Complaint is being timely filed in accordance with 35 U.S.C. § 154(b)(4)(A) and Fed. R. Civ. P. 6(a)(1).

THE PARTIES

6. BioGeneriX is a corporation organized and existing under the laws of Germany, with its principal place of business at Graf-Arco-Strasse 3, D-89079 Ulm, Germany.

7. Defendant David J. Kappos is sued in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office ("PTO"). The Director of the PTO is designated by statute as the official responsible for determining the period of patent term adjustments and, therefore, is the proper defendant in a suit seeking review of such determinations. *See* 35 U.S.C. §§ 154(b)(3) and 154(b)(4)(A).

BACKGROUND

Patent Term Adjustment

8. Section 154 of title 35 of the United States Code requires that the Director of the PTO grant a patent term adjustment ("PTA") in accordance with the provisions of section 154(b).

9. Walter Hinderer and Christian Scheckermann are the inventors of United States Patent Application No. 12/201,705 ("the '705 application"), which was filed on August 29, 2008 ("the filing date").

10. On September 23, 2008, the PTO mailed a Notice of Missing Parts. On November 24, 2008, BioGeneriX responded to the Notice of Missing Parts.

11. On April 9, 2009, BioGeneriX filed an Information Disclosure Statement ("IDS") with the PTO.

12. On June 1, 2009, the PTO mailed a Non-Final Office Action with respect to the '705 application. BioGeneriX responded to the Non-Final Office Action on August 3, 2009.

13. On September 23, 2009, the PTO mailed a second Non-Final Office Action as to the '705 application. BioGeneriX responded to the second Non-Final Office Action on December 22, 2009.

14. On February 4, 2010, the PTO mailed a third Non-Final Office Action as to the '705 application. BioGeneriX responded to the third Non-Final Office Action on July 2, 2010.

15. On July 22, 2010, the PTO mailed a fourth Non-Final Office Action as to the '705 application. BioGeneriX responded to the fourth Non-Final Office Action on January 21, 2011.

16. On March 2, 2011, the PTO mailed a fifth Non-Final Office Action as to the '705 application. BioGeneriX responded to the fifth Non-Final Office Action on June 2, 2011.

17. As of August 29, 2011 ("the 3 year date"), the '705 application had been pending at the PTO for three years.

18. On November 2, 2011, the PTO mailed a "Final" Office Action as to the '705 application. BioGeneriX filed a Request for Continued Examination ("RCE") together with a response to the "Final" Office Action and an IDS on January 26, 2012.

19. On March 1, 2012, the PTO mailed a Notice of Allowance and Fees Due for the '705 application.

20. On May 29, 2012, BioGeneriX paid the issue fee for the '705 application, thereby satisfying all outstanding requirements for issuance of a patent.

21. On June 26, 2012, the '705 application issued as the '112 patent, reflecting a Patent Term Adjustment of zero days. A true and correct copy of the '112 patent is attached hereto as Exhibit A.

Patent Term Guarantee

22. 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.

23. 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").

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

25. In calculating PTA, Defendant must take into account PTO delays under 35 U.S.C. § 154(b)(l), 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).

26. Under 35 U.S.C. § 154(b)(l)(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").

27. Under 35 U.S.C. § 154(b)(l)(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").

28. 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)(l)] 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."

29. On January 7, 2010, the Court of Appeals for the Federal Circuit in *Wyeth v. Kappos*, 591 F.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.

30. 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").

31. 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

32. Defendant has improperly calculated PTA 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).

33. 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.

34. Instead, 35 U.S.C. § 154(b)(l)(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.

35. 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)(l)(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).

36. 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)(l)(B) on the basis of time consumed by examination after filing of an RCE.

37. 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 35 U.S.C. § 154(b)(l)(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.

38. Accordingly, the plain language of 35 U.S.C. § 154(b)(l)(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)(l)(B), subject only to the specific limitations set forth at 35 U.S.C. § 154(b)(2).

