

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

NAPO PHARMACEUTICALS, INC.
250 E. Grand Avenue, Suite 90, South
San Francisco, CA 94080-4824

Plaintiff,

v.

HON. JON W. DUDAS
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 Napo Pharmaceuticals, Inc. ("Napo"), for its Complaint against the Honorable Jon W. Dudas, states as follows:

NATURE OF THE ACTION

1. This is an action by patentee of United States Patent No. 7,341,744 (the "744 patent") seeking review of the denial of the correct patent term adjustment for the patent by the defendant Director of the United States Patent and Trademark Office ("PTO"). Plaintiff is seeking a judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '744 patent be changed from 453 days to 1007 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 Napo is a corporation organized under the laws of Delaware, having a principal place of business at 250 E. Grand Avenue, Suite 90, South San Francisco, CA 94080-4824.

4. Defendant Jon W. Dudas is the Under Secretary of Commerce for Intellectual Property and Director of the 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 adjustments under 35 U.S.C. § 154.

JURISDICTION AND VENUE

5. 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.

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).

FACTS APPLICABLE TO ALL COUNTS

8. US patent application serial number 09/712,033 (the “‘033 application”) was filed on November 14, 2000 and issued as the ‘744 patent on March 11, 2008. The ‘744 patent is attached hereto as Exhibit A.

9. The inventors of the ‘744 patent are Edward James Rozhon, Atul S. Khandwala, Akram Sabouni, Gul P. Balwani, Jody Wai-Han Chan, and David S. Sesin.

10. Plaintiff Napo is the assignee of the ‘744 patent, as evidenced by records recorded in the PTO, and is the real party in interest in this case.

11. Section 154 of 35 U.S.C. 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.”

12. In calculating the patent term adjustment, the Director has to take into account PTO delays under 35 U.S.C. § 154(b)(1)(A) and (B), 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.

15. The patent term adjustment for the ‘744 patent, as determined by the defendant under 35 U.S.C. § 154(b), and listed on the face of the ‘744 patent, is 453 days. (See Ex. A at p.1).

16. The determination of the 453 day patent term adjustment is in error in that pursuant to 35 U.S.C. § 154(b)(2)(A), the PTO has miscalculated the overlap of PTO delays under 35 U.S.C. § 154(b)(1). The correct patent term adjustment for the ‘744 patent is 1007 days based on the PTO’s calculation of 1621 days of combined PTO delay under 35 U.S.C. § 154(b)(1)(A) and (B), minus 19 days of overlap of PTO delays under 35 U.S.C. § 154(b)(2)(A), and minus 595 days of applicant delay under 35 U.S.C. § 154(b)(2)(C).

17. Under 35 U.S.C. § 154(b)(1)(A), the PTO has determined that the following periods of time are attributable to PTO examination delay:

- a. A period of 554 days under 35 U.S.C. § 154(b)(1)(A)(i) (“14 Month Delay”) due to failure by the PTO to mail an action under 35 U.S.C. § 132 not later than 14 months from the actual filing date of the application (*i.e.*, the period from January 14, 2002 until July 22, 2003).
- b. A period of 19 days under 35 U.S.C. § 154(b)(1)(A)(ii) (“4 Month Delay”) due to failure by the PTO to mail an action under 35 U.S.C. § 132 not later than 4 months from the filing of a reply (*i.e.*, the period from March 2, 2005 to March 21, 2005).

18. Under 35 U.S.C. § 154(b)(1)(B), the PTO has determined that the following period of time is attributable to PTO examination delay:

- a. A period of 1048 days, which is the number of days beginning three years from the filing date of the ‘033 application until the filing of a request for continued examination (*i.e.*, from November 14, 2003 until the first RCE was filed on September 27, 2006, also referred to as “Three Year Delay”).

19. The total PTO delay under 35 U.S.C. § 154(b)(1)(A) and (B) is the sum of 14 Month Delay, 4 Month Delay, and Three Year Delay (*i.e.*, 554 days + 19 days + 1048 days) for a total of 1621 days.

20. 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 subsections shall not exceed the actual number of days the issuance of the patent was delayed.”

21. Of the delays attributable to the PTO for the '744 patent, only the 19 days of 4 Month Delay from March 2, 2005 to March 21, 2005 overlap with the Three Year Delay (November 14, 2003 until September 27, 2006). This 19-day overlapping period is not included in the adjustment sought by the plaintiff.

22. Thus, upon removal of overlapping days under 35 U.S.C. § 154(b)(2)(A), the remaining period of PTO delay is 1602 days (*i.e.*, 554 days of 14 Month Delay + 19 days of 4 Month Delay + 1048 days of Three Year Delay - 19 days of overlap).

23. Under 35 U.S.C. § 154(b)(2)(C), the remaining period of PTO delay is reduced by the period of applicant delay, which is 595 days as determined by the PTO.

24. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is 1007 days which is the difference between the period of non-overlapping PTO delay (1602 days) and the period of applicant delay (595 days).

25. The PTO arrived at the incorrect 453 day patent term adjustment by miscalculating the overlap under 35 U.S.C. § 154(b)(2)(A) for PTO delays under 35 U.S.C. § 154(b)(1). The PTO incorrectly determined that both the 14 Month Delay and the 4 Month Delay overlap with the Three Year Delay to arrive at a period of 1048 days of non-overlapping PTO delay (*i.e.*, 554 days of 14 Month Delay + 19 days of 4 Month Delay + 1048 days of Three Year Delay - 573 days of overlap = 1048 days). Upon further subtraction of the period of applicant delay (*i.e.*, 1048 days - 595 days), the PTO erroneously calculated a patent term adjustment of 453 days.

26. The PTO erred in its interpretation and determination under 35 U.S.C. § 154(b)(2)(A) that the 14 Month Delay (*i.e.*, January 14, 2002 until July 22, 2003) overlaps with

the Three Year Delay (*i.e.*, November 14, 2003 until September 27, 2006), and its corresponding excessive reduction by 554 days of the patent term adjustment for the '744 patent.

27. On November 16, 2007, patentee timely filed a Request for Reconsideration of Patent Term Adjustment under 37 CFR § 1.705(b) ("Request for Reconsideration") for the '744 patent, requesting that it be granted a corrected patent term adjustment. The PTO held a decision in abeyance until after issuance of the patent to allow a final determination of patent term adjustment. On May 6, 2008, patentee timely re-filed a Request for Reconsideration of Patent Term Adjustment under 37 CFR § 1.705(d) ("Second Request for Reconsideration") for the '744 patent, requesting that it be granted a corrected final patent term adjustment of 1007 days based on the PTO's calculation of delay under 35 U.S.C. § 154(b)(1)(A) and (B). The Second Request for Reconsideration is still pending before the PTO.

28. The defendant's denial of the full patent term adjustment of 1007 days under 35 U.S.C. § 154(b) for the '744 patent is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

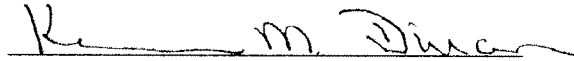
WHEREFORE, Plaintiff respectfully prays that this Court:

29. Issue an Order changing the period of patent term adjustment for the '744 patent term from 453 days to 1007 days and requiring defendant to alter the terms of the '744 patent to reflect the 1007 day patent term adjustment.

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

Dated: September 5, 2008

Respectfully submitted,



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