

FILED

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

2013 MAY -3 P 3: 31

CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

GENENTECH, INC.
1 DNA Way,
South San Francisco, California 94080,

Plaintiff,

v.

HON. TERESA STANEK REA,
Acting Under Secretary of Commerce for
Intellectual Property and Acting 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, Virginia 22314,

Defendant.

Civil Action No. 1:13 cv 556
CMH/IDD

COMPLAINT

1. Plaintiff Genentech, Inc. ("Plaintiff"), for its Complaint against Defendant the Honorable Teresa Stanek Rea ("Defendant" or "the Director"), in her official capacity as Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office ("USPTO"), respectfully alleges the following:

NATURE OF THE ACTION

2. This is an action by Plaintiff seeking review of the determination by Defendant of the patent term adjustment (“PTA”) under 35 U.S.C. § 154(b) for U.S. Patent No. 8,303,955 (“the ’955 Patent”). Specifically, this is an action by Plaintiff pursuant to 35 U.S.C. § 154(b)(4)(A) and 5 U.S.C. §§ 701-706 seeking a judgment correcting the PTA for the ’955 Patent from 857 days to a number of days not less than 1048 days. A true and correct copy of the ’955 Patent is attached hereto as Exhibit A.

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

THE PARTIES

4. Genentech, Inc. is a corporation organized and existing under the laws of the State of Delaware with a place of business at 1 DNA Way, South San Francisco, California 94080.

5. The Director is the Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the USPTO, and is sued here in her official capacity. The Director is head of the USPTO and is responsible for all duties required by law with respect to the granting and issuing of patents. The Director is designated by statute as the official responsible for determining PTA under 35 U.S.C. § 154 for any patent granted or issued by the USPTO.

JURISDICTION AND VENUE

6. This Court has jurisdiction to hear this action and to grant Plaintiff’s requested relief pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1361; 35 U.S.C. § 154; and 5 U.S.C. §§ 701-706.

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

8. This Complaint is being filed within 180 days of the grant of the '955 Patent, and is therefore timely filed in accordance with 35 U.S.C. § 154(b)(4)(A).

THE '955 PATENT

9. Leonard G. Presta and Lori Y. O'Connell are named as the joint inventors of the inventions claimed in the '955 Patent.¹ The named inventors have assigned their entire interests in the '955 Patent to Genentech, Inc., as evidenced by the assignments recorded in the USPTO at Reel/Frame Nos. 021643/0027 and 024356/0004. Accordingly, Genentech, Inc. is the sole owner by assignment of all right, title, and interest in and to the '955 Patent. Plaintiff is therefore the real party in interest in this action, and has standing to request the relief prayed for herein.

10. The '955 Patent issued from United States Patent Application No. 11/913,305 ("the '305 Application"), which is a United States national stage application of international application No. PCT/US2006/020688 ("the PCT '688 Application"). The PCT '688 Application was filed on May 26, 2006, and claims priority to United States Provisional Patent Application No. 60/684,853, filed May 26, 2005. The '305 Application entered the United States national stage from the PCT '688 Application on October 31, 2007, which is the date that is 30 months from the claimed priority date of the PCT '688 Application ("the 30-Month Date").

THE STATUTORY AUTHORITY FOR PATENT TERM ADJUSTMENTS

11. The Director of the USPTO is required to extend the term of an issued patent to include any periods of delay attributable to the USPTO. 35 U.S.C. § 154(b). The length of a patent term extension is based on determinations to be made by the Director pursuant to the

¹ The face of the '955 Patent also names Svetlana O. Doronina as a joint inventor. Ms. Doronina was removed as an inventor pursuant to the Certificate of Correction issued by the United States Patent and Trademark Office on January 29, 2013. *See* Exhibit A at p. 49.

provisions of § 154(b). Specifically, 35 U.S.C. § 154(b) provides that “[t]he Director shall proceed to grant the patent after completion of the Director’s determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination.”

