

FILED

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

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CLERK US DISTRICT COURT  
ALEXANDRIA, VIRGINIA

Eisai R&D Management Co., Ltd.  
6-10, Koishikawa 4-chome, Bunkyo-ku  
Tokyo 112-8088 Japan

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

Defendant.

Civil Action No. 1:12cv 1138  
AJT/JFA

COMPLAINT

Plaintiff, Eisai R&D Management Co., Ltd. ("Eisai"), 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. 8,158,620 ("the '620 patent") seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '620 patent be changed from 394 days to 443 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 Eisai is a corporation organized under the laws of Japan, having a principal place of business at 6-10, Koishikawa 4-chome, Bunkyo-ku, Tokyo 112-8088 Japan.

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 12/355,154 was filed on January 16, 2009, and issued as the ‘620 patent on April 17, 2012. The claims of the ‘620 patent are directed to inhibitors of amyloid-beta protein production and methods of use of the inhibitors to treat a subject in need thereof. The ‘620 patent is attached as **Exhibit A**.

9. Plaintiff Eisai is the assignee of the ‘620 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 ‘620 patent is entitled to 394 days of patent term adjustment pursuant to 35 U.S.C. § 154(b)(3) and issued the ‘620 patent reflecting that determination.

13. On June 14, 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 June 19, 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 13, 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 October 2, 2012, the Director mailed a Decision on Request for Reconsideration of Patent Term Adjustment ("Decision II") dismissing 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 Eisai hereby brings the present action for judicial review of the PTO's calculation of patent term adjustment for the '620 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 '620 patent, as determined by the Director under 35 U.S.C. § 154(b), and as set forth in the '620 patent, is 394 days. The determination of this 394 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 '620 patent is 443 days.

21. Under 35 U.S.C. § 154(b)(1)(A), the correct number of days attributable to PTO examination delay (“A Delay”) is 399 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 49 days. The Director incorrectly calculated a length of B Delay of 0 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 January 17, 2012 (the day after the date that is three years after January 16, 2009, the date on which the application was filed), and ending April 17, 2012 (the date the patent was issued), is 92 days in length. The PTO mailed a Notice of Allowance on February 17, 2012, thereby closing examination of the application on that date. No continued examination took place during the period from February 17, 2012 (the mailing date of the Notice of Allowance), until April 17, 2012 (the date the patent was issued). The PTO improperly excluded from B Delay the number of days corresponding to the period beginning on January 5, 2012 (the date on which a Request for Continued Examination was filed) and ending on April 17, 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 43 day period beginning on January 5, 2012 (the date on which a Request for Continued Examination was filed) and ending on February 16, 2012 (the day before the mailing date of the Notice of Allowance). Accordingly, 49 days of B Delay (92 days – 43 days) should have been awarded instead of the 0 days accorded by the Director.

23. Under 35 U.S.C. § 154(b)(2)(C), the correct number of days of applicant delay is 5 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 ‘620 patent is 0 days. The Director correctly calculated the overlap between the A Delay period and the B Delay period.

25. The ‘620 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 (399 days + 49 days = 448 days) minus the number of days of overlap of A Delay and B Delay (0 days) and applicant delay (5 days), for a net correct patent term adjustment of 443 days for the ‘620 patent.

27. Accordingly, the Director’s determination that the ‘620 patent is entitled to only 394 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**

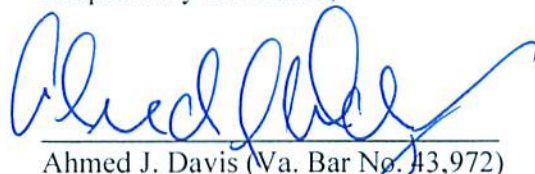
Wherefore, Plaintiff demands judgment against Defendant and respectfully requests that this Court enter Orders:

A. Changing the period of patent term adjustment for the ‘620 patent term from 394 days to 443 days, and requiring the Director to extend the term of the ‘620 patent to reflect the correct 443 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 11, 2012

Respectfully Submitted,



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pending)  
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