

**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. 7,579,449 (“the ’449 patent,” attached as Exhibit A) seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the ’449 patent be changed from 206 days to at least 235 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. Matthias Eckhardt, Peter Eickelmann, Frank Himmelsbach, Edward Leon Barsoumian, and Leo Thomas are the inventors of the invention claimed in U.S. patent application number 11/080,150 (“the ’150 application”) entitled “Glucopyranosyl-Substituted Phenyl Derivatives, Medicaments Containing Such Compounds, And Their Use And Process for Their Manufacture,” which issued as the ’449 patent on August 25, 2009. The ’449 patent is directed to compounds useful for treatment of metabolic disorders associated with the sodium-dependent glucose cotransporter SGLT2. The ’449 patent is attached as Exhibit A.

11. Plaintiff Boehringer Ingelheim International GmbH is the assignee of the ’449 patent, as evidenced by the assignment document recorded at Reel 016191, Frame 0600 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 '449 patent reflecting that determination. On February 17, 2009, 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 '449 patent, as determined by the Director under 35 U.S.C. § 154(b) and indicated on the face of the '449 patent, is 206 days. (*See* Ex. A at 1). The determination of this 206 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 '449 application, pursuant to 35 U.S.C. § 154(b)(1)(A). The correct patent term adjustment for the '449 patent is at least 235 days.

18. The '150 application was filed on March 15, 2005, and issued as the '449 patent on August 25, 2009.

19. Under 35 U.S.C. § 154(b)(1)(A), the number of days attributable to PTO examination delay ("**A Delay**") is **302 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 May 16, 2006. The date of mailing of the first action on the merits under 35 U.S.C. § 132 is March 13, 2007. The number of days beginning on May 16, 2006 and ending on March 13, 2007 is 302 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 '150 application (*i.e.*, March 16, 2008) and the date that a Request for Continued Examination of the '150 application was filed (*i.e.*, April 14, 2008) ("**B Delay**") is **29 days**.

21. Under 35 U.S.C. § 154(b)(2)(C), the number of days of applicant delay is 96 days. This figure is calculated as follows. An action on the merits was issued May 11, 2007, to which a response was not filed by Boehringer Ingelheim until November 8, 2007. Because this response was filed 89 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 Boehringer Ingelheim filed its response on November 8, 2007, it subsequently filed an Information Disclosure Statement on November 15, 2007. The filing of the Information Disclosure Statement constitutes an additional 7 days of delay attributable to Boehringer Ingelheim. The combined period is therefore 89 days + 7 days = **96 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 ’449 patent (*i.e.*, there is no period of “A Delay” that occurred between March 13, 2007, and March 16, 2008).

23. The ’449 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” (302 + 29 = 331 days) reduced by the number of days of applicant delay (96 days), for a net patent term adjustment of **235 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 '449 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 29 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 206 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 '449 patent is properly determined to be 235 days, as explained above.

27. The Director’s determination that the '449 patent is entitled to only 206 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**

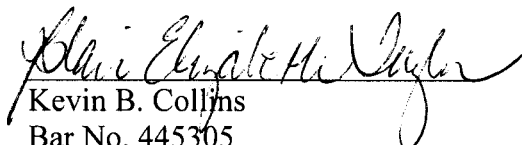
Wherefore, Plaintiffs demand judgment against Defendant and respectfully request that this Court enter Orders:

A. Changing the period of patent term adjustment for the '449 patent term from 206 days to 235 days and requiring the Director to extend the term of the '449 patent to reflect the 235 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 18, 2010

Respectfully submitted,



Kevin B. Collins

Bar No. 445305

Blair Elizabeth Taylor, Ph.D.

Bar No. 485831

COVINGTON & BURLING LLP

1201 Pennsylvania Avenue, N.W.

Washington, DC 20005

Tel: (202) 662-6000

Fax: (202) 662-6291

*Attorneys for Plaintiffs*

*Boehringer Ingelheim Pharma GmbH & Co. KG*

*Boehringer Ingelheim International GmbH*

*Boehringer Ingelheim Pharmaceuticals, Inc.*