12. In making a PTA determination pursuant to 35 U.S.C. § 154(b), the Director must account for periods of USPTO delay under three distinct statutory categories; namely, periods governed by § 154(b)(1)(A) (“A Delay”), periods governed by § 154(b)(1)(B) (“B Delay”) and periods governed by § 154(b)(1)(C) (“C Delay”).

13. In general, an “A Delay” specified in § 154(b)(1)(A) includes periods of time that follow any of a number of specific deadlines for action by the USPTO during examination of a patent application. These deadlines are specified in § 154(b)(1)(A)(i) to (iv).

14. In general, a “B Delay” specified in § 154(b)(1)(B) includes periods of time where 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 an application under section 111(a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application...” These USPTO delay periods exclude certain periods of delay attributable to the applicant, as discussed further below.

15. In general, a “C Delay” specified in § 154(b)(1)(C) includes delays due to specific circumstances that may occur in the USPTO; namely, where the application was delayed due to an interference proceeding under 35 U.S.C. § 135(a), due to imposition of a secrecy order under 35 U.S.C. § 181, or due to appellate review by the Patent Trial and Appeal Board or by a Federal

Court in a case in which the patent was issued under a decision in the review reversing an adverse determination of patentability.

16. The period of extension of a patent required to be provided pursuant to 35 U.S.C. § 154(b) is calculated by (i) adding the total number of days attributable to USPTO delay determined pursuant to 35 U.S.C. §§ 154(b)(1)(A), (B) and (C), and (ii) subtracting from that total the number of days permitted to be reduced from the period pursuant to the provisions of 35 U.S.C. § 154(b)(2).

17. There are three grounds that can be used to reduce the period of an extension specified in § 154(b)(2).

18. First, pursuant to 35 U.S.C. § 154(b)(2)(A), the Director is not required to double-count days which would qualify as delays under two or more of the periods specified in § 154(b)(1)(A), (B) and (C), and which thus “overlap.” See *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010) (“The limitation in section 154(b) only arises when ‘periods of delay’ resulting from violations of the three guarantees ‘overlap.’ 35 U.S.C. § 154(b)(2)(A). Significantly, the A and B guarantees expressly designate when and for what period they each respectively apply.”)

19. Second, the Director may reduce the period to account for any disclaimer of patent term by the applicant pursuant to 35 U.S.C. § 154(b)(2)(B).

20. Finally, the period of extension may be reduced by the Director to account for periods of applicant delay under 35 U.S.C. § 154(b)(2)(C).

THE USPTO’S PTA DETERMINATION FOR THE ’955 PATENT

21. The bases underlying the Director’s PTA determination for the ’955 Patent are set forth in the USPTO’s Patent Application Information Retrieval (“PAIR”) system. A copy of the

PAIR record reflecting the bases of the Director's PTA determination for the '955 Patent is attached hereto as Exhibit B.

22. The Director made a determination that the period for extension under § 154(b) for the '955 Patent was 857 days, which is reflected on the first page of the '955 Patent.

23. The Director identified one period of A Delay that occurred during the pendency of the '305 Application. This period began on December 25, 2009, which is the date that is 14 months after the § 371(c) date for the '955 Patent, and ended on September 26, 2011, the date the Director mailed an Office Action pursuant to 35 U.S.C. § 132. Accordingly, the Director determined that the '955 Patent was entitled to a period of 641 days of "A Delay" pursuant to 35 U.S.C. § 154(b)(1)(A)(i)(II).

24. Plaintiff agrees with the Director's determination that the '955 Patent is entitled to a period of 641 days of "A Delay" pursuant to 35 U.S.C. § 154(b)(1)(i)(II) for the period December 25, 2009 to September 26, 2011.

25. The Director identified one period of "B Delay" that occurred during the pendency of the '305 Application, which started on November 27, 2010 and ended on April 29, 2012. Accordingly, the Director determined that the total period of USPTO B Delay for the '955 Patent was 520 days.

