

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CEPHALON, INC.
41 Moores Road
Frazer, PA 19355

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 22314

Defendant.

Civil Action No. _____

Plaintiff Cephalon, Inc. ("Cephalon"), 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. 7,576,206 ("the '206 patent") seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '206 patent be changed from 428 days to at least 838 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, Cephalon is a corporation, organized, existing and doing business under and by virtue of the laws of Delaware, with its office and principal place of business located at 41 Moores Road, Frazer, PA 19355.

4. Defendant David J. Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent & Trademark Office (“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 adjustment under 35 U.S.C. § 154.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of 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. Plaintiff Cephalon is the assignee of all right, title and interest in the ‘206 patent, as evidenced by records on deposit with the PTO, and is the real party in interest in this case.

9. Raffaella Bernardini, Alberto Bernareggi, Paolo G. Cassara, Sankar Chatterjee, Germano D'Arasmo, Sergio De Munari, Edmondo Ferretti, Mohamed Iqbal, Ernesto Menta, Patricia A. Messina McLaughlin, and Ambrogio Olivia are the inventors of the patent application serial number 10/918,664 ("the '664 application").

10. The '664 application was filed on August 12, 2004 and issued as the '206 patent on August 18, 2009, indicating a patent term adjustment of 428 days. The '206 patent is attached hereto as Exhibit A.

11. 35 U.S.C. § 154(b) requires that patent terms be adjusted to compensate for failures of the PTO to take certain actions on patent applications within designated time limits. 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."

12. In calculating the patent term adjustment, the Director must 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).

13. 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

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

15. The currently challenged patent term adjustment of the '206 patent, as determined by the Defendant under 35 U.S.C. § 154(b), and listed on the face of the '206 patent, is 428 days. (*See* Exhibit A at 1). This determination of the 428-day patent term adjustment is in error. Pursuant to 35 U.S.C. § 154(b)(1)(B), the PTO failed to issue the '206 patent within 3 years of the actual filing date in the United States. Therefore, the correct patent term adjustment for the '206 patent is at least 838 days.

16. Under 35 U.S.C. § 154(b)(1)(A), Plaintiff is entitled to an adjustment of the term of the '206 patent of 537 days, the number of days attributable to PTO examination delay ("A Delay"). The A Delay consists of a period of 537 days pursuant to 35 U.S.C. § 154(b)(1)(A)(i) due to the PTO's failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the date on which an application was filed under 35 U.S.C. § 111(a); this period consists of the length of time from October 12, 2005 (14 months after the filing date of the '664 application) to April 2, 2007 (the mailing date of the First Office Action).

17. Under 35 U.S.C. § 154(b)(1)(B), Plaintiff is entitled to an additional adjustment of the term of the '206 patent of 410 days due to the PTO's failure to issue a patent within 3 years after the actual filing date of the application in the United States ("B Delay"). The B Delay

consists of the length of time from August 12, 2007 (3 years after the filing date of the '664 application) to August 18, 2009 (the issue date of the '206 patent) minus the period from September 26, 2008 (the date on which a Request for Continued Examination was filed) to August 18, 2009 (the issue date of the '206 patent). See 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1).

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 subsection shall not exceed the actual number of days the issuance of the patent was delayed.” For the '206 patent, 0 days of the A Delay overlaps with the B Delay period.

19. Thus, the total period of PTO delay is 947 days, which is the sum of the period of A Delay (537 days) and the period of B Delay (410 days) minus the period of overlap (0 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 109 days as determined by the Defendant.

21. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is 838 days, which is the difference between the total period of PTO delay (947 days) and the period of applicant delay (109 days).

22. Moreover, Defendant's determination that the period of the patent term adjustment for the '206 patent is only 428 days is in conflict with this Court's decision in *Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir. Jan. 7, 2010), *aff'g Wyeth v. Dudas*, Civ. Action No. 2008

WL 4445642 (D.D.C. Sept. 30, 2008), which explains the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b).

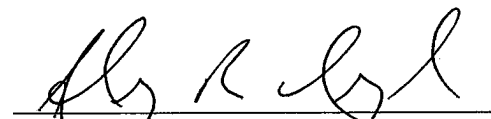
WHEREFORE, Plaintiff respectfully prays that this Court:

A. Issue an Order changing the period of patent term adjustment for the '206 patent from 428 days to 838 days, and requiring Defendant to alter the term of the '206 patent to reflect the 838 day patent term adjustment; and

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

Dated: February 12, 2010

Respectfully Submitted,



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