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

40. In *Exelixis, Inc. v. Kappos*, 2012 WL 5398876 at *6 (E.D. Va. Nov. 1, 2012), the District Court for the Eastern District of Virginia agreed that "RCE's have no impact on the PTA after the three year deadline has passed and [35 U.S.C. § 154(b)(1)] subparagraph (B) clearly provides no basis for any RCEs to reduce PTA." *Id.* In other words, the Court held that the proper measure of B delay was from three years after the application filing date to the date the patent issued. *Id.* The Court likewise held that "the PTO's interpretation of [35 U.S.C. § 154(b)(1)] subparagraph (B) must be set aside as 'not in accordance with law' and 'in excess of [its] statutory . . . authority' pursuant to 5 U.S.C. § 706(a)(A) and (C)." *Id* .at *8.

41. Even if, for some reason, the remedy afforded under 35 U.S.C. § 154(b)(l)(B) somehow can be construed to be limited by "any time consumed by continued examination of the application requested by the applicant under section 132(b)," the PTO still has improperly calculated PTA in a manner that deprives patentees of B Delay due to its incorrect interpretation of the effect of filing an RCE.

42. The only time that possibly is "time consumed by continued examination" is the period from the date the applicant files an RCE through the date the PTO thereafter mails a Notice of Allowance, an event that concludes the Continued Examination. The period encompassed by mailing a Notice of Allowance to issuance of a patent occurs in all cases where a patent issues and is not unique to situations where an RCE was filed and thus cannot be considered to be "any time consumed by continued examination." Accordingly, irrespective of

the filing of an RCE, an applicant is entitled to accrue B Delay for the period from the date of the mailing of a Notice of Allowance through the date of issuance of the patent.

The Proper Calculation of PTA for the '112 Patent

43. Under 35 U.S.C. § 154(b)(l)(A)(i), which calculates A Delay, BioGeneriX is entitled to an adjustment of the term of the '112 patent by a period of 31 days.

44. The A Delay period is attributable to the PTO's failure to respond under 35 U.S.C. § 132 within four months of BioGeneriX's June 2, 2011 response to the PTO's fifth Non-Final Office Action. This period consists of the period from October 3, 2011 (the day after 4 months after the Response to Office Action) through November 2, 2011 (the mailing date of the "Final" Office Action).

45. Under 35 U.S.C. § 154(b)(1)(B), BioGeneriX is entitled to an adjustment of the term of the '112 patent for a period of 302 days. This B Delay period consists of the period from August 30, 2011 (the day after three years from the filing date) through June 26, 2012 (the issue date of the '112 patent).

46. Under 35 U.S.C. § 154(b)(l)(B), BioGeneriX is at least entitled to an adjustment of the term of the '112 patent for a period of 267 days. This B Delay period consists of the period from August 30, 2011 (the day after three years from the filing date) through January 26, 2012 (filing of the RCE) and the period from March 1, 2012 (mailing of the Notice of Allowance) through June 26, 2012 (the issue date of the '112 patent).

47. A Delay entirely overlaps with B Delay for the '705 application pursuant to 35 U.S.C. § 154(b)(2)(A).

48. Under 35 U.S.C. § 154(b)(2)(C)(i), 150 days of delay is attributable to BioGeneriX. This Applicant Delay Reduction resulted from BioGeneriX's delay in filing a

response to the second Non-Final Action from May 5, 2010, to July 2, 2010, a date in excess of three months by 59 days, and BioGeneriX's delay in filing a response to the third Office Action from October 23, 2010, to January 21, 2011, a date in excess of three months by 91 days.

49. The correct PTA for the '112 patent is 152 days: 302 days of B Delay minus the 150 days of Applicant Delay.

50. If the filing of an RCE initiated a period of time "consumed by continued examination," then the correct PTA for the '112 patent is at least 117 days: 267 days of B Delay, minus the 150 days of Applicant Delay.

CLAIMS FOR RELIEF

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

51. The allegations of paragraphs 1-50 are incorporated in this claim for relief as if fully set forth herein.

52. The PTO's calculation of B Delay for the '112 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 BioGeneriX filed the RCE.

53. BioGeneriX filed an RCE during prosecution of the '705 application more than three years after the filing date of that application.

