

FILED

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

2012 NOV 30 P 4:40
CLERK OF DISTRICT COURT
ALEXANDRIA, VIRGINIA

SUPERMUS PHARMACEUTICALS, INC.)
1550 East Gude Drive,)
Rockville, MD 20850)

Plaintiff,)

v.)

Civil Action No. 1:12cv1385

CMH/JFA

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)
P.O. Box 1450, Arlington, VA 22313)
Madison Building East, Room 10B20)
600 Dulany Street, Alexandria, VA 22314)

Defendant.)

COMPLAINT

Plaintiff Supernus Pharmaceuticals, Inc. (“Supernus”), for its Complaint against Defendant, the Honorable David J. Kappos (“Defendant”), respectfully states as follows:

1. This is an action by Supernus, the assignee and owner of United States Patent No. 8,193,211 (“the ‘211 patent”), seeking review of inaccurate and erroneous patent term adjustment calculations made by the United States Patent & Trademark Office (“PTO”). Specifically, this is an action by Supernus under 35 U.S.C. § 154(b)(4)(A) seeking a judgment that the patent term adjustment for the ‘211 patent be changed from 1174 days to 1691 days.

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

THE PARTIES

3. Plaintiff Supernus Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 1550 East Gude Drive, Rockville, MD 20850.

4. Defendant Honorable David J. Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and is sued here in his official capacity.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action and is authorized to issue the requested relief sought by Supernus 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.

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

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

BACKGROUND

8. Plaintiff Supernus is the assignee of all right, title and interest in the '211 patent, as evidenced by records on deposit with the PTO and the face of the '211 patent.

9. The '211 patent issued on June 5, 2012, based on U.S. patent application number 11/239,638, filed on September 30, 2005. The application that issued as the '211 patent claims priority to U.S. provisional patent application number 60/614,622, filed on September 30, 2004. A true and correct copy of the '211 patent is attached hereto as Exhibit A.

10. The PTO originally awarded the '211 patent 1079 days of patent term adjustment under 35 U.S.C. § 154(b), as is reflected on the face of the patent. Patentee contested the PTO's calculation and sought correction of the patent term adjustment to 1174 days.

11. The PTO agreed and issued a Certificate of Correction on September 4, 2012 (attached hereto as Exhibit B), awarding the '211 patent 1174 days of patent term adjustment under 35 U.S.C. § 154(b). The '211 patent is not subject to a terminal disclaimer.

12. When the PTO issued the '211 patent on June 5, 2012 and issued the Certificate of Correction on September 4, 2012, it erroneously calculated the patent term adjustment for the '211 patent. Had the PTO calculated the patent term adjustment properly, the '211 patent would be entitled to no less than 1691 days of patent term adjustment.

13. 35 U.S.C. § 154(b)(1)(B), entitled "Guarantee of no more than 3-year application pendency," provides for an extension of one day of patent term for each day following three years from the actual filing date of a patent application, until the patent issues. This provision applies "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)."

14. The PTO's interpretation of 35 U.S.C. § 154(b)(1)(B) is set forth in 37 C.F.R. § 1.703(b), which provides in relevant part for an award of patent term adjustment under 35 U.S.C. § 154(b)(1)(B) equal to "the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed ... and ending on the date a patent was issued, but not including ... (i) The number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. § 132(b) was filed and ending on the date the patent was issued." That is, the PTO does not award patent term adjustment under 35 U.S.C. § 154(b)(1)(B) for any time after a Request for Continued Examination ("RCE") is filed.

15. During prosecution of the '211 patent, the applicant filed an RCE on January 6, 2011, more than three years after the September 30, 2005 actual filing date of the application that issued as the '211 patent. When calculating the patent term adjustment for the '211 patent, the PTO relied on its interpretation of 35 U.S.C. § 154(b)(1)(B) and did not award any patent term adjustment under this provision of the statute for the days following the filing of the RCE on January 6, 2011 until the patent issued.

