

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

Ironwood Pharmaceuticals, Inc.
320 Bent Street,
Cambridge, MA 02141

Plaintiff,

v.

HON. JON W. DUDAS
Under Secretary of Commerce for
Intellectual Property and Director of the
United States Patent and Trademark Office.
Office of General Counsel, United States
Patent and Trademark Office, P.O. Box
15667, Arlington, VA 22215
Madison Building East, Rm 10B20, 600
Dulany Street, Alexandria, VA 22314

Defendant.

Case: 1:08-cv-01932
Assigned To : Collyer, Rosemary M.
Assign. Date : 11/7/2008
Description: Admin. Agency Review

Plaintiff Ironwood Pharmaceuticals, Inc. ("Ironwood"), for its complaint against the Honorable Jon W. Dudas, states as follows:

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 7,371,727 ("the '727 patent") seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '727 patent be changed from 411 days to 702 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 Ironwood is a corporation organized under the laws of Delaware, having a principal place of business at 320 Bent Street, Cambridge, Massachusetts 02141.

4. Defendant Jon W. Dudas is the Under Secretary of Commerce for Intellectual Property and Director of the PTO, acting in his official capacity. The Director is the head of the PTO and is responsible for superintending or performing all duties required by law with respect to the granting and issuing of patents, and is designated by statute as the official responsible for determining the period of patent term adjustments under 35 U.S.C. § 154.

JURISDICTION AND VENUE

5. 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.

6. Venue is proper in this district by virtue of 35 U.S.C. § 154(b)(4)(A).

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

BACKGROUND

8. Mark G. Currie, Shalina Mahajan-Miklos, Angelika Fretzen; Li Jing Sun, Thea Norman, and G. Todd Milne are inventors of the patent application number 10/899,806 (“the ‘806 application”) which issued as the ‘727 patent, entitled Methods and Compositions for the Treatment of Gastrointestinal Disorders, on May 13, 2008. The ‘727 patent concerns a method for producing a particular peptide by chemical synthesis which is useful in treating constipation and irritable bowel syndrome. The ‘727 patent is attached hereto as Exhibit A.

9. Plaintiff Ironworks is the assignee of the ‘727 patent, as evidenced by records in the PTO, and is the real party in interest in this case.

10. Section 154 of 35 U.S.C. requires that the Director of the PTO grant a patent term adjustment in accordance with the provisions of section 154(b). Specifically, 35 U.S.C. § 154(b)(3)(D) 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 calculating the patent term adjustment, the Director has to take into account PTO delays under 35 U.S.C. § 154(b)(1), 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).

12. 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 remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action.”

CLAIM FOR RELIEF

13. The allegations of paragraphs 1-12 are incorporated in this claim for relief as if fully set forth.

14. The patent term adjustment for the ‘727 patent, as determined by the defendant under 35 U.S.C. § 154(b), and listed on the face of the ‘727 patent, is 411 days. (*See* Ex. A at 1). The determination of the 411-day patent term adjustment is in error in that, pursuant to 35 U.S.C. § 154(b)(1)(B), the PTO failed to allow an adjustment for the time exceeding three years after the actual filing date of the ‘806 application to the date when the ‘727 patent issued. The correct patent term adjustment for the ‘727 patent is at least 702 days.

15. The ‘806 application was filed on July 27, 2004, and issued as the ‘727 patent on May 13, 2008.

16. Under 35 U.S.C. § 154(b)(1)(A), the plaintiff is entitled to an adjustment of the term of the ‘727 patent of a period of 472 days, which is the number of days attributable to PTO examination delay (“A Delay”).

17. Under 35 U.S.C. § 154(b)(1)(B), the plaintiff is entitled to an additional adjustment of the term of the '727 patent of a period of 291 days, which is the number of days the issue date of the '727 patent exceeds three years from the filing date of the application ("B Delay").

18. Section 35 U.S.C. § 154(b)(2)(A) states that "to the extent . . . periods of delay attributable to grounds specified in paragraph [154(b)(1)] overlap, the period of any adjustment granted under this subsections shall not exceed the actual number of days the issuance of the patent was delayed." For the '727 patent, none of the A Delay overlaps with the B Delay period. Therefore, there is no period of overlap to be excluded for the patent term adjustment.

19. Thus, the total period of PTO delay is 763 days, which is the sum of the period of A Delay (472 days) and the period of B Delay (291 days).

20. Under 35 U.S.C. § 154(b)(2)(C), the total period of PTO delay is reduced by the period of applicant delay, which is 61 days as determined by the PTO.

21. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is 702 days, which is the difference between the total period of PTO delay (763 days) and the period of applicant delay (61).

22. The defendant's imposition of only 411 days of patent term adjustment for the '727 patent is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

23. This Court, in Wyeth v. Dudas, Civ. Action No. 1:07-cv-01492-JR, recently issued an opinion explaining the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b). (*See Wyeth v. Dudas*, Case No. 1:07-cv-01492-JR, Mem. Op., Sept. 20, 2008, dkt. no. 27, attached hereto as Exhibit B).

WHEREFORE, Plaintiff respectfully prays that this Court:

- A. Issue an Order changing the period of patent term adjustment for the '727 patent term from 411 days to 702 days and requiring defendant to alter the term of the '727 patent to reflect the 702-day patent term adjustment.
- B. 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,

FISH & RICHARDSON P.C.



Brian T. Racilla (Bar. No. 473395)
Andrew R. Kopsidas (Bar No. 476237)

FISH & RICHARDSON P.C.
1425 K Street, N.W.

11th Floor
Washington, D.C. 20005
Telephone: (202) 783-5070
Facsimile: (202) 783-2331

Attorneys for Plaintiff
Ironwood Pharmaceuticals, Inc.

Dated: November 7, 2008