

FILED

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

2013 FEB 12 A 11: 05

CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

CELLERANT THERAPEUTICS, INC.,
1561 Industrial Road
San Carlos, California 94070

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. 1:13cv201
CMH/IDD

COMPLAINT

Plaintiff Cellerant Therapeutics, Inc. (“Plaintiff” or “Cellerant”), 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”)¹, respectfully alleges the following:

¹ The Honorable David J. Kappos served as Under Secretary of Commerce for Intellectual Property and Director of the USPTO at the time of the relevant agency action. The Honorable Mr. Kappos resigned from that position effective January 31, 2013. The Honorable Ms. Rea is named as a defendant in this action because, as of February 1, 2013, she was appointed as the Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the USPTO.

NATURE OF THE ACTION

1. This is an action by Cellerant, the assignee and owner of all right, title, and interest in and to United States Patent No. 8,252,587 (“the ‘587 Patent”), seeking review of the determination by Defendant of the patent term adjustment under 35 U.S.C. § 154(b) (“PTA”) for the ‘587 Patent. Specifically, this is an action by Cellerant 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 ‘587 Patent from 0 days to a number of days no less than 979 days.

2. 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

3. Cellerant is a corporation organized and existing under the laws of the State of Delaware with a place of business at 1561 Industrial Road, San Carlos, California 94070.

4. 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

5. This Court has jurisdiction to hear this action and to grant Cellerant’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.

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

7. This Complaint is being filed within 180 days of the issuance of the '587 Patent, and is therefore timely filed in accordance with 35 U.S.C. § 154(b)(4)(A).

THE '587 PATENT

8. Timothy C. Fong, Adrianus Geertrudis Wilhelmus Domen, and Julie Lynne Christensen are named as the joint inventors of the inventions claimed in the '587 Patent. Each of the named inventors has assigned his or her interest in the '587 Patent to Cellerant, as evidenced by the assignment recorded in the USPTO at Reel/Frame No. 017205/0273. Accordingly, Cellerant is the owner by assignment of all right, title, and interest in and to the '587 Patent. Cellerant is therefore the real party in interest in this action, and has standing to request the relief prayed for herein.

9. The '587 Patent was filed on October 25, 2005 as United States Patent Application No. 11/259,592 ("the '592 Application"), entitled "Methods of Expanding Myeloid Cell Populations and Uses Thereof," and issued on August 28, 2012. A copy of the '587 Patent is attached hereto as Exhibit A.

PATENT TERM GUARANTEE AND DEFENDANT'S PTA DETERMINATION

10. Title 35, Section 154 of the United States Code requires the Director to determine the PTA for each patent issued by the USPTO, and to do so in accordance with Section 154(b). Specifically, 35 U.S.C. § 154(b) states 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."

11. In making this PTA determination, the Director must account for periods of delay, including periods of USPTO delay under 35 U.S.C. § 154(b)(1)(A) ("A Delay"), periods of

USPTO delay under 35 U.S.C. § 154(b)(1)(B) (“B Delay”), any overlap among periods of A Delay and B Delay under 35 U.S.C. § 154(b)(2)(A), any disclaimer of patent term by the applicant under 35 U.S.C. § 154(b)(2)(B), and any periods of applicant delay under 35 U.S.C. § 154(b)(2)(C).

12. The Director made a determination that the PTA for the ‘587 Patent is 0 days, which is reflected on its cover page.

13. The bases underlying the Director’s PTA determination for the ‘587 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 ‘587 Patent is attached hereto as Exhibit B.

14. The Director identified four periods of A Delay that occurred during the pendency of the ‘592 Application, which include the following periods of time: (a) from December 26, 2006 to January 8, 2007 (14 days); (b) from June 9, 2007 to September 11, 2007 (95 days); (c) from May 12, 2008 to May 16, 2008 (5 days); and (d) from September 11, 2010 to August 17, 2011 (341 days). Accordingly, the Director determined that the total amount of USPTO A Delay for the ‘587 Patent is 455 days.

15. The Director identified one period of B Delay that occurred during the pendency of the ‘592 Application, which is a period of time from October 26, 2008 to November 5, 2008 (11 days). Accordingly, the Director determined that the total amount of USPTO B Delay for the ‘587 Patent is 11 days.

16. The Director identified no periods of overlapping A Delay and B Delay. Accordingly, the Director determined that the total period of overlapping USPTO delay for the

'587 Patent is 0 days. Accordingly, the Director determined that the total USPTO delay for the '587 Patent is 466 days (455 days + 11 days – 0 days).

17. The '587 Patent is not subject to a terminal disclaimer or to any other disclaimer that would shorten its term to a period ending earlier than 20 years from its actual filing date in the United States plus any applicable adjustment or extension of its term under the provisions of 35 U.S.C. §§ 154-156 and 173.

18. The Director identified nine periods of applicant delay that occurred during the pendency of the '592 Application, which include the following periods of time: (a) from February 19, 2006 to February 21, 2006 (3 days); (b) from December 12, 2007 to January 11, 2008 (31 days); (c) from January 12, 2008 to April 22, 2008 (102 days); (d) from August 17, 2008 to November 6, 2008 (82 days); (e) from April 29, 2009 to July 28, 2009 (91 days); (f) from July 29, 2009 to October 9, 2009 (73 days); (g) from February 11, 2010 to May 10, 2010 (89 days); (h) from November 18, 2011 to December 15, 2011 (28 days); and (g) from December 16, 2011 to January 23, 2012 (39 days). Accordingly, the Director determined that the total period of applicant delay for the '587 Patent is 538 days.

