

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS AG
Lichtstrasse 35
CH-4056, Basel
Switzerland

Plaintiff,

v.

HON. JOHN J. DOLL
Acting Under Secretary of Commerce for
Intellectual Property and Acting Director of the
United States Patent and Trademark Office
Office of the General Counsel
United States Patent and Trademark Office
P.O. Box 15667, Arlington, VA 22215
Madison Building East, Room 10B20
600 Dulany Street, Alexandria, VA 22314

Defendant.

Civil Action No. _____

COMPLAINT

Plaintiff Novartis AG (“Novartis” or “Plaintiff”), for its complaint against the Honorable John J. Doll (“Doll” or “Defendant”), states as follows:

NATURE OF THE ACTION

1. This is an action by Novartis, the owner and assignee of United States Patent No. 7,473,761 (“the ‘761 patent”) for review of the determination by Defendant, pursuant to 35 U.S.C. § 154(b)(3)(B), of the patent term adjustment of the ‘761 patent. Novartis seeks a judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the ‘761 patent be changed from 878 days to 1,458 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. Novartis is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

4. Doll is the Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office (“PTO”), acting in his official capacity. The Acting 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(b)(3)(B).

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

8. Novartis is the assignee of all right, title and interest in the ‘761 patent, as evidenced by records on deposit with the PTO and the face of the ‘761 patent. As such, Novartis is the real party in interest in this case.

9. Rainer Albert, Wilfried Bauer, David Bodmer, Christian Bruns, Ivo Felner, Heribert Hellstern, Ian Lewis, Mark Meisenbach, Gisbert Weckbecker, and Bernhard Wietfeld are the inventors of patent application number 10/343,288 (“the ‘288 application”) which was

filed (*i.e.*, met all 371(c) requirements) on August 26, 2003 (the "Filing Date"). The '288 application claims Patent Cooperation Treaty ("PCT") priority to August 1, 2000, the commencement date for international patent application number PCT/EP01/08824 (the "PCT Priority Date").

10. On June 6, 2007, the PTO mailed a Requirement for Restriction/Election as to the '288 application (the "First Office Action").

11. On March 27, 2008, Novartis filed its response to the PTO's October 12, 2007 Non-Final Rejection as to the '288 application (the "Non-Final Rejection").

12. On October 2, 2008, the PTO mailed a Notice of Allowance and Fees Due for the '288 application ("Notice of Allowance"). Included in the Notice of Allowance was a Determination of Patent Term Adjustment in which the PTO indicated that the patent term adjustment to date for the '288 application was 878 days.

13. On November 25, 2008, Novartis paid the issue fee for the '288 application, thereby satisfying all outstanding requirements for issuance of a patent therefrom.

14. On December 17, 2008, the PTO mailed an Issue Notification for the '288 application. Included in the Issue Notification was a Determination of Patent Term Adjustment in which the PTO indicated that the patent term adjustment for the '288 application was 878 days.

15. On January 6, 2009, the '288 application issued as the '761 patent, reflecting a patent term adjustment of 878 days. A true and correct copy of the '761 patent is attached hereto as Exhibit A.

16. On January 26, 2009, Novartis filed with the PTO an Application for Patent Term Adjustment Post-Grant requesting that the PTO change its patent term adjustment for the '761

patent (the "PTA Application").

17. The PTA Application is still pending before the PTO.

18. 35 U.S.C. § 154(b) requires that patent terms be adjusted to compensate for failure of the PTO to take certain actions on patent applications within designated time limits. 35 U.S.C. § 154(b)(3) requires the Director of the PTO to determine the patent term adjustment for each patent.

19. 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).

20. 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

21. The allegations of paragraphs 1-20 are incorporated in this claim for relief as if fully set forth herein.

22. The currently challenged patent term adjustment for the '761 patent, as determined by the Defendant under 35 U.S.C. § 154(b) and listed on the face of the '761 patent, is 878 days. (See Exh. A at p. 1). This determination of the 878-day patent term adjustment is in error.

23. Under 35 U.S.C. § 154(b)(1)(A)(i), Novartis is entitled to an adjustment of the term of the '761 patent for a period of 953 days, the number of days attributable to PTO examination delay ("A Delay"). The A Delay period of 953 days is due to the PTO's failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the actual filing date of the

application. This period consists of the length of time from October 26, 2004 (14 months after the Filing Date) to June 6, 2007 (the mailing date of the First Office Action).

24. Under 35 U.S.C. § 154(b)(1)(B), Novartis is entitled to an additional adjustment of the term of the '761 patent for a period of 1,070 days, the number of days attributable to the PTO's "failure . . . to issue a patent within 3 years after the actual filing date of the application in the United States," but not including "any time consumed by continued examination of the application requested by the applicant under section 132 (b)" ("B Delay"). The B Delay period consists of the period commencing February 1, 2006 (three years and thirty months after the PCT Priority Date) until January 1, 2009 (the issue date of the '761 patent).

25. 35 U.S.C. § 154(b)(2)(A) provides that "to the extent that 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 '761 patent, the period February 1, 2006 through June 6, 2007 constitutes overlap of the A Delay period and the B Delay period. Therefore, 490 days of § 154(b)(1) delay must be excluded from the determination of patent term adjustment for the '761 patent as duplicative under 35 U.S.C. § 154(b)(2)(A).

26. 35 U.S.C. § 154(b)(2)(C)(i) provides that "the period of adjustment of the term of a patent under paragraph [154(b)(1)] shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." 35 U.S.C. § 154(b)(2)(C)(ii) provides that "an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request." ("C

Reduction”).

27. For the ‘761 patent, C Reduction is attributable only to the delay by Novartis in filing its response to the Non-Final Rejection on March 27, 2008, a date in excess of 3 months by 75 days.

28. Accordingly, the correct patent term adjustment for the ‘761 patent is 1,458 days: the sum of the 953 days of A Delay and the 1,070 days of B Delay, minus the 490 day of overlap between the A Delay period and the B Delay period, minus the 75 days of C Reduction.

29. Defendant’s determination that the period of the patent term adjustment for the ‘761 patent is only 878 days is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

30. Moreover, Defendant’s determination that the period of the patent term adjustment for the ‘761 patent is only 878 days conflicts with this Court’s judgment in Wyeth v. Dudas, 580 F.Supp.2d 138 (D.D.C. 2008), which explains the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b).

WHEREFORE, Novartis respectfully prays that this Court:

A. Issue an Order changing the period of patent term adjustment for the '761 patent from 878 days to 1,533 days, and requiring Defendant to alter the term of the '761 patent to reflect the 1,553-day patent term adjustment; and

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

Respectfully submitted,



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Dated: June 30, 2009

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