26. The Director identified one period of overlapping A Delay and B Delay; namely, the period starting on November 27, 2010 and ending on September 26, 2011, or a total of 304 days.

27. No disclaimers subject to § 154(b)(2)(B) were made by the owner of the '955 Patent. There is, therefore, no basis for reducing the period of extension of the '955 Patent based on § 154(b)(2)(B).

28. The Director determined there were no periods of applicant delay subject to 35 U.S.C. § 154(b)(2)(C) that occurred during examination of the '305 Application. *See* Exhibit B. There is thus no basis for reducing the period of extension of the '955 Patent based on § 154(b)(2)(C).

29. Based on these findings, the Director determined that the total amount of USPTO delay for the '955 Patent pursuant to § 154(b) was 857 days, which is the number of days that results from adding 641 days to 520 days (1161 days), and then subtracting 304 days from that total.

30. USPTO regulations provide in part that "...If the patent indicates or should have indicated a revised patent term adjustment, any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and must comply with the requirements of paragraphs (b)(1) and (b)(2) of this section." *See* 37 C.F.R. 1.705(d).

31. A request for reconsideration of the Director's patent term adjustment period for the '955 Patent was timely filed with the USPTO on January 3, 2013, and complied with the applicable regulatory requirements. The petition is attached as Exhibit C.

32. For reasons unknown to Plaintiff, the Director has not yet responded to Plaintiff's timely filed request for reconsideration of patent term adjustment.

33. It is anticipated that the PTO will deny Plaintiff's request for reconsideration in view of the positions the Director has taken in concurrent proceedings before this Court and before the Court of Appeals for the Federal Circuit, as explained *infra*, at ¶ 55. It is thus futile for Plaintiff to defer filing this action until the Office responds to Plaintiff's request for reconsideration.

LEGAL STANDARD FOR DETERMINING B DELAY

34. 35 U.S.C. § 154(b)(1)(B) provides that “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, not including . . . any time consumed by continued examination of the application requested by the applicant under section 132(b); . . . the term of the patent shall be extended for 1 day for each day after the end of that 3-year period until the patent is issued.” This “1 day for each day” extension is referred to above as “B Delay.”

35. On November 1, 2012, in *Exelixis, Inc. v. Kappos*, Civil Action No. 1:12-cv-00096, 2012 WL 5398876, at *6-*8 (E.D. Va. Nov. 1, 2012), this Court held that PTA awards arising from the failure of the USPTO to grant a patent within three years of an application’s actual filing date in the United States (“B Delay”) are not tolled by the filing of a request for continued examination (“RCE”) under 35 U.S.C. § 132(b), unless the RCE was filed during the first three years after the application was filed in the United States.

36. This Court subsequently reached a contrary result in *Exelixis, Inc. v. Kappos*, Civil Action No. 1:12-cv-00574, 2013 WL 314754, at *5-*9 (E.D. Va. Jan. 28, 2013). Both this later judgment and the earlier judgment were appealed to the United States Court of Appeals for the Federal Circuit; the appeals have been consolidated. *Exelixis v. Rea*, Nos. 2013-1175, 2013-1198 (Fed. Cir. filed February 6, 2013).

37. On information and belief, the Director tolled and continues to toll the accrual of B Delay pursuant to 35 U.S.C. § 154(b)(1)(B), even when the first filing of an RCE in an application occurs more than three years after the actual filing date of that application under 35 U.S.C. § 111(a) or, in the case of an international application, the date of commencement of the national stage of the international application in the United States.

38. The Director's conduct in this respect is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the law, and in excess of statutory jurisdiction, authority, and limitation.

THE B DELAY DETERMINATION FOR THE '955 PATENT WAS INCORRECT

39. The date of commencement of the national stage of the international application (i.e., the '305 application) that issued as the '955 Patent was November 26, 2007. This is the date that is 30 months after the international filing date of the '955 Patent (the "30-Month Date").²

40. The first RCE filed in the '305 Application was filed on April 30, 2012, which is after November 26, 2010, the date that is 3-years after the 30-Month Date.

