

**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.

Civil Action No. _____

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:**

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 7,491,824 (“the ’824 patent,” attached as Exhibit) seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the ’824 patent be changed from 478 days to at least 656 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. Ralf Lock, Werner Belzer, Rainer Hamm, and Monika Hofmann are the inventors of the invention claimed in U.S. patent application number 11/209,323 (“the ’323 application”) entitled “Method for Preparing Tiotropium Salts,” which issued as the ’824 patent on February 17, 2009. The ’824 patent is directed to processes for preparing tiotropium salts, which are anticholinergic agents useful in the treatment of diseases such as asthma and chronic obstructive pulmonary disease. The ’824 patent is attached as Exhibit A.

11. Plaintiff Boehringer Ingelheim Pharma GmbH & Co. KG is the assignee of the ’824 patent, as evidenced by the assignment document recorded at Reel 016955, Frame 0728 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 '824 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 1-14 are incorporated in this claim for relief as if fully set forth.

17. The patent term adjustment for the '824 patent, as determined by the Director under 35 U.S.C. § 154(b) and indicated on the face of the '824 patent, is 478 days. (*See Ex. at 1*). The determination of this 478 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 '323 application, pursuant to 35 U.S.C. § 154(b)(1)(A). The correct patent term adjustment for the '824 patent is at least 656 days.

18. The '323 application was filed on August 23, 2005, and issued as the '824 patent on February 17, 2009.

19. Under 35 U.S.C. § 154(b)(1)(A), the number of days attributable to PTO examination delay ("A Delay") is 515 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 '323 application (*i.e.*, August 23, 2005) and the date that the '824 patent was granted (*i.e.*, February 17, 2009) ("B Delay") is 178 days.

21. Under 35 U.S.C. § 154(b)(2)(C), the number of days of applicant delay is 37 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 '824 patent (*i.e.*, there is no period of "A Delay" that occurred between August 23, 2005 and February 17, 2009).

23. The '824 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” (515 + 178 = 693 days) reduced by the number of days of applicant delay (37 days), for a net patent term adjustment of 656 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 '323 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 178 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 478 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 '824 patent is properly determined to be 656 days, as explained above.

27. The Director's determination that the '824 patent is entitled to only 478 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

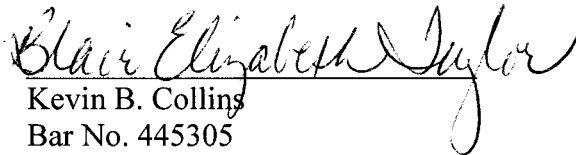
Wherefore, Plaintiffs demand judgment against Defendant and respectfully request that this Court enter Orders:

A. Changing the period of patent term adjustment for the '824 patent term from 478 days to 656 days and requiring the Director to extend the term of the '824 patent to reflect the 656 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: August 14, 2009

Respectfully submitted,



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