

FILED

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

2012 DEC 21 PM 2:48

U.S. DISTRICT COURT
ALEXANDRIA DIVISION

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

Plaintiff,)

v.)

Civil Action No. 1:12cv1485

LMB/TRJ

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. 8,206,740 ("the '740 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 '740 patent be changed from 626 days to 703 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. The '740 patent issued on June 26, 2012, based on U.S. patent application number 12/155,676, filed on June 6, 2008. The application that issued as the '740 patent is a continuation of U.S. patent application number 10/819,620 (now United States Patent No. 7,749,532), filed on April 7, 2004, which claims priority to U.S. provisional patent application numbers 60/460,963 and 60/547,964, filed on April 7, 2003 and February 26, 2004, respectively. A true and correct copy of the '740 patent is attached hereto as Exhibit A.

9. The face of the '740 patent reflects a patent term adjustment under 35 U.S.C. § 154(b) of 626 days. The '740 patent is subject to a terminal disclaimer over U.S. Patent No. 7,749,532.

10. Plaintiff Supernus is the assignee and owner of the '740 patent, as evidenced by records on deposit with the PTO and the face of the '740 patent.

11. When the PTO issued the '740 patent on June 26, 2012, it erroneously calculated the patent term adjustment for the '740 patent as 626 days. Had the PTO calculated the patent term adjustment properly, the '740 patent would be entitled to no less than 703 days of patent term adjustment.

12. 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)."

13. 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.

14. During prosecution of the '740 patent, the applicant filed an RCE on April 11, 2012, more than three years after the June 6, 2008 actual filing date of the application that issued as the '740 patent. When calculating the patent term adjustment for the '740 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 April 11, 2012 until the patent issued.

15. At least some of the errors in the PTO's patent term adjustment calculation for the '740 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 B.

16. 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 '740 patent.

17. 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. 8,206,740

18. Plaintiff incorporates by reference the allegations in paragraphs 1-17 above, as if fully set forth herein.

19. The PTO determined that the patent term adjustment for the '740 patent is 626 days, calculated as follows:

Total PTO delay under §154(b)(1)(A): 469 days

Total PTO delay under §154(b)(1)(B): 309 days

Total Applicant delay under §154(b)(2)(C): (152 days)

20. This determination is erroneous because it improperly limits the patent term adjustment under 35 U.S.C. § 154(b)(1)(B) awarded to the '740 patent to the period beginning three years from the June 6, 2008 filing date and ending one day prior to the April 11, 2012 RCE filing date (*i.e.*, 309 days). The PTO's determination fails to include within the patent term adjustment, as required by 35 U.S.C. § 154(b)(1)(B), the 77-day period of time from applicant's April 11, 2012 RCE filing date to the June 26, 2012 issue date, as shown in the chart attached as Exhibit C.

21. 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 April 11, 2012 during prosecution of the '740 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 June 6, 2008 actual filing date of the application to the June 26, 2012 issue date.

22. Because it failed to include the 77-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 '740 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.

23. According to this Court's interpretation of 35 U.S.C. § 154(b), the 77-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 '740 patent. *Exelixis*, 2012 U.S. Dist. LEXIS 157762 at *26. The correct patent term adjustment for the '740 patent is thus 703 days, which includes both the 626-day adjustment calculated by the PTO and the 77-day period that it improperly failed to include, as shown in the Exhibit C.

WHEREFORE, Plaintiff respectfully prays that this Court:

A. Issue an Order changing the period of patent term adjustment for the '740 patent term from 626 days to no less than 703 days and requiring Defendant to alter the term of the '740 patent to reflect the at least 703 days of actual patent term adjustment due the '740 patent.

B. Grant such other and further relief as the nature of the case may admit or require, including additional patent term for the '740 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: December 21, 2012

Respectfully submitted,



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