

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA
Civil Division

MEDAREX, INC.,
707 State Road
Princeton, NJ 08540-1437

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 22313

Defendant.

Civil Action No.: _____

COMPLAINT

Plaintiff Medarex, Inc. ("Medarex"), for its complaint against the Honorable Jon W.

Dudas, states as follows:

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 7,387,776 (hereinafter "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 231 days to 521 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 Medarex is a corporation organized under the laws of New Jersey, having a principal place of business at 707 State Road, Princeton, NJ 08540-1437.

4. Defendant Jon W. Dudas is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (hereinafter "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 court 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. Tibor Keler, Robert Graziano, John Treml, and Yashwant Deo are inventors of the patent application number 10/338,366 (hereinafter "the '366 application") which issued as the '776 patent, entitled Human Monoclonal Antibodies Against CD30, on June 17, 2008. The '776 patent concerns isolated monoclonal antibodies which bind to human CD30. The '776 patent is attached hereto as Exhibit A.

9. Plaintiff Medarex is the assignee of the '776 patent, as evidenced by the records in the PTO, and is the real party in interest in the case.

10. 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), which set forth a "Guarantee of prompt Patent and Trademark Office responses" and a "Guarantee of no more than 3-year application pendency."

11. 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), any disclaimer of patent term by the applicant under 35 U.S.C. § 154(b)(2)(B), and any applicant delays under 35 U.S.C. § 154(b)(2)(C).

12. 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

13. The allegations of paragraphs 1-12 are incorporated in this claim for relief as if fully set forth.

14. The patent term adjustment for the '776 patent, as determined by the Director under 35 U.S.C. § 154(b) and listed on the face of the '776 patent, is 231 days (*See* Ex. A at 1).

15. The Director's determination of the 231-day patent term adjustment is in error because the PTO did not properly calculate and allow an adjustment for the delay in issuance of the '776 patent beyond three years after the actual filing date of the application for the patent. The correct patent term adjustment for the '776 patent is at least 521 days.

16. The '366 application was filed on January 7, 2003, and the '776 patent was issued on June 17, 2008.

17. The plaintiff is entitled to an adjustment of the term of the '776 patent under 35 U.S.C. § 154(b)(1)(A) in the amount of 492 days, which is the number of days attributable to PTO examination delay during prosecution of the '336 application ("A Delay").

18. The plaintiff is also entitled to an additional adjustment of the term of the '776 patent under 35 U.S.C. § 154(b)(1)(B) in the amount of 290 days, which is the number of days the issuance of the '776 patent was delayed beyond three years after the actual filing date of the '336 application ("B Delay").

19. Section 35 U.S.C. § 154(b)(2)(A) states that "[t]o 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 '776 patent, none of the A Delay overlapped with the period of B Delay. Therefore, there is no period of overlap to be excluded from the patent term adjustment.

20. The total period of PTO delay was 782 days, which is the sum of the A Delay (492 days) and the B Delay (290 days), as shown in the chart attached hereto as Exhibit B.

21. The '776 patent is not subject to a disclaimer of term. Therefore, the period of patent term adjustment is not limited under 35 U.S.C. § 154(b)(2)(B).

22. The total period of PTO delay is reduced under 35 U.S.C. § 154(b)(2)(C) by the period of applicant delay, which the PTO determined for the '776 patent was 261 days.

23. Accordingly, the correct patent term adjustment to which the plaintiff is entitled under 35 U.S.C. § 154(b)(1) and (2) is 521 days, which is the total period of PTO delay (492 days + 290 days = 782 days), less the period attributable to applicant delay (782 days - 261 days = 521 days).

24. The Director erred in the determination of patent term adjustment for the '776 patent by erroneously treating the entire period of B Delay as overlapping with the A Delay, and crediting only the greater of the two delays (*i.e.*, the A delay of 492 days), instead of correctly crediting the sum of both the A and B delays. Thus, the Director incorrectly calculated a patent term adjustment for the '776 patent as 231 days (492 days - 261 days = 231 days). By this erroneous calculation, the Director has deprived the plaintiff of the full patent term adjustment to which it is entitled (calculated above as 521 days).

25. In its opinion in *Wyeth v. Dudas*, Civ. Action No. 1:07-cv-01492-JR, this Court explained the proper construction and application of the provisions of 35 U.S.C. § 154(b) for determining patent term adjustment. See, Mem. Op. dated 30 September 2008, docket no. 27, reported as *Wyeth v. Dudas*, 2008 U.S. Dist. LEXIS 76063, 88 U.S.P.Q.2d (BNA) 1538 (D.D.C. Sept. 30, 2008). In accord with this Court's determination of the proper method for calculating patent term adjustment in accordance with 35 U.S.C. § 154(b), as set forth in the decision in *Wyeth*, the patent term adjustment for the '776 patent is properly determined to be 521 days, as set forth above.

26. The Director's allowance of only 231 days of patent term adjustment for the '776 patent is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

WHEREFORE, Plaintiff respectfully prays that this Court:

A. Issue an Order changing the period of patent term adjustment for the '776 patent term from 231 days to 521 days, and requiring the Director to alter the term of the '776 patent to reflect the 521 day patent term adjustment.

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

Dated: December 12, 2008

Respectfully Submitted,

MEDAREX, INC.

By its attorneys,



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