

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Merck Serono S.A.
Centre Industriel
CH-1267 Coinsins, Vaud
SWITZERLAND

Plaintiff

v.

HON. DAVID J. KAPPOS
Under Secretary of Commerce for
Intellectual Property and Director of the
United States Patent and Trademark Office

Civil Action No. _____

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.

COMPLAINT

Plaintiff Merck Serono S.A. ("Merck Serono"), for its complaint against the Honorable David J. Kappos, states as follows:

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 7,585,840 ("the '840 patent"), seeking a judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '840 patent be changed from 491 days to 923 days.

2. This action arises under 35 U.S.C. § 154 and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

PARTIES

3. Plaintiff Merck Serono is a corporation organized under the laws of Switzerland, having a principal place of business at Centre Industriel, CH-1267 Coinsins, Vaud, Switzerland.

4. Defendant David J. Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (“USPTO”), acting in his official capacity. The Director is the head of the USPTO and is responsible for superintending or performing all duties required by law with respect to the granting and issuing of patents. The Director is designated by statute as the official responsible for determining the period of patent term adjustment 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 judicial district under 35 U.S.C. § 154(b)(4)(A).

7. This Complaint is timely filed in accordance with 35 U.S.C. § 154(b)(4)(A) and Fed. R. Civ. P. 6(a).

BACKGROUND FACTS

8. Plaintiff Merck Serono is the assignee of the '840 patent, as evidenced by assignment documents recorded at the USPTO. The entire right, title, and interest to the '840 patent, including the right to sue and recover for past infringement thereof, is assigned to and is owned by Merck Serono. Merck Serono is therefore the real party in interest in this case.

9. Under 35 U.S.C. § 154(a)(2), a successful patent applicant is entitled to a 20-year patent term beginning on the date its application was first filed with the USPTO. Because this period starts to run with the filing of the application rather than with the grant of the patent, any administrative delay by the USPTO in processing of an application reduces the applicant's effective patent term.

10. To prevent such administrative delays from causing unfair losses of patent protection, 35 U.S.C. § 154(b) requires the Director of the USPTO to 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."

11. Accordingly, the USPTO must grant successful applicants upward adjustments of their patent terms to compensate for three categories of processing delay by the USPTO. Those three categories, set forth in 35 U.S.C. § 154(b)(1)(A), (B) and (C) are known as "A delays," "B delays" and "C delays", respectively. Only A delays and B delays are at issue in this case.

12. "A delays" occur when the USPTO fails to take one of several specified actions within a particular time period. For example, such a delay occurs if the USPTO does not "issue a patent within 4 months after the date on which the issue fee was paid . . . and all other outstanding requirements were satisfied." 35 U.S.C. §154(b)(1)(A)(iv). The statute provides that "the term of the patent shall be extended by 1 day for each day

after the end of the period specified . . . until the action described . . . is taken." *Id.* § 154(b)(1)(A).

13. "B delays" occur when the USPTO fails to issue a patent within 3 years of the filing of the patent applications, excluding certain specified periods of delay. 35 U.S.C. § 154(b)(1)(B). As with "A delays", the statute provides for a day-for-day patent term adjustment to compensate for any "B delays": "[T]he term of the patent shall be extended by 1 day for each day after the end of that 3-year period until the patent is issued." *Id.*

14. In calculating a patent term adjustment, however, Congress directed that overlapping periods of "A delay" and "B delay" may not be double-counted: "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). In addition, in calculating the patent term adjustment, the Director must account for any disclaimer of patent term by the applicant under § 154(b)(2)(B), and any delay attributable to the applicant under § 154(b)(2)(C).

15. The dispute in this case concerns the proper interpretation of the provision limiting the patent term adjustment by any overlapping "A delays" and "B delays."

16. In particular, the USPTO has taken the position that whenever an application is subject to both an "A delay" and a "B delay", those periods *always* "overlap" within the meaning of § 154(b)(2)(A) – even if they occur on different calendar days. *See* 69 Fed. Reg. 34,283 (June 21, 2002). The result of this interpretation is that an applicant is entitled to an adjustment equal to *either* the "A delay" or the "B delay", whichever is longer, but never to an adjustment equal to the "A delay" *plus* the "B delay".

17. This Court rejected the PTO's interpretation of § 154(b)(2)(A) in *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008). Giving the words of the statute their plain meaning, the Court observed that "[t]he only way that periods of time can 'overlap' is if they occur on the same day." *Id.* at 141. The Court thus held that "[i]f an 'A delay' occurs on one calendar day and a 'B delay' occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day." *Id.* at 141-42.

18. This Court's decision recently was affirmed by the U.S. Court of Appeals for the Federal Circuit in an action entitled *Wyeth v. Kappos*, 2010 U.S. App. LEXIS 300, 93 U.S.P.Q. 2d 1257 (Fed. Cir., Jan. 7, 2010).

19. 35 U.S.C. § 154(b)(4)(A) provides that "[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."