54. BioGeneriX filing of the RCE during prosecution of the '705 application has no effect upon the accrual of B Delay for the '112 patent.

55. If the filing of an RCE initiated a period of time "consumed by continued examination," then the PTO's calculation of B Delay for the '112 patent was based upon an interpretation of 35 U.S.C. § 154(b)(1)(B) that improperly excluded PTO delay that was not "consumed by continuing examination."

56. If the filing of an RCE initiated a period of time "consumed by continued examination" of the '705 application, then such period of time concluded on the date the PTO mailed the Notice of Allowance to BioGeneriX.

57. The '112 patent accrued B Delay for the period from the date the PTO mailed the Notice of Allowance to BioGeneriX through the date of issuance of that patent.

58. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(l)(B) resulted in an incorrect calculation B Delay for the '112 patent that deprived BioGeneriX of the appropriate PTA for this patent.

59. BioGeneriX is entitled to additional patent term for the '112 patent such that the PTA granted by the PTO should be changed from zero to 152 days or, if the filing of an RCE initiated a period of time "consumed by continued examination," at least 117 days.

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

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

61. 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."

62. BioGeneriX enjoys a substantial and cognizable private property right in the full and complete term of the '112 patent.

63. BioGeneriX has not failed to pay any necessary maintenance fees to the PTO required to maintain its rights in the '112 patent.

64. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1), the regulatory subsection interpreting 35 U.S.C. § 154(b)(l)(B)(i), and reliance upon this regulatory subsection in

improperly calculating B Delay when determining PTA for the '112 patent permanently deprived BioGeneriX of patent term to which it was entitled under 35 U.S.C. § 154(b).

65. Defendant's purposeful and deliberate diminution of the patent term of the '112 patent constitutes a taking of BioGeneriX's property without just compensation, in violation of the Fifth Amendment of the Constitution of the United States.

66. BioGeneriX is entitled to additional patent term for the '112 patent such that the PTA granted by the PTO should be changed from zero to 152 days or, if the filing of an RCE initiated a period of time "consumed by continued examination," to at least 117 days.

COUNT THREE
(Declaratory Judgment Under The Administrative Procedures Act, 5 U.S.C. § 702 et seq.)

67. The allegations of paragraphs 1-66 are incorporated in this claim for relief as if fully set forth herein.

68. 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 its improper calculation of B Delay when determining PTA for the '112 patent were contrary to law.

69. Defendant's promulgation of 37 C.F.R. § 1.703(b)(l) and determination of PTA for the '112 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 BioGeneriX'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).

70. Defendant's promulgation of 37 C.F.R. § 1.703(b)(l) and determination of PTA for the '112 patent were final agency actions that are reviewable by a district court in accordance with 5 U.S.C. § 704.

71. BioGeneriX 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.

72. BioGeneriX 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 '112 patent.

73. BioGeneriX will suffer irreparable injury if 37 C.F.R. § 1.703(b)(l) is not invalidated and Defendant is not directed to recalculate PTA for the '112 patent.

74. An order invalidating 37 C.F.R. § 1. 703(b)(1) and directing Defendant to recalculate PTA for the '112 patent would not substantially injure any other interested parties, and the public interest will be furthered by invalidation of a regulatory subsection and recalculation of PTA that is contrary to law.

75. BioGeneriX is entitled to patent term adjustment for the '112 patent such that the PTA granted by the PTO should be changed from zero days to 152 days or, if the filing of an RCE initiated a period of time "consumed by continued examination," to at least 117 days.

PRAYER FOR RELIEF

WHEREFORE, BioGeneriX respectfully prays that this Court:

A. Issue an Order changing the period of PTA for the '112 patent from zero days to 152 days or, if the filing of an RCE initiated a period of time "consumed by continued examination," to at least 117 days, and requiring Defendant to alter the term of the '112 patent to reflect such additional PTA;

B. Declare pursuant to 28 U.S.C. § 2201 that 37 C.F.R. § 1.703(b)(1) is invalid, unconstitutional and contrary to law; and

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

Respectfully submitted,

Date: December 21, 2012

By: _____

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