

FILED

SEP 11 2009

**Clerk, U.S. District and
Bankruptcy Courts**

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

Boehringer Ingelheim Pharma GmbH & Co. KG
Binger Strasse 173
Ingelheim, Germany 55216

Boehringer Ingelheim International GmbH
Binger Strasse 173
Ingelheim, Germany 55216

and

Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
Ridgefield, CT 06877

Plaintiffs,

v.

HON. DAVID KAPPOS
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 Dulaney Street, Alexandria, VA 22314

Defendant.

Case: 1:09-cv-01729
Assigned To : Friedman, Paul L.
Assign. Date : 9/11/2009
Description: General Civil

COMPLAINT

Plaintiffs Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively, "Boehringer Ingelheim") for their complaint against the Honorable David Kappos, state as follows:

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NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 7,504,378 (“the ’378 patent,” attached as Exhibit) seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the ’378 patent be changed from 332 days to at least 429 days in view of this Court’s decision in *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008), as set forth below.

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

JURISDICTION AND VENUE

3. 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.

4. Venue is proper in this district by virtue of 35 U.S.C. § 154(b)(4)(A).

5. This Complaint is timely filed in accordance with U.S.C. § 154(b)(4)(A).

THE PARTIES

6. Plaintiff Boehringer Ingelheim Pharma GmbH & Co. KG is a private limited liability company organized under the laws of Germany, having a principal place of business at Binger Strasse 173, Ingelheim, Germany.

7. Plaintiff Boehringer Ingelheim International GmbH is a holding company organized under the laws of Germany, having a principal place of business at Binger Strasse 173, Ingelheim, Germany.

8. Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. is a corporation organized under the laws of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, CT 06877.

9. Defendant David Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (“PTO”), acting in his official capacity. The Director is the head of the agency, charged by statute with providing management supervision for the PTO and for the issuance of patents. The Director is the official responsible for determining the period of patent term adjustment under 35 U.S.C. § 154.

BACKGROUND

10. Montse Llinas-Brunet and Murray D. Bailey are the inventors of the invention claimed in U.S. patent application number 11/298,443 (“the ’443 application”) entitled “Macrocyclic Peptides Active Against the Hepatitis C Virus,” which issued as the ’378 patent on March 17, 2009. The ’378 patent is directed to compounds and pharmaceutically acceptable salts of those compounds useful for inhibition of the hepatitis C virus NS3 protease. The ’378 patent is attached as Exhibit A.

11. Plaintiff Boehringer Ingelheim International GmbH is the assignee of the ’378 patent, as evidenced by the assignment document recorded at Reel 014618/, Frame 0661 in the PTO.

12. Section 154 of title 35 of the United States Code requires that the Director of the PTO 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.”

13. In determining patent term adjustment, the Director is required to extend the term of a patent for a period equal to the total number of days attributable to delay by the PTO under 35 U.S.C. § 154(b)(1), as limited by any overlapping periods of delay by the PTO as specified 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 delay attributable to the applicant under 35 U.S.C. § 154(b)(2)(C).

14. The Director made a determination of patent term adjustment pursuant to 35 U.S.C. § 154(b)(3) and issued the '378 patent reflecting that determination.

15. 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 grant of the patent. Chapter 7 of title 5 shall apply to such an action.”

CLAIM FOR RELIEF

16. The allegations of paragraphs 1-15 are incorporated in this claim for relief as if fully set forth.

17. The patent term adjustment for the '378 patent, as determined by the Director under 35 U.S.C. § 154(b) and indicated on the face of the '378 patent, is 332 days. (*See Ex. at 1*). The determination of this 332 day patent term adjustment is in error because the PTO failed to properly account for the delays that occurred before the date that was three years after the

actual filing date of the '443 application, pursuant to 35 U.S.C. § 154(b)(1)(A). The correct patent term adjustment for the '378 patent is at least 429 days.

18. The '443 application was filed on December 10, 2005, and issued as the '378 patent on March 17, 2009.

19. Under 35 U.S.C. § 154(b)(1)(A), the number of days attributable to PTO examination delay ("A Delay") is 332 days.

20. Under 35 U.S.C. § 154(b)(1)(B), the number of days between the date that was three years after the actual filing date of the '443 application (*i.e.*, December 10, 2008) and the date that the '378 patent was granted (*i.e.*, March 17, 2009) ("B Delay") is 97 days.

21. Under 35 U.S.C. § 154(b)(2)(C), the number of days of applicant delay is 0 days.

22. 35 U.S.C. § 154(b)(2)(A) provides that "to the extent that periods of delay attributable to grounds specified in paragraph [b](1) overlap, the period of any adjustment ... shall not exceed the actual number of days the issuance of the patent was delayed." There is no overlap between the "A Delay" period and the "B Delay" period in the prosecution of the '378 patent (*i.e.*, there is no period of "A Delay" that occurred between December 10, 2008, and March 17, 2009).

23. The '378 patent is not subject to a disclaimer of term. Thus the period of patent term adjustment is not limited under 35 U.S.C. § 154(b)(2)(B).

24. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is the sum of the “A Delay” and “B Delay” ($332 + 97 = 429$ days) reduced by the number of days of applicant delay (0 days), for a net patent term adjustment of 429 days.

25. The Director erred in the determination of patent term adjustment by treating the entire period of PTO examination delay — instead of only any period of PTO examination delay that occurred after the date that was three years after the actual filing date of the '443 application — as the period of overlap between the “A Delay” and the “B Delay.” Thus, the Director erroneously determined that the net patent term adjustment should be limited under 35 U.S.C. § 154(b)(2)(A) by 97 days, rather than correctly determining that there was no limit under 35 U.S.C. § 154(b)(2)(A), and arrived at an incorrect net patent term adjustment of 332 days.

26. In *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008), this Court explained the proper construction of the provisions of 35 U.S.C. § 154(b) for determining patent term adjustment. In accordance with *Wyeth*, the patent term adjustment for the '378 patent is properly determined to be 429 days, as explained above.

27. The Director's determination that the '378 patent is entitled to only 332 days of patent term adjustment is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority, or limitation.

PRAYER FOR RELIEF

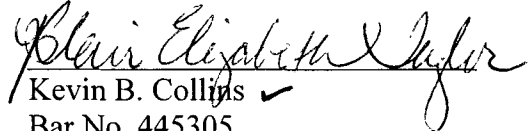
Wherefore, Plaintiffs demand judgment against Defendant and respectfully request that this Court enter Orders:

A. Changing the period of patent term adjustment for the '378 patent term from 332 days to 429 days and requiring the Director to extend the term of the '378 patent to reflect the 429 day patent term adjustment.

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

Dated: September 11, 2009

Respectfully submitted,



Kevin B. Collins ✓
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Blair Elizabeth Taylor, Ph.D.

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