IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Chugai Seiyaku Kabushiki Kaisha (also known as Chugai Pharmaceutical Co., Ltd.)
No. 5-1, 5-Chome, Ukima, Kita-ku
Tokyo, 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 22314

Defendant.

COMPLAINT

Plaintiff, Chugai Seiyaku Kabushiki Kaisha (also known as Chugai Pharmaceutical Co., Ltd.) ("Chugai"), 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. 7,517,965 ("the '965 patent") seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '965 patent be changed from 356 days to at least 716 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 Chugai is a corporation organized under the laws of Japan, having a principal place of business at No. 5-1, 5-Chome, Ukima, Kita-ku, Tokyo, Japan.

7. Defendant David J. Kappos 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. Takaki Koga, Tsukasa Suzuki, and Hiroyuki Saito are the inventors of U.S. patent application number 10/522,086 ("the '086 application") entitled "Non-Neutralizing Anti-aPC Antibodies," which was issued as the '965 patent on April 14, 2009. The '965 patent is attached as Exhibit A.

9. Plaintiff Chugai is the assignee of the '965 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)(l)(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 '965 patent reflecting that determination.

13. On June 11, 2009, in accordance with 37 C.F.R. § 1.705(d), Chugai filed an application for Patent Term Adjustment with the PTO to correct errors in the Director's determination. On September 29, 2009, in response to the application, the PTO adjusted its calculation providing an additional 88 days of adjustment. The PTO's "Letter Regarding Patent Term Adjustment and Notice of Intent to Issue Certificate of Correction" reflecting the new adjustment is attached as Exhibit B.

14. Title 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."

CLAIM FOR RELIEF

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

16. The patent term adjustment for the '965 patent, as determined by the Director under 35 U.S.C. § 154(b) and indicated on the face of the '965 patent (Ex. A) and Certificate of Correction (Ex. B), is 356 days. The determination of this 356-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)(l)(A) and 35 U.S.C. § 154(b)(l)(B), to the extent such delays did not occur on the same days. The correct patent term adjustment for the '965 patent is at least 716 days.

17. The '086 application completed the requirements of 35 U.S.C. § 371 on October 5, 2005, and issued as the '965 patent on April 14, 2009.

18. Under 35 U.S.C. § 154(b)(l)(A), the number of days attributable to PTO examination delay ("A Delay") is 360 days. Chugai does not contest this determination by the PTO.

19. Under 35 U.S.C. § 154(b)(l)(B), the number of days attributable to application pendency in excess of three years ("B Delay") is 448 days. Chugai does not contest this determination by the PTO.

20. Under 35 U.S.C. § 154(b)(2)(C), the number of days of applicant delay is 92 days. Chugai does not contest this determination by the PTO.

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](l) overlap, the period of any adjustment . . . shall not exceed the actual number of days the issuance of the patent was delayed." There was no overlap between the "A Delay" period and the "B Delay" period in the prosecution of the '965 patent.

22. The '965 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)(l) and (2) is the sum of the "A Delay" and "B Delay" (360 + 448 = 808 days), reduced by the number of days of overlap of "A Delay" and "B Delay" (0 days) and applicant delay (92 days), for a net adjustment of 716 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." Specifically, the Director erroneously discounted the 360-day "A Delay" period as overlapping with the period of "B Delay." Thus, the Director erroneously arrived at a net patent term adjustment of 356 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 '965 patent is properly determined to be 716 days, as set forth above.

26. The Director's determination that the '965 patent is entitled to only 356 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 '965 patent term from 356 days to 716 days and requiring the Director to extend the term of the '965 patent to reflect the 716-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 9, 2009

Respectfully Submitted,

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