16. At least some of the errors in the PTO's patent term adjustment calculation for the '211 patent are detailed in a recent order from this Court in an action titled *Exelixis, Inc. v. Kappos*, Case No. 1:12cv96, 2012 U.S. Dist. LEXIS 157762 (Nov. 1, 2012), where the Court granted summary judgment in favor of Exelixis and held that the PTO's patent term adjustment calculation methodology with respect to 35 U.S.C. § 154(b)(1)(B) and RCEs filed more than three years after the application's actual filing date was erroneous as a matter of law and inconsistent with the plain text of 35 U.S.C. § 154(b). Specifically, the Court in *Exelixis* concluded that "RCE's have no impact on [patent term adjustment] if filed after the three year deadline has passed" and that in such cases "[t]he proper measure of B delay ... is from ... three years after the application filing date ... to ... the date the patent issued." 2012 U.S. Dist. LEXIS 157762 at *26. The *Exelixis v. Kappos* opinion is attached as Exhibit C.

17. The patent term adjustment methodology set forth by this Court in the *Exelixis v. Kappos* action is believed to govern the patent term adjustment for Plaintiff's '211 patent.

18. Under 35 U.S.C. § 154(b)(4)(A), "[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have a 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."

COUNT 1: U.S. PATENT NO. 8,193,211

19. Plaintiff incorporates by reference the allegations in paragraphs 1-18 above, as if fully set forth herein.

20. The PTO determined that the patent term adjustment for the '211 patent is 1174 days, calculated as follows:

Total Non-Overlapping PTO delay under §154(b)(1)(A) and (B): 1497 days

Total offsetting Applicant delay under §154(b)(2)(C): (323 days)

21. This determination is erroneous because it improperly limits the patent term adjustment under 35 U.S.C. § 154(b)(1)(B) awarded to the '211 patent to the period beginning three years from the September 30, 2005 filing date and ending one day prior to the January 6, 2011 RCE filing date. The PTO's determination fails to include within the patent term adjustment, as required by 35 U.S.C. § 154(b)(1)(B), the 517-day period of time from applicant's January 6, 2011 RCE filing date to the June 5, 2012 issue date, as shown in the chart attached as Exhibit D.

22. In *Exelixis*, this Court set aside the PTO's interpretation of 35 U.S.C. § 154(b)(1)(B) as "not in accordance with law," concluding that "RCE's have no impact on [patent term adjustment] if filed after the three year deadline has passed," and that in such cases "[t]he proper measure of B delay . . . is from . . . three years after the application filing date . . . to . . . the date the patent issued." *Exelixis*, 2012 U.S. Dist. LEXIS 157762 at *26. The RCE filed January 6, 2011 during prosecution of the '211 patent was filed after the three year deadline had passed; thus, it should have had no impact on patent term adjustment, and patent term adjustment awarded under 35 U.S.C. § 154(b)(1)(B) should have run from three years from the September 30, 2005 actual filing date of the application to the June 5, 2012 issue date.

23. Because it failed to include the 517-day period from the date of filing the RCE to the patent issue date within the patent term adjustment awarded under 35 U.S.C. § 154(b)(1)(B), the PTO's patent term adjustment for the '211 patent is "not in accordance with law" and should be set aside as exceeding its statutory authority pursuant to 5 U.S.C. § 706(2)(A) and (C). *Exelixis*, 2012 U.S. Dist. LEXIS 157762 at *26.

24. According to this Court's interpretation of 35 U.S.C. § 154(b), the 517-day period from the date of filing the RCE to the patent issue date should "have no impact" on the patent term adjustment for the '211 patent. *Exelixis*, 2012 U.S. Dist. LEXIS 157762 at *26. The correct patent term adjustment for the '211 patent is thus 1691 days, which includes both the 1174-day adjustment calculated by the PTO and the 517-day period that it improperly failed to include, as shown in the Exhibit D.

WHEREFORE, Plaintiff respectfully prays that this Court:

A. Issue an Order changing the period of patent term adjustment for the '211 patent term from 1174 days to no less than 1691 days and requiring Defendant to alter the term of the '211 patent to reflect the at least 1691 days of actual patent term adjustment due the '211 patent.

B. Grant such other and further relief as the nature of the case may admit or require, including additional patent term for the '211 patent if further errors are identified and found in the PTO's patent term adjustment calculation methodology, and any such other and further relief as may be deemed just and equitable by this Court.

Dated: November 30, 2012

Respectfully submitted,



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