UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK SHARP & DOHME CORP. 126 East Lincoln Avenue Rahway, NJ 07065 Plaintiff, 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

Plaintiff Merck Sharp & Dohme Corp. for its complaint against the Honorable David Kappos, states as follows:

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 7,572,922 ("the '922 patent," attached as Exhibit) seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '922 patent be changed from 537 days to at least 878 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 Merck Sharp & Dohme Corp. is a corporation organized under the laws of New Jersey, having a principal place of business at 126 Lincoln Avenue, Rahway, NJ 07065.

7. 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

8. Emma Parmee, Subhaerekha Raghavan, Teresa Beeson, and Dong-Ming Shen, are the inventors of the invention claimed in U.S. patent application number 10/543,290 ("the '290 application") entitled "Substituted Pyrazoles, Compositions Containing Such Compounds and Methods of Use," which issued as the '922 patent on August 11, 2009. The '922 patent is directed to substituted pyrazoles, which are glucagon receptor antagonists, and compositions

containing such pyrazoles that are useful in the treatment, prevention or in delaying the onset of type 2 diabetes mellitus. The '922 patent is attached hereto as Exhibit.

9. Plaintiff Merck Sharp & Dohme Corp. is the assignee of the '922 patent, as evidenced by the assignment document recorded at Reel 023870, Frame 0001 in the PTO.

10. 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."

11. 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).

12. The Director made a determination of patent term adjustment pursuant to 35 U.S.C. § 154(b)(3) and issued the '922 patent reflecting that determination.

13. 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

14. The allegations of paragraphs 1-13 are incorporated in this claim for relief as if fully set forth.

15. The patent term adjustment for the '922 patent, as determined by the Director under 35 U.S.C. § 154(b) and indicated on the face of the '922 patent, is 537 days. (*See* Ex. at 1). The determination of this 537 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 '290 application, pursuant to 35 U.S.C. § 154(b)(1)(B). The correct patent term adjustment for the '922 patent is at least 879 days.

16. The '290 patent application entered the United States as a national phase filing under 35 U.S.C. 371 of international application number PCT/US04/01927, filed January 23, 2004, which claims the benefit of priority of U.S. provisional application number 60/442,828, filed January 27, 2003. The national stage "commenced" under the provisions of 35 U.S.C. § 371(b), i.e., no later than the expiration of 30 months from the priority date of the international application. Consequently, the '290 application has a national phase filing date of July 25, 2005. This application issued as the '922 patent on August 11, 2009.

17. Under 35 U.S.C. § 154(b)(1)(A), the number of days attributable to PTO examination delay ("A Delay") is 580 days. The PTO was due to issue a first action on the merits on or before September 25, 2006, the date that is fourteen months after the date on which the application fulfilled the requirements of 35 U.S.C. § 371. The 580 day figure accounts for

PTO delay from July 26, 2005 (the day after the date that if fourteen months after the date on which the application fulfilled the requirements of 35 U