

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS VACCINES AND
DIAGNOSTICS, INC.
4560 Horton Street
Emeryville, CA 94608-2916

Civil Action No. _____

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.

COMPLAINT

Plaintiff Novartis Vaccines and Diagnostics, Inc. ("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. 7,470,709 ("the '709 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 '709 patent. Novartis seeks a judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '709 patent be changed from 392 days to 811 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 Delaware with its principal place of business at 350 Massachusetts Avenue, Cambridge, MA 02139.

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 ‘709 patent, as evidenced by records on deposit with the PTO and the face of the ‘709 patent. As such, Novartis is the real party in interest in this case.

9. Paul A. Barsanti, Dirksen Bussiere, Stephen D. Harrison, Carla C. Heise, Johanna M. Jansen, Elisa Jazan, Timothy D. Machajewski, Christopher McBride, William R. McCrea, Jr., Simon Ng, Zhi-Jie Ni, Sabina Pecchi, Keith B. Pfister, Savithri Ramurthy, Paul A. Renhowe, Cynthia M. Shafer, Joel B. Silver, Allan S. Wagman, Marion Wiesmann, and Kelly Wayman are

the inventors of patent application number 10/644,055 (“the ‘055 application”) which was filed on August 19, 2003 (the “Filing Date”).

10. On June 13, 2006, the PTO mailed a Requirement for Restriction/Election as to the ‘055 application (the “First Office Action”).

11. On March 16, 2007, Novartis filed its response to the PTO’s September 18, 2006 Non-Final Rejection as to the ‘055 application (the “First Non-Final Rejection”).

12. On October 12, 2007, Novartis filed a Request for Continued Examination in response to the PTO’s June 11, 2007 Final Rejection as to the ‘055 application (the “Final Rejection”).

13. On June 20, 2008, Novartis filed its response to the PTO’s December 21, 2007 Non-Final Rejection as to the ‘055 application (the “Second Non-Final Rejection”).

14. On August 15, 2008, the PTO mailed a Notice of Allowance and Fees Due for the ‘055 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 ‘055 application was 392 days.

15. On November 12, 2008, Novartis paid the issue fee for the ‘055 application, thereby satisfying all outstanding requirements for issuance of a patent therefrom.

16. On December 10, 2008, the PTO mailed an Issue Notification for the ‘055 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 ‘055 application was 392 days.

17. On December 30, 2008, the ‘055 application issued as the ‘709 patent, reflecting a patent term adjustment of 392 days. A true and correct copy of the ‘709 patent is attached hereto

as Exhibit A.

18. On February 25, 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 '709 patent (the "PTA Application").

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

20. 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.

21. 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).

22. 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

23. The allegations of paragraphs 1-22 are incorporated in this claim for relief as if fully set forth herein.

24. The currently challenged patent term adjustment for the '709 patent, as determined by the Defendant under 35 U.S.C. § 154(b) and listed on the face of the '709 patent, is 392 days. (See Exh. A at p. 1). This determination of the 392-day patent term adjustment is in error.

25. Under 35 U.S.C. § 154(b)(1)(A)(i), Novartis is entitled to an adjustment of the term of the '709 patent for a period of 602 days, the number of days attributable to PTO examination delay ("A Delay"). The A Delay period of 602 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 19, 2004 (14 months after the Filing Date) to June 13, 2006 (the mailing date of the First Office Action).

26. Under 35 U.S.C. § 154(b)(1)(B), Novartis is entitled to an additional adjustment of the term of the '709 patent for a period of 419 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 August 19, 2006 (three years after the filing date of the '055 application) until October 12, 2007 (the filing date of the Request for Continued Examination).

27. 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 '709 patent, none of the A Delay period overlaps with the B Delay period. Therefore, there is no period of overlap to be excluded from the determination of patent term adjustment for the '709 patent under 35 U.S.C. § 154(b)(2)(A).

28. 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”).

29. For the ‘709 patent, a total of 210 days constitute C Reduction as follows:

a. Delay by Novartis in filing its response to the First Non-Final Rejection on March 16, 2007, a date in excess of 3 months by 88 days.

b. Delay by Novartis in filing of its Request for Continued Examination in response to the Final Rejection on October 12, 2007, a date in excess of 3 months by 31 days.

c. Delay by Novartis in filing its response to the Second Non-Final Rejection on June 20, 2008, a date in excess of 3 months by 91 days.

30. Accordingly, the correct patent term adjustment for the ‘709 patent is 811 days: the sum of the 602 days of A Delay and the 419 days of B Delay, minus the 210 days of C Reduction.

31. Defendant’s determination that the period of the patent term adjustment for the ‘709 patent is only 392 days is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

32. Moreover, Defendant’s determination that the period of the patent term adjustment for the ‘709 patent is only 392 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 '709 patent from 392 days to 811 days, and requiring Defendant to alter the term of the '709 patent to reflect the 811-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,



Dated: June 30, 2009

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