

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Biogen Idec MA Inc.
14 Cambridge Center
Cambridge, MA 02142

Plaintiff,

v.

HON. JOHN J. DOLL
Acting Under Secretary of Commerce for
Intellectual Property and
Acting 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.

FILED

APR 23 2009

**Clerk, U.S. District and
Bankruptcy Courts**

Case: 1:09-cv-00754

Assigned To : Collyer, Rosemary M.

Assign. Date : 4/23/2009

Description: General Civil

COMPLAINT

Plaintiff, Biogen Idec MA Inc., for its complaint against the Honorable John J. Doll, states as follows:

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 7,442,370 ("the '370 patent") seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '370 patent be changed from 310 days to at least 774 days.

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

JURISDICTION AND VENUE

3. 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.

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

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

THE PARTIES

6. Plaintiff Biogen Idec MA Inc. is a corporation organized under the laws of Massachusetts, having a principal place of business at 14 Cambridge Center, Cambridge, Massachusetts 02142.

7. Defendant John J. Doll is the Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office (“PTO”), acting in his official capacity. The Director is the head of the agency, charged by statute with providing management supervision for the PTO and for the issuance of patents. The Director is the official responsible for determining the period of patent term adjustment under 35 U.S.C. § 154.

BACKGROUND

8. Dinah Wen-Yee Sah, R. Blake Pepinsky, Paula Ann Boriack-Sjodin, Stephan S. Miller, Anthony Rossomando and Laura Silvian are the inventors of U.S. patent application number 10/356,264 (“the ’264 application”) entitled “Polymer Conjugates of Mutated Neublabin,” which was issued as the ’370 patent on October 28, 2008. The claims of the ’370 patent are directed to polypeptides and related compositions. The ’370 patent is attached as Exhibit A.

9. Plaintiff Biogen Idec MA Inc. is the assignee of the '370 patent, as evidenced by the assignment documents recorded in the PTO.

10. Section 154 of title 35 of the United States Code 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 determining patent term adjustment, the Director is required to extend the term of a patent for a period equal to the total number of days attributable to delay by the PTO under 35 U.S.C. § 154(b)(1)(A), (B), and (C), as limited by any overlapping periods of delay by the PTO as specified 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 delay attributable to the applicant under 35 U.S.C. § 154(b)(2)(C).

12. The Director made a determination of patent term adjustment pursuant to 35 U.S.C. § 154(b)(3) and issued the '370 patent reflecting that determination.

13. 35 U.S.C. § 154(b)(4)(A) provides that “[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 grant of the patent. Chapter 7 of title 5 shall apply to such an action.”

14. On December 19, 2008, in accordance with 37 CFR 1.705(d), Biogen Idec MA Inc. filed an application for Patent Term Adjustment with the PTO to correct errors in the

Director's determination. Having received no response to its application, Biogen Idec MA Inc. is hereby bringing this Complaint.

CLAIM FOR RELIEF

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

16. The patent term adjustment for the '370 patent, as determined by the Director under 35 U.S.C. §154(b) and indicated on the face of the '370 patent, is 310 days. (*See* Ex. A at 1.) The determination of this 310 day patent term adjustment is in error because the PTO failed to properly account for delays that occurred pursuant to both 35 U.S.C. § 154(b)(1)(A) and 35 U.S.C. § 154(b)(1)(B), to the extent such delays did not occur on the same days. The correct patent term adjustment for the '370 patent is at least 774 days.

17. The '264 application was filed on January 31, 2003, and issued as the '370 patent on October 28, 2008.

18. Under 35 U.S.C. § 154(b)(1)(A), the number of days attributable to PTO examination delay ("A Delay") is 674 days.

19. Under 35 U.S.C. § 154(b)(1)(B), the number of days attributable to application pendency in excess of three years ("B Delay") is 706 days.

20. Under 35 U.S.C. § 154(b)(2)(C), the number of days of applicant delay is 595 days.

21. 35 U.S.C. § 154(b)(2)(A) provides that "to the extent that periods of delay attributable to grounds specified in paragraph [b](1) overlap, the period of any adjustment . . . shall not exceed the actual number of days the issuance of the patent was delayed." The overlap

between the “A Delay” period and the “B Delay” period in the prosecution of the ’370 patent is 11 days.

22. The ’370 patent is not subject to a disclaimer of term. Thus the period of patent term adjustment is not limited under 35 U.S.C. § 154(b)(2)(B).

23. Accordingly, the correct patent term adjustment under 35 U.S.C. §154(b)(1) and (2) is the sum of the “A Delay” and “B Delay” ($674 + 706 = 1,380$ days), reduced by the number of days of overlap of “A Delay” and “B Delay” (11 days) and applicant delay (595 days), for a net adjustment of 774 days.

24. The Director erred in the determination of patent term adjustment by treating the entire period of “A Delay,” and not only the period of “A Delay” that occurred on the same calendar days as “B Delay,” as the period of overlap between the “A Delay” and the “B Delay.” Thus, the Director erroneously arrived at a net patent term adjustment of 310 days.

25. In *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008), this Court explained the proper construction of the provisions of 35 U.S.C. § 154(b) for determining patent term adjustment. In accordance with *Wyeth*, the patent term adjustment for the ’370 patent is properly determined to be 774 days, as set forth above. A copy of the *Wyeth* ruling is attached as Exhibit B.

26. The Director's determination that the ’370 patent is entitled to only 310 days of patent term adjustment is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority, or limitation.

PRAYER FOR RELIEF

Wherefore, Plaintiff demands judgment against Defendant and respectfully requests that this Court enter Orders:

A. Changing the period of patent term adjustment for the '370 patent term from 310 days to 774 days and requiring the Director to extend the term of the '370 patent to reflect the 774 day patent term adjustment.

B. Granting such other and future relief as the nature of the case may admit or require and as may be just and equitable.

Dated: April 23, 2009

Respectfully Submitted,



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