20. The Plaintiff has submitted a Request for Recalculation of Patent Term Adjustment in view of *Wyeth* ("the Request;" Form PTO/SB/131). *See* Hopenfeld Decl., Ex. A. Nevertheless, because the USPTO's position is that "to preserve the right to review in the United States District Court for the District of Columbia of the USPTO's patent term adjustment determination, a patentee must ensure that he or she also takes the steps required under 35 U.S.C. 154(b)(3) and (b)(4) and 37 CFR 1.705 in a timely manner" Merck Serono is filing this Complaint, *inter alia*, to preserve the right to review.

THE COUNT: U.S. PATENT NO. 7,585,840

21. The allegations of paragraphs 1-13 are incorporated in this count as if fully set forth.

22. Christine Power and Christine Plater-Zyberk are the inventors of U.S. Patent Application No. 10/966,845 ("the '845 application"), entitled "Use of osteoprotegerin for the treatment and/or prevention of fibrotic disease." The '845 application was filed on October 15, 2004, and issued as the '840 patent on September 8, 2009. *See Hopenfeld Decl., Ex. B ('840 patent).*

23. When the USPTO issued the '840 patent on September 8, 2009, it erroneously calculated the entitled patent term adjustment for the '840 patent as 491 days. *See Hopenfeld Decl., Ex. B at 1.*

24. The determination of the 491-day patent term adjustment is in error because it includes only an adjustment for "B delays", pursuant to 35 U.S.C. § 154(b)(1)(B). In particular, the USPTO's patent term adjustment fails to include an adjustment, as required by 35 U.S.C. § 154(b)(1)(A), for "A delays," the number of days attributable to USPTO examination delay. The number of the days attributable to USPTO examination delay is 432 days.

25. Section 35 U.S.C. § 154(b)(2)(A) states that "to the extent that periods of [A and B delay] 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 '840 patent, there is no overlap between the periods of A and B delay. Therefore, there is no period of overlap to be excluded from the patent term adjustment calculation.

26. Thus, the total period of USPTO delay is 1126 days, which is the sum of the period of A delay (432 days) and the period of B delay (694 days).

27. Pursuant to 35 U.S.C. § 154(b)(2)(C), the total period of USPTO delay is reduced by the period of applicant delay, which is 203 days as determined by the USPTO.

28. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154 is 923 days, which is the difference between the total period of USPTO delay (1126 days) and the period of applicant delay (203 days).

29. Notably, pursuant to 35 U.S.C. § 154(b)(2)(B), there is no reduction in patent term adjustment due the '840 patent, even though the '840 patent is subject to a Terminal Disclaimer. The Terminal Disclaimer disclaims the term that would extend beyond the expiration date of U.S. Application. No. 10/510,876 ("the '876 application"), which eventually issued as U.S. Patent No. 7,638,480 ("the '480 patent") on December 29, 2009. *See* Hopenfeld Decl., Ex. C ('480 Patent).

30. The '845 application (which lead to the '840 patent) is a continuation-in-part of the '876 application, such that the unadjusted patent terms of the '840 patent and the '480 patent would expire on the same date, March 26, 2023. The '480 patent issued with a patent term adjustment of 715 days listed on its face, as determined by the USPTO. The Plaintiff has filed at the USPTO a request for reconsideration of the patent term adjustment for the '480 patent in view of the *Wyeth* decision and in view of the start of the three year pendency period as the national stage entry date under 35 U.S.C. § 371(b) (*see* Hopenfeld Decl., Ex. D), not the completion of all requirements under 35 U.S.C. § 371. This request for reconsideration states the USPTO should have awarded the '480 patent 1062 days of patent term adjustment. Thus, if the request for reconsideration with respect to the '480 patent is properly granted, the Terminal Disclaimer in the '845

application over the '876 application would have no effect on the patent term adjustment awarded to the '840 patent, because the '840 patent would still expire (923 days after March 26, 2023) before '480 patent (1062 days after March 26, 2023).

31. The Defendant's imposition of only 491 days of patent term adjustment for the '840 patent is arbitrary, capricious, an abuse of discretion, inconsistent with the language of 35 U.S.C. § 154 and related rules, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

PRAYER FOR RELIEF

32. The allegations of paragraphs 1-26 are incorporated in this prayer for relief as if fully set forth.

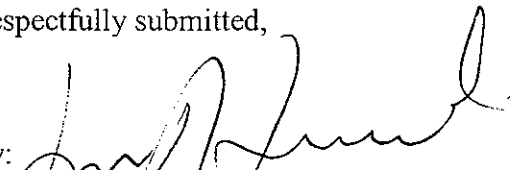
WHEREFORE, Merck Serono prays that the Court:

A. Issue an Order changing the period of patent term adjustment for the '840 patent from 491 days to at least 923 days, and requiring Defendant to alter the term of the '840 patent to reflect the 923-day patent term adjustment; and

B. Grant to Merck Serono such other and further relief as the nature of the case may admit or require and as this Court deems just and proper.

Respectfully submitted,

By:



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Dated: March 3, 2010

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