

FILED

APR 24 2009

Clerk, U.S. District and
Bankruptcy Courts

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

HOFFMANN-LA ROCHE INC.
340 Kingsland Street
Nutley, NJ 07110
USA,

Plaintiff,

v.

HON. JOHN J. DOLL
Acting Under Secretary of Commerce for
Intellectual Property and Acting Director of tl
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.

Case: 1:09-cv-00760
Assigned To : Bates, John D.
Assign. Date : 4/24/2009
Description: General Civil

Plaintiff, Hoffmann-La Roche Inc. ("Hoffmann-La Roche"), for its Complaint against the
Honorable John J. Doll, states as follows:

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 7,442,776 ("the '776 patent") seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '776 patent be changed from 580 days to 841 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 Hoffmann-La Roche is a corporation organized under the laws of New Jersey, having a principal place of business at 340 Kingsland Street, Nutley, NJ.

4. Defendant John J. 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 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).

BACKGROUND

8. David S. F. Young, Susan E. Hahn, and Helen P. Findlay are inventors of the patent application No. 10/810,163 (“the ‘163 application”), which issued on October 8, 2008 as the ‘776 patent, entitled “Cancerous Disease Modifying Antibodies”. A copy of ‘776 patent is attached hereto as Exhibit A.

9. Plaintiff Hoffmann-La Roche is the assignee of the ‘776 patent as evidenced by records in the PTO and is the real party in interest in this case.

10. Section 154(b) of 35 U.S.C. requires that the Director of the PTO grant a patent term adjustment. 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

17. Under 35 U.S.C. § 154(b)(1)(B), the plaintiff is entitled to an additional adjustment of the term of the '776 patent of a period of 445 days, which is the number of days the issue date of the '776 patent exceeds three years from the filing date of the application, up to the June 13, 2008, filing date of the Request for Continued Examination ("B Delay").

18. Title 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." For the '776 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 patent term adjustment.

19. Thus, the total period of PTO delay is 1,025 days, which is the sum of the period of A Delay (580 days) and the period of B Delay (445 days).

20. Under 35 U.S.C. § 154(b)(2)(C), the total period of PTO delay is reduced by the period of applicant delay, which, in this case, is 184 days as determined by the PTO.

21. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is 841 days, which is the difference between the total period of PTO delay (1,025 days) and the period of applicant delay (184 days).

22. The defendant's imposition of only 580 days of patent term adjustment for the '776 patent is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

23. The defendant's determination that the period of the patent term adjustment for the '776 patent is only 580 days is in conflict with this Court's decision in *Wyeth v. Dudas*, 580 F. Supp.2d 138, 88 USPQ2d 1538 (D.D.C. 2008), which explains the proper method for

calculating patent term adjustments under 35 U.S.C. § 154(b). A copy *Wyeth v. Dudas* decision is attached hereto as Exhibit B.

WHEREFORE, Plaintiff respectfully prays that this Court:

A. Issue an Order changing the period of patent term adjustment for the '776 patent from 580 days to 841 days and requiring defendant to alter the term of the '776 patent to reflect the 841-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,

FISH & RICHARDSON P.C.



Andrew R. Kopsidas (Bar No. 476237) ✓

FISH & RICHARDSON P.C.

1425 K Street, N.W.

11th Floor

Washington, D.C. 20005

Telephone: (202) 783-5070

Facsimile: (202) 783-2331

Attorneys for Plaintiff
Hoffmann-La Roche Inc.

Dated: April 24, 2009

Of Counsel:

Todd E. Garcia, Esq.
FISH & RICHARDSON P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070