41. Under 35 U.S.C. § 154(b)(1)(B), the "B Delay" period for accruing patent term adjustment credit for the '955 Patent began on November 27, 2010 and ended on the date the Director issued the '955 Patent, which occurred on November 6, 2012. The period of "B Delay" for the '955 Patent is thus 711 days.

42. The Director erred in her determination of the "B Delay" period applicable to the '955 Patent by disregarding the period following the date the first RCE was filed in the '305 Application (i.e., April 30, 2012) until the date the '305 Application issued as the '955 Patent (i.e., November 6, 2012). The Director thus improperly tolled the accrual of B Delay applicable to the '955 Patent during the period from April 30, 2012 to November 6, 2012.

² For purposes of calculating B Delay, the 30-Month Date is treated as the filing date of the '305 Application. See 35 U.S.C. § 154(b)(1)(B) (defining 3-year period to start on ". . . the actual filing date of the application under section 111 (a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application . . ."); 37 C.F.R. § 1.703(b).

43. Because April 30, 2012 is more than three years after the 30-Month Date, the Director's conduct in this respect was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the law, and in excess of statutory jurisdiction, authority, and limitation.

44. A portion of the period of "B Delay" applicable to the '955 Patent overlaps with a portion of the period of the "A Delay" applicable to the '955 Patent; namely, during the period starting on November 27, 2010 and ending on September 26, 2011. As explained in ¶ 23, there is a period of "A Delay" applicable to the '955 Patent that started on December 25, 2009 and ended on September 26, 2011.

45. The number of overlapping days in the "A Delay" and "B Delay" periods applicable to the '955 Patent totals 304 days.

46. The total period of "A Delay" and "B Delay" applicable to the '955 Patent, minus the number of overlapping days of those two periods, is 1048 days, which is the number that results when 641 days is added to 711 days (1352 days), and 304 days are subtracted from that total. Thus, under 35 U.S.C. § 154(b), the correct period of non-overlapping days of "A Delay" and "B Delay" applicable to the '955 Patent is 1048 days.

47. As the Director has not identified any periods pursuant to 35 U.S.C. § 154(b)(2)(C) during which the Applicant failed to engage in reasonable efforts to conclude prosecution of the application, and because there has been no disclaimer of term of the '955 Patent subject to 35 U.S.C. § 154(b)(2)(B), no reduction of the period of patent term adjustment under 35 U.S.C. § 154(b)(2) is applicable to the '955 Patent.

48. Consequently, the '955 Patent is entitled to a patent term adjustment under 35 U.S.C. § 154(b) of no less than 1048 days.

CLAIMS FOR RELIEF

COUNT 1: CORRECTION OF PTA DETERMINATION – 35 U.S.C. § 154(b)(4)(A)

49. Plaintiff incorporates by reference the allegations set forth in ¶¶ 1-48 above, as if fully set forth herein.

50. Because this Complaint is filed within 180 days of the grant of the '955 Patent, Plaintiff is entitled to challenge the Director's incorrect PTA determination in this Court and to request correction thereof pursuant to 35 U.S.C. § 154(b)(4)(A).

51. The Director's determination of PTA for the '955 Patent was based on an interpretation of 35 U.S.C. § 154(b)(1)(B) that is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the law, and in excess of statutory jurisdiction, authority, and limitation, which caused her to thereby improperly exclude otherwise compensable USPTO delay that by law continued to accrue on and after April 30, 2012 up to and including November 6, 2012.

52. Plaintiff is legally entitled to PTA for the '955 Patent in an amount not less than 1048 days, which is greater than the 857 days of PTA that the Director determined to be applicable to the '955 Patent.