19. The Director determined that the PTA for the '587 Patent is 0 days because the total number of days of applicant delay determined by the Director (538 days) exceeded total the number of days of USPTO delay determined by the Director (466 days).

LEGAL STANDARD FOR DETERMINING B DELAY

20. 35 U.S.C. § 154(b)(1)(B) states 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.”

21. 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), when the first filing of an RCE in an application occurs more than three years after the actual filing date of the application in the United States.²

22. On information and belief, the Director has 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 in the United States.

23. 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 ‘587 PATENT

24. The actual filing date of the ‘592 Application in the United States is October 25, 2005. October 25, 2008 is the date that is three years from the actual filing date of the ‘592 Application in the United States.

² This Court reached a contrary result in *Exelixis, Inc. v. Kappos*, Civil Action No. 12-cv-00574-LMB-TRJ, 2013 WL 314754, at *5-*9 (E.D. Va. Jan. 28, 2013). This later judgment has been appealed to the United States Court of Appeals for the Federal Circuit, pursuant to the Notice of Appeal filed by Exelixis, Inc. on February 6, 2013.

25. No RCE was filed in the '592 Application on or before the date that is three years from the actual filing date of the '592 Application in the United States, i.e., on or before October 25, 2008.

26. An RCE was filed in the '592 Application on November 6, 2008, which is more than three years after the actual filing date of the '592 Application in the United States. This RCE was the first RCE filed in the '592 Application. A second RCE was filed in the '592 Application on May 10, 2010. No other RCEs were filed in the '592 Application.

27. Under 35 U.S.C. § 154(b)(1)(B), the '592 Application began to accrue B Delay starting on October 26, 2008.

28. In making the PTA determination for the '587 Patent, the Director tolled the accrual of B Delay from November 6, 2008 to August 28, 2012. Thus, in making the PTA determination for the '587 Patent, the Director tolled the accrual of B Delay from the date when the first RCE was filed in the '592 Application to the date when the '592 Application issued as the '587 Patent.

29. Because November 6, 2008 is more than three years after the actual filing date of the '592 Application in the United States, 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.

30. Under 35 U.S.C. § 154(b)(1)(B), the correct period of B Delay for the '587 Patent runs from October 26, 2008 to (and including) August 28, 2012, the issue date of the '587 Patent. This period of time includes 1403 days.

31. The period of B Delay from October 26, 2008 to August 28, 2012 overlaps with one of the periods of A Delay identified above in Paragraph 14, i.e., the period of A Delay from September 11, 2010 to August 17, 2011, which includes 341 days.

32. Accordingly, for the '587 Patent, the sum of the total USPTO A Delay and the total USPTO B Delay, minus their overlap, is 1517 days (455 days + 1403 days – 341 days). Thus, under 35 U.S.C. § 154(b), the correct total USPTO delay for the '587 Patent is 1517 days.

33. The difference between the correct total USPTO delay (1517 days) and the total applicant delay determined by the Director (538 days) for the '587 Patent is 979 days. Thus, under 35 U.S.C. § 154(b), the correct PTA for the '587 Patent is a number of days no less than 979 days.

CLAIMS FOR RELIEF

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

34. Cellerant incorporates by reference the allegations set forth in Paragraphs 1-33 above, as if fully set forth herein.

35. The Director's determination of PTA for the '587 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, and which improperly excluded otherwise compensable USPTO delay that by law continued to accrue on and after November 6, 2008 up to and including August 28, 2012.

36. Cellerant is legally entitled to PTA for the '587 Patent in an amount not less than 979 days, which is greater than the 0 days of PTA that the Director determined.

37. Because this Complaint is filed within 180 days of the issuance of the '587 Patent, Cellerant 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).

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

34. Cellerant incorporates by reference the allegations set forth in Paragraphs 1-37 above, as if fully set forth herein.

35. The Director's determination of PTA for the '587 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, and which improperly excluded otherwise compensable USPTO delay that by law continued to accrue on and after November 6, 2008 up to and including August 28, 2012.

36. Cellerant is legally entitled to PTA for the '587 Patent in an amount not less than 979 days, which is greater than the 0 days of PTA that the Director determined.

37. Because the Director's determination of PTA for the '587 Patent is a final agency action, Cellerant 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.

PRAYER FOR RELIEF

WHEREFORE, Cellerant respectfully prays that this Court:

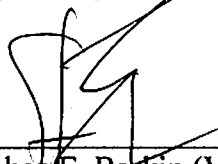
a. Issue an Order changing the PTA for the '587 Patent from 0 days to a number of days no less than 979 days, and require Defendant to issue a Certificate of Correction for the '587 Patent reflecting a PTA of no less than 979 days;

b. Enjoin Defendant from assessing additional periods of applicant delay against the total PTA for the '587 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 '587 Patent; and

c. Grant such other and further relief as the nature of the case may admit or require, including additional PTA for the '587 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.

Dated: February 12, 2013

Respectfully submitted,



Stephen E. Baskin (VA Bar No. 47567)
Eric M. Gold (VA Bar No. 78515)
KILPATRICK TOWNSEND & STOCKTON LLP
607 14th Street, N.W., Suite 900
Washington, DC 20005-2018
Tel. 202-508-5800
Fax 202-508-5858

Attorneys for Plaintiff Cellerant Therapeutics, Inc.

Of Counsel:

Robert S. Dailey
KILPATRICK TOWNSEND & STOCKTON LLP
607 14th Street, N.W., Suite 900
Washington, DC 20005-2018
Tel. 202-508-5800
Fax 202-508-5858