

**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
10B20, Madison Building East,
600 Dulany Street, Alexandria VA 22314

Defendant.

Civil Action No. _____

COMPLAINT

Biogen Idec MA Inc. (“Biogen”), for its complaint against the Honorable John J. Doll, states as follows:

NATURE OF THE ACTION

1. This is an action by Biogen, the applicant and owner of United States Patent No. 7,446,173 (“the ‘173 patent”) for review of the determination by the U.S. Patent and Trademark Office (“USPTO”), pursuant to 35 U.S.C. § 154(b)(3)(B), of the patent term adjustment of the ‘173 patent. Plaintiff seeks a judgment, pursuant to 35 U.S.C. § 154(b)(4)(A) that the patent term adjustment for the ‘173 patent be changed from 502 days to 807 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. 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.

4. John H. Doll is the Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the USPTO, currently serving as Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the USPTO, acting in his official capacity (the “Acting Director”). The Acting Director is the head of the agency, charged by statute with providing management supervision for the USPTO and for the issuance of patents. The Acting Director is the official responsible for determining the period of patent term adjustment under 35 U.S.C. § 154(b)(3)(B).

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).

FACTS

8. Blake Pepinsky, Laura Runkel, Margot Brickelmaier, Adrian Whitty, and Paula Hochman are the inventors of U.S. Patent Application Serial No. 10/802,540 (“the ‘540 application”). The ‘540 application was filed on March 16, 2004 and issued as the ‘173 patent on November 4, 2008. The ‘173 patent is attached as Exhibit A.

9. Biogen is the assignee of all right, title and interest in the ‘173 patent, as evidenced by records on deposit with the USPTO, and is the real party in interest in this case.

10. On January 8, 2008, the USPTO mailed a Notice of Allowance and Fees Due for the ‘540 application. A Determination of Patent Term Adjustment was included in the Notice of Allowance and Fees Due. The USPTO indicated that the patent term adjustment to date for the ‘540 application was 502 days.

11. The ‘173 patent issued on November 4, 2008, indicating a patent term adjustment of 502 days.

12. On November 19, 2008, Biogen filed a Request for Reconsideration of the Patent Term Adjustment as determined on January 8, 2008. The USPTO has not acted on Biogen’s Request for Reconsideration.

13. Section 154 of title 35, U.S.C., requires that the Director of the USPTO 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.”

14. In calculating the patent term adjustment, the Director must take into account USPTO delays under 35 U.S.C. § 154(b)(1), any overlapping periods in the USPTO delays 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 applicant delays under 35 U.S.C. § 154(b)(2)(C).

15. 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

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

17. The currently challenged patent term adjustment for the ‘173 patent, as determined by the USPTO under 35 U.S.C. § 154(b), and listed on the face of the ‘173 patent, is 502 days. (*See* Ex. A at p.1). This determination of the 502-day patent term adjustment is in error in that it fails to include an adjustment, as required by 35 U.S.C. § 154(b)(1)(B), for the time from three years after the filing date of the ‘540 application to the date the patent issued, not including applicant’s delays (*i.e.*, not including Applicant’s delay in responding to an action under 35 U.S.C. § 132 and the period of time between filing an Amendment under 37 C.F.R. § 1.312 and the grant of the ‘173 patent). Biogen is entitled to an adjustment of the term of the ‘173 patent of at least 807 days.

18. Under 35 U.S.C. § 154(b)(1)(A), the number of days attributable to USPTO examination delay (“A delay”) is 590 days. The A delay period consists of the period commencing May 16, 2005 (14 months after the filing date of the ‘540 application) until December 27, 2006 (the mailing date of the first action under 35 U.S.C. § 132).

19. Under 35 U.S.C. § 154(b)(1)(B), the number of days attributable to USPTO’s “failure . . . to issue a patent within 3 years after the actual filing date of the [‘540] application,” but not including “any time consumed by continued examination of the application requested by the applicant under section 132 (b)” or “any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C)” (“B delay”) is 305 days. The B delay period consists of the period commencing March 16, 2007 (three years after the actual filing date of the ‘540 application) and November 4, 2008 (the date that the ‘173 patent was issued) excluding the period between January 15, 2008 (the filing date of an Amendment under 37 C.F.R. § 1.312) and November 4, 2008 (the date that the ‘173 patent was issued).

20. The net patent term adjustment is determined as the sum of the “A delay” and “B delay,” subject to the limitations specified at 35 U.S.C. § 154(b)(2)(A)-(C).

21. 35 U.S.C. § 154(b)(2)(A) states that “to the extent that periods of delay attributable to grounds specified in paragraph [154(b)(1)] overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” For the ‘173 patent, none of the A delay period overlaps with the B delay period. Therefore, there is no period of overlap to be excluded

from the determination of patent term adjustment for the '173 patent under 35 U.S.C. § 154(b)(2)(A).

22. The '173 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. The number of days attributable to applicant delay in the prosecution of the '540 application, as determined by the USPTO under 35 U.S.C. § 154(b)(2)(C), is 88 days.

24. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is the sum of "A delay" and "B delay" ($590 + 305 = 895$ days), reduced by applicant delay of 88 days, for a net adjustment of 807 days.

25. The USPTO's determination that the period of the patent term adjustment for the '173 patent is only 502 days and his failure to include in the patent term adjustment the 599 days required by 35 U.S.C. § 154(b)(1)(B) are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority, or limitation.

26. Moreover, the USPTO's determination that the period of the patent term adjustment for the '173 patent is 502 days is in conflict with this Court's judgment in Wyeth v. Dudas, 580 F. Supp. 2d 138 (D.D.C. 2008), which explains the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b).

WHEREFORE, Plaintiff respectfully prays that this Court:

A. Issue an Order changing the period of patent term adjustment for the '173 patent from 502 days to 807 days, and requiring the Defendant to alter the term of the '173 patent to reflect the 807-day patent term adjustment; and

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,

Dated: April 30, 2009


Timothy C. Bickham (DC Bar No. 456414)

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