

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

BANYU PHARMACEUTICAL CO. LTD)
Kitanomaru Square,)
1-13-12, Kudankita, Chiyoda-ku,)
Tokyo, 103-8416 Japan,)

Civil Action No. _____

MERCK SHARP & DOHME RESEARCH LTD.)
96 Pitts Bay Road)
Pembroke, HM08, Bermuda)
and)

MERCK & CO., INC.)
One Merck Drive)
Whitehouse Station, NJ 08889)

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.)

COMPLAINT

Plaintiffs Banyu Pharmaceutical Co. Ltd., Merck Sharp & Dohme Research Ltd. and Merck & Co., Inc. (collectively, "Banyu") 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. 7,521,455 (“the ’455 patent,” attached as Exhibit A) seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the ’455 patent be changed from 635 days to at least 817 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 Banyu Pharmaceutical Co., Ltd. is a company organized under the laws of Japan, having a principal place of business at Kitanomaru Square, 1-13-12, Kudankita, Chiyoda-ku, Tokyo 102-8667, Japan.

7. Plaintiff Merck Sharp & Dohme Research Ltd. is a company organized under the laws of Bermuda, having a principal place of business at 96 Pitts Bay Road, Pembroke, HM08, Bermuda.

8. Plaintiff Merck & Co., Inc. is a corporation organized under the laws of New Jersey, having a principal place of business at One Merck Drive, Whitehouse Station, NJ 08889

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. Tsuyoshi Nagase, Nagaaki Sato, Akio Kanatani, and Shigeru Tokita, are the inventors of the invention claimed in U.S. patent application number 11/058,444 (“the ’444 application”) entitled “Fused Ring 4-Oxopyrimidine Derivative,” which issued as the ’455 patent on April 21, 2009. The ’455 patent is directed to compounds having histamine H3 receptor antagonist or inverse agonist properties, which are useful for prophylaxis or therapy of metabolic diseases, circulatory diseases, or nervous system diseases. The ’455 patent is attached hereto as Exhibit A.

11. Plaintiff Banyu Pharmaceutical Co., Ltd. is the assignee of the ’455 patent, as evidenced by the assignment document recorded at Reel 016173, Frame 0543 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 '455 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 '455 patent, as determined by the Director under 35 U.S.C. § 154(b) and indicated on the face of the '455 patent, is 635 days. (*See Ex. A at 1*). The determination of this 635 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 '444 application, pursuant to 35 U.S.C. § 154(b)(1)(A). The correct patent term adjustment for the '455 patent is at least 817 days.

18. The '444 application was filed on February 14, 2005, and issued as the '455 patent on April 21, 2009.

19. Under 35 U.S.C. § 154(b)(1)(A), the number of days attributable to PTO examination delay ("A Delay") is **635** 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 '444 application (*i.e.*, February 14, 2008) and the date that the '455 patent was granted (*i.e.*, April 21, 2009) is 432 days. This total must be reduced by 250 days due to the filing by Banyu of a Request for Continued Examination on August 14, 2008. Thus, the appropriate calculation is the difference between the date the '444 application should have issued (February 14, 2008) and the actual date it issued as the '455 patent (April 21, 2009) of **432** days minus **250** days - the period between the date on which the request for Continued Examination was filed (August 14, 2008) and the date that the patent issued (April 21, 2009) - which is **182** days ("B Delay").

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 '455

patent (*i.e.*, there is no period of “A Delay” that occurred between February 14, 2008, and April 21, 2009).

23. The '455 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” ($635 + 182 = 817$ days) reduced by the number of days of applicant delay (0 days), for a net patent term adjustment of 817 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 '444 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 182 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 635 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 '455 patent is properly determined to be 817 days, as explained above.

27. The Director's determination that the '455 patent is entitled to only 635 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

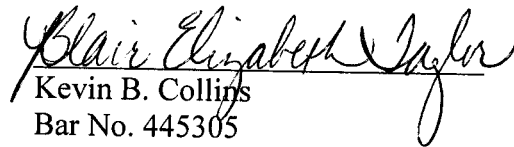
Wherefore, Plaintiffs demand judgment against Defendant and respectfully request that this Court enter Orders:

A. Changing the period of patent term adjustment for the '455 patent term from 635 days to 817 days and requiring the Director to extend the term of the '455 patent to reflect the 817 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: October 16, 2009

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

Merck & Co., Inc.

Merck Sharp & Dohme Research Ltd.

Banyu Pharmaceutical Co. Ltd.