COUNT 2: CORRECTION OF PTA DETERMINATION – 5 U.S.C. §§ 701-706

53. Plaintiff incorporates by reference the allegations set forth in ¶¶ 1-52 above, as if fully set forth herein.

54. Because Plaintiff is compelled to comply with the 180-day period for contesting the Director's PTA determination under 35 U.S.C. § 154(b)(4)(A) in order to fully preserve its rights, and because the Director has failed to respond to Plaintiff's timely filed request for

reconsideration, Plaintiff has effectively exhausted all of its available administrative remedies under 35 U.S.C. § 154.

55. Alternatively, or in conjunction with the conclusion set forth in ¶ 54, pursuit of any further administrative remedies with the Director is futile. While the Director has not yet issued a decision on Plaintiff's timely filed request for reconsideration, Plaintiff expects that, in light of the position the Director has taken in concurrent litigation presenting the same legal question, the Director will dismiss Plaintiff's petition.³

56. Should the Director contest Plaintiff's standing under the Administrative Procedure Act, Plaintiff respectfully requests that the Court take judicial notice of the Director's position that the filing of an RCE in an application more than three years after the actual filing date of that application in the United States tolls the accrual of B Delay under 35 U.S.C. § 154(b)(1)(B), and to find on such basis that Plaintiff has effectively exhausted its available administrative remedies and/or that pursuit of any further administrative remedies from the Director is futile, or, in the alternative, to stay this proceeding until the Director issues a decision regarding Plaintiff's request for reconsideration.

57. Because the Plaintiff has effectively exhausted all of its available administrative remedies and/or pursuit of any further administrative remedies from the Director is futile, Plaintiff is entitled to challenge the Director's incorrect PTA determination in this Court and to request correction thereof pursuant to 5 U.S.C. §§ 701-706.

58. The Director's determination of PTA for the '955 Patent was based on an interpretation of 35 U.S.C. § 154(b)(1)(B) that is arbitrary, capricious, an abuse of discretion, and

³ See, e.g., *Exelixis, Inc. v. Kappos*, Civil Action No. 1:12-cv-00096, 2012 WL 5398876, at *7-*8 (E.D. Va. Nov. 1, 2012) (arguing that the filing of a request for an examination tolls the accrual of B Delay); *Exelixis, Inc. v. Kappos*, Civil Action No. 1:12-cv-00574, 2013 WL 314754, at *6-*7 (E.D. Va. Jan. 28, 2013) (same).

otherwise not in accordance with the law, and in excess of statutory jurisdiction, authority, and limitation, and which improperly excluded otherwise compensable USPTO delay that by law continued to accrue on and after April 30, 2012, up to and including November 6, 2012.

59. Plaintiff is legally entitled to PTA for the '955 Patent in an amount not less than 1048 days, which is each greater than the 857 days of PTA that the Director found applicable to the '955 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays that this Court:

a. Issue an Order to the Defendant to alter the PTA for the '955 Patent from 857 days to a number of days not less than 1048 days, and to require Defendant to issue a Certificate of Correction for the '955 Patent reflecting a PTA of no less than 1048 days;

b. Enjoin Defendant from assessing additional periods of applicant delay against the total PTA for the '955 Patent, particularly if Defendant seeks to do so pursuant to any regulations or other public notices promulgated or announced after the issue date of the '955 Patent; and

c. Grant such other and further relief as the nature of the case may admit or require, including additional PTA for the '955 Patent if further errors are identified and found in the Director's PTA determination, and any such other relief as may be deemed just and equitable by this Court.

d. To the extent that the Federal Circuit holds, in connection with the pending appeals in *Exelixis v. Rea*, Nos. 2013-1175, 2013-1198 (Fed. Cir. filed February 6, 2013), that § 154(b) entitles a patent holder to a period of PTA greater than that which the Defendant has granted Plaintiff for the '955 Patent, Plaintiff respectfully requests that the Court issue an Order to require Defendant to grant Plaintiff the PTA to which it is entitled under such basis.

Dated: May 3, 2013

Respectfully submitted,

SIDLEY AUSTIN LLP

By:  _____

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