

**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. 7,582,770 (“the ’770 patent,” attached as Exhibit A) seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the ’770 patent be changed from 492 days to at least 1124 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 35 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. Youla Tsantrizos, Catherine Chabot, Pierre Beaulieu, Christian Brochu, Timothy Stammers, Bounkham Thavonekham, and Jean Rancourt are the inventors of the invention claimed in U.S. patent application number 11/062,305 (“the ’305 application”) entitled “Viral Polymerase Inhibitors,” which issued as the ’770 patent on September 1, 2009. The ’770 patent is directed to compounds useful for inhibiting the RNA-dependent RNA polymerase activity of the enzyme NS5B encoded by the hepatitis C virus. The ’770 patent is attached as Exhibit A.

11. Plaintiff Boehringer Ingelheim International GmbH is the assignee of the ’770 patent, as evidenced by the assignment document recorded at Reel 016314, Frame 0066 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 '770 patent reflecting that determination. Boehringer Ingelheim filed a Patent Term Adjustment Petition under 37 CFR §1.705(b) on March 20, 2009, which was dismissed as premature because the '770 patent claims had been allowed, but the patent had not yet issued. On October 20, 2009, Boehringer Ingelheim filed another Patent Term Adjustment Petition in the PTO. That Petition was never acted upon by the PTO. On February 25, 2010, Boehringer Ingelheim filed a Request For Recalculation of Patent Term Adjustment In View Of Wyeth, PTO Form SB/131, seeking additional review of the patent term adjustment determination made by the Director. A copy of Boehringer Ingelheim's Form SB/131 is attached as Exhibit B. The PTO has not yet acted on Boehringer Ingelheim's Form SB/131 submission, which is a newly available option for administrative relief.

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.” Boehringer Ingelheim submits this Complaint within the statutory period provided under § 154(b)(4)(A), thereby preserving its rights to judicial relief.

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 '770 patent, as determined by the Director under 35 U.S.C. § 154(b) and indicated on the face of the '770 patent, is 492 days. (*See Ex. A at 1*). The determination of this 492 day patent term adjustment is in error because the PTO failed to properly account for the delays that occurred after the date that was three years after the actual filing date of the '770 application, pursuant to 35 U.S.C. § 154(b)(1)(B), and failed to properly calculate the number of days of delay due to Applicant under 35 U.S.C. § 154(b)(2)(C). The correct patent term adjustment for the '770 patent is at least 1124 days.

18. The '305 application was filed on February 18, 2005, and issued as the '770 patent on September 1, 2009.

19. Under 35 U.S.C. § 154(b)(1)(A), the number of days attributable to PTO examination delay (“**A Delay**”) is **631 days**. This figure is calculated as follows. The day after the date that is 14 months after the date on which the application was filed under 35 U.S.C. § 111(a) is April 18, 2006. The date of mailing of the first action on the merits under 35 U.S.C. § 132 is January 9, 2008. The number of days beginning on April 18, 2006 and ending on January 9, 2008, is 631 days.

20. Under 35 U.S.C. § 154(b)(1)(B), the number of days beginning on the date that was three years after the actual filing date of the '305 application (*i.e.*, February 19, 2008) and the date that the '305 application issued as the '770 patent (*i.e.*, September 1, 2009) (“**B Delay**”) is **561 days**. The PTO erroneously calculated this period of delay to be 38 days.

21. Under 35 U.S.C. § 154(b)(2)(C), the number of days of Applicant Delay is 67 days. This figure is calculated as follows. An action on the merits was issued May 6, 2008, to which Boehringer Ingelheim did not respond until October 2, 2008. Because this response was filed 57 days beyond the 3 month period for filing a response under 37 C.F.R. § 1.704(b), Boehringer Ingelheim must account for this period of Applicant delay in its overall patent term adjustment calculus. After the Notice of Allowance was issued for the '305 application, Boehringer Ingelheim filed an Amendment under 37 C.F.R. § 1.312 on March 24, 2009, a response to which was issued on April 1, 2009 which totals 9 days of additional delay. Further, a request to amend inventorship was filed by Boehringer Ingelheim on March 20, 2009, a date also after the issuance of the Notice of Allowance. The PTO entered the corresponding Application Data Sheet on the same day, meaning an additional 1 day of delay was incurred by the filing of the request to correct inventorship. The PTO, however, calculated a 111 day delay for the inventorship correction for which Boehringer Ingelheim finds no basis. This PTO error cost the '770 patent 100 days of term. The combined period is therefore 57 days + 9 days + 1 day = **67 days of Applicant Delay**.

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 '770

patent (*i.e.*, there is no period of “A Delay” that occurred between January 10, 2008, and February 19, 2008).

23. The '770 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” (631 + 561 = 1192 days) reduced by the number of days of applicant delay (67 days), for a net patent term adjustment of **1125 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 '305 application — as the period of overlap between the “A Delay” and the “B Delay.” The PTO has admitted to incorrectly allowing only the longer of the two periods. *See Wyeth, infra*. The Director also incorrectly calculated the number of days due to Applicant Delay, thereby improperly reducing the term due the '770 patent by 100 days. Thus, the Director erroneously determined that the net patent term adjustment should be limited by an additional 633 days, and arrived at an incorrect net patent term adjustment of 492 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. This construction was recently upheld on appeal. *Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir. Jan. 7, 2010). In accordance with the this Court’s decision in *Wyeth*, the patent term adjustment for the '770 patent is properly determined to be 1125 days, as explained above.

27. The Director's determination that the '770 patent is entitled to only 492 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

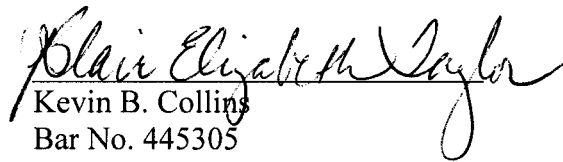
Wherefore, Plaintiffs demand judgment against Defendant and respectfully request that this Court enter Orders:

A. Changing the period of patent term adjustment for the '770 patent term from 492 days to 1125 days and requiring the Director to extend the term of the '770 patent to reflect the 1125 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: February 26, 2010

Respectfully submitted,



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