

FILED

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION

2012 OCT 19 P 3:39

CLERK OF DISTRICT COURT  
ALEXANDRIA, VIRGINIA

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

Plaintiff,

v.

HON. DAVID J. KAPPOS  
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 223144

Civil Action No. 1:12cv 1171 LO/TCB

Defendant.

**COMPLAINT**

Plaintiff, Biogen Idec MA Inc. ("Biogen Idec"), for its complaint against the Honorable David J. Kappos, states as follows:

**NATURE OF THE ACTION**

1. This is an action by the assignee of United States Patent No. 8,163,875 ("the '875 patent") seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '875 patent be changed from 1,324 days to 1,449 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 is a corporation organized under the laws of Massachusetts, having a principal place of business 14 Cambridge Center, Cambridge, Massachusetts 02142.

7. Defendant, the Honorable David J. Kappos (“Director”), is the Under Secretary of Commerce for Intellectual Property and 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. U.S. patent application number 10/553,710 was filed on February 27, 2007, and issued as the ‘875 patent on April 24, 2012. The claims of the ‘875 patent are directed to polypeptide compositions and methods of use to treat a subject in need thereof. The ‘875 patent is attached as **Exhibit A**.

9. Plaintiff Biogen Idec is the assignee of the ‘875 patent.

10. Under 35 U.S.C. § 154(b), the Director of the PTO must grant a patent term adjustment in accordance with the provisions of section 154(b), which states, in pertinent part,

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.” 35 U.S.C. § 154(b)(3)(D).

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 the following: (i) any overlapping periods of PTO delay as specified by 35 U.S.C. § 154(b)(2)(A); (ii) any disclaimer of patent term by the applicant under 35 U.S.C. § 154(b)(2)(B); and (iii) any delay attributable to the applicant under 35 U.S.C. § 154(b)(2)(C).

12. The Director determined that the ‘875 patent is entitled to 1,324 days of patent term adjustment pursuant to 35 U.S.C. § 154(b)(3) and issued the ‘875 patent reflecting that determination.

13. On June 21, 2012, in accordance with 37 C.F.R. § 1.705(d), Plaintiff filed an Application for Patent Term Adjustment (“Application for PTA”) with the PTO to request correction of the Director’s patent term adjustment determination. The Application for PTA is attached as **Exhibit B**.

14. On July 2, 2012, the Director mailed a Decision on Request for Reconsideration of Patent Term Adjustment (“Decision I”) dismissing Plaintiff’s request for reconsideration presented in the Application for PTA. Decision I is attached as **Exhibit C**.

15. On August 30, 2012, Plaintiff filed a Petition Under 37 C.F.R. § 1.181(a)(3) to Invoke the Supervisory Authority of the Director (“181 Petition”) with the PTO to request

supervisory review of the Director's patent term adjustment determination. The 181 Petition is attached as **Exhibit D**.

16. On September 24, 2012, the Director mailed a Decision on Petition and Decision for Request for Reconsideration of Patent Term Adjustment ("Decision II") denying Plaintiff's request for reconsideration presented in the 181 Petition. Decision II is attached as **Exhibit E**.

17. Section 154(b)(4)(A) of Title 35 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 the grant of the patent. Chapter 7 of title 5 shall apply to such an action." Section 702 of Title 5 further provides, in pertinent part, that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." Plaintiff Biogen Idec hereby brings the present action for judicial review of the PTO's calculation of patent term adjustment for the '875 patent.

#### **CLAIM FOR RELIEF**

18. The allegations of paragraphs 1-17 are incorporated into this claim for relief as if fully set forth herein.

19. The patent term adjustment for the '875 patent, as determined by the Director under 35 U.S.C. § 154(b), and as set forth in the '875 patent, is 1,324 days. The determination of this 1,324 day patent term adjustment is in error because the PTO, and the Director acting in his official capacity, improperly calculated the length of the statutory delay period defined by 35 U.S.C. § 154(b)(1)(B).

20. The correct patent term adjustment for the '875 patent is 1,449 days.

21. Under 35 U.S.C. § 154(b)(1)(A), the correct number of days attributable to PTO examination delay (“A Delay”) is 1,059 days. The Director correctly calculated the A Delay.

22. Under 35 U.S.C. § 154(b)(1)(B), the correct number of days attributable to application pendency in excess of three years (“B Delay”) is 1,275 days. The Director incorrectly calculated a length of B Delay of 1,150 days. Section 154(b)(1)(B)(i) of Title 35 excludes from the calculation of B Delay “any time consumed by continued examination of the application.” The Director erred in the calculation of patent term adjustment by subtracting from B Delay a period of time that was not “consumed by continued examination of the application.” The period beginning on October 19, 2008 (the day after the date that is three years after October 18, 2005, the date that the national stage commenced), and ending April 24, 2012 (the date the patent was issued), is 1,284 days in length. The PTO mailed a Notice of Allowance on December 22, 2011, thereby closing examination of the application on that date. No continued examination took place during the period from December 22, 2011 (the mailing date of the Notice of Allowance), until April 24, 2012 (the date the patent was issued). The PTO improperly excluded from B Delay the number of days corresponding to the period beginning on December 13, 2011 (the date on which a Request for Continued Examination was filed) and ending on April 24, 2012 (the date the patent was issued). This entire period should not have been excluded from B Delay because it does not correspond exactly to continued examination. The period that should have been excluded from B Delay is the 9 day period beginning on December 13, 2011 (the date on which a Request for Continued Examination was filed) and ending on December 21, 2011 (the day before the mailing date of the Notice of Allowance). Accordingly, 1,275 days of B Delay (1,284 days – 9 days) should have been awarded instead of the 1,150 days accorded by the Director.

23. Under 35 U.S.C. § 154(b)(2)(C), the correct number of days of applicant delay is 0 days. The Director correctly calculated the amount of applicant delay.

24. Section 154(b)(2)(A) of Title 35 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 ‘875 patent is 885 days. The Director correctly calculated the overlap between the A Delay period and the B Delay period.

25. The ‘875 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).

26. 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 (1,059 days + 1,275 days = 2,334 days) minus the number of days of overlap of A Delay and B Delay (885 days) and applicant delay (0 days), for a net correct patent term adjustment of 1,449 days for the ‘875 patent.

27. Accordingly, the Director’s determination that the ‘875 patent is entitled to only 1,324 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**

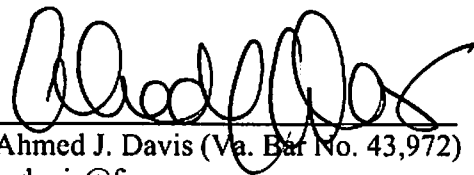
Wherefore, Plaintiff demands judgment against Defendant and respectfully requests that this Court enter Orders:

A. Changing the period of patent term adjustment for the ‘875 patent term from 1,324 days to 1,449 days, and requiring the Director to extend the term of the ‘875 patent to reflect the correct 1,449 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: October 19, 2012

Respectfully Submitted,



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