IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Japan Tobacco Inc.
2-1, Toranomon 2-chome, Minato-ku
Tokyo 105-8422, 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.

COMPLAINT

Plaintiff, Japan Tobacco Inc. ("Japan Tobacco"), 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. 7,635,704 ("the '704 patent") seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '704 patent be changed from 237 days to 520 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 Japan Tobacco is a corporation organized under the laws of Japan, having a principal place of business at 2-1, Toranomon 2-chome, Minato-ku, Tokyo 105-8422, Japan.

7. Defendant 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. Motohide Satoh, Takahisa Motomura, Takashi Matsuda, Kentaro Kondo, Koji Ando, Koji Matsuda, Shuji Miyake, and Hideto Uehara are the inventors of U.S. patent application number 11/133,471 ("the '471 application") entitled "Stable Crystal of 4-Oxoquinoline Compound," which was issued as the '704 patent on December 22, 2009. The claims of the '704 patent are directed to crystals, pharmaceutical compositions, and methods of treatment. The '704 patent is attached as Exhibit A.

9. Plaintiff Japan Tobacco is the assignee of the '704 patent. Assignment documents evidencing this fact are recorded in the PTO and attached as Exhibit B.

10. Under Section 154 of Title 35 of the United States Code, 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)(l)(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 made a determination of patent term adjustment pursuant to 35 U.S.C. § 154(b)(3) and issued the '704 patent reflecting that determination. At patent issuance, the Director properly did not reduce patent term adjustment under 37 C.F.R. 1.703(b)(4) for prosecution events related to the filing of two Notices of Appeal.

13. On February 22, 2010, in accordance with 37 C.F.R. 1.705(d), Japan Tobacco filed an Application for Patent Term Adjustment ("Application") with the PTO to correct an error in the Director's patent term adjustment determination. In addition to the request for correction, the Application noted that the Director correctly did not apply 37 C.F.R. 1.703(b)(4)

to cause a reduction in patent term adjustment for the '704 patent. The Application is attached as Exhibit C.

14. On April 20, 2010, in response to the Application, the PTO issued a Decision on Request for Reconsideration of Patent Term Adjustment ("PTO Decision"). The PTO Decision corrected the error in the patent term adjustment calculation identified by Japan Tobacco in the Application. However, the PTO Decision applied for the first time the patent term adjustment reduction under 37 C.F.R. 1.703(b)(4) that is the subject of this complaint. As noted above, the contested patent term adjustment reduction was not applied by the Director in the calculation of patent term adjustment at patent issuance. The PTO Decision is attached as Exhibit D.

15. On May 19, 2010, Japan Tobacco filed a Response to the PTO Decision ("Response"). The Response is attached as Exhibit E.

16. 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." Having received no reply from the PTO to its Response, Plaintiff Japan Tobacco hereby brings the present action for judicial review of the PTO's calculation of patent term adjustment for the '704 patent.

CLAIM FOR RELIEF

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

18. The patent term adjustment for the '704 patent, as determined by the Director under 35 U.S.C. § 154(b), and as set forth in the PTO Decision, is 237 days. (Ex. D at 1.) The determination of this 237 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)(l)(B), by subtracting from the statutory delay period: (i) the number of days from the filing of a first Notice of Appeal until the mailing of a non-final Office Action; and (ii) the number of days from the filing of a second Notice of Appeal until the mailing of a Notice of Allowance.

19. The correct patent term adjustment for the '704 patent is 520 days.

20. The '471 application was filed on May 20, 2005, and issued as the '704 patent on December 22, 2009.

21. Under 35 U.S.C. § 154(b)(1)(A), the correct number of days attributable to PTO examination delay ("A Delay") is 44 days. The Director, as evidenced by the PTO Decision, correctly calculated the A Delay. (Ex. D at 3.)

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 581 days. The Director, as evidenced by the PTO Decision, incorrectly calculated a length of B Delay of 298 days. (Ex. D at 3.)

23. Under 35 U.S.C. § 154(b)(2)(C), the correct number of days of applicant delay is 93 days. The Director, as evidenced by the PTO Decision, correctly calculated the amount of applicant delay. (Ex. D at 3.)

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 correct overlap between the A Delay period and the B Delay period in the prosecution of the '704 patent is 12 days. The Director, as evidenced by the PTO Decision, correctly calculated the overlap between the A Delay period and the B Delay period. (Ex. D at 3.)

25. The '704 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. Accordingly, 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 (44 days + 581 days = 625 days) minus the number of days of overlap of A Delay and B Delay (12 days) and applicant delay (93 days), for a net correct patent term adjustment of 520 days for the '704 patent.

27. The Director, as evidenced by the PTO Decision, erred in the calculation of patent term adjustment by subtracting from the B Delay period a total of 283 days corresponding to the sum of the following two periods: (i) the period from the filing of a first Notice of Appeal on May 4, 2007 to the mailing of a non-final Office Action on September 20, 2007 (140 days); and (ii) the period from the filing of a second Notice of Appeal on December 17, 2008 to the mailing of a Notice of Allowance on May 8, 2009 (143 days). Thus, the Director, as evidenced by the PTO Decision, erroneously calculated a B Delay period of 298 days and a corresponding net patent term adjustment of 237 days for the '704 patent.

28. Section 154(b)(1)(B) of Title 35 excludes from the calculation of B Delay "time consumed by appellate review by the Board of Patent Appeals and Interferences." The two periods the Director subtracted from the calculation of B Delay, as evidenced by the PTO Decision, are not "time consumed by appellate review by the Patent Appeals and Interferences" as contemplated by 35 U.S.C. § 154(b)(1)(B). The PTO Decision, citing 37 C.F.R. 1.703(b)(4)

as authority, subtracted from the calculation of B Delay two time periods during which jurisdiction never passed to the Board of Patent Appeals and Interferences ("the Board"). Thus, the Director's calculation of B Delay, as evidenced by the PTO Decision, clearly deviates from 35 U.S.C. § 154(b)(1)(B) because it excludes from the calculation of B Delay time periods during which appellate review by the Board did not occur.

29. By its unambiguous plain meaning, "appellate review by the Board of Patent Appeals and Interferences" can only occur when the Board reviews an appeal. In the case of the '704 patent, the Examiner withdrew both final rejections without filing an Examiner's answer, and without jurisdiction over the proceeding ever having passed to the Board. "Appellate review," as that term is used in 35 U.S.C. § 154(b)(1)(B), if it ever occurs at all after the filing of a Notice of Appeal, cannot occur until jurisdiction passes to the Board. In the case of the '704 patent, there was clearly no appellate review by the Board after the filing of either of the Notices of Appeal that served as the basis for the Director's erroneous calculation of B Delay. *See* 37 C.F.R. 1.703(b)(4). Section 154(b)(1)(B) of Title 35 does not permit reduction of B Delay where there has been no appellate review by the Board.

30. The B Delay period for the '704 patent began on May 21, 2008, the day after the date that is three years after the date on which the '471 application was filed. The first Notice of Appeal period occurred in its entirety before the '471 application had been pending for three years, with the period beginning on May 4, 2007 (filing of the first Notice of Appeal) and ending on September 20, 2007 (mailing of a non-final Office Action). The Director incorrectly applied 37 C.F.R. 1.703(b)(4) to the prosecution events of the '704 patent, subtracting the first Notice of Appeal period from B Delay even though it occurred before the '471 application had been pending for three years. According to the plain language of 37 C.F.R. 1.703(b)(4), a Notice of

Appeal period is excluded from a period of delay that begins only after an application has been pending for three years. For this additional reason, the Director erred in the calculation of B Delay for the '704 patent.

31. In accordance with the correct application of 35 U.S.C. § 154(b)(1)(B), the Director should have calculated the length of B Delay to be 581 days, and should have accorded the '704 patent a net patent term adjustment of 520 days.

32. Accordingly, the Director's determination that the '704 patent is entitled to only 237 days of patent term adjustment, as evidenced by the PTO Decision, 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 '704 patent term from 237 days to 520 days, and requiring the Director to extend the term of the '704 patent by 283 days to reflect the correct 520 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: June 17, 2010

Respectfully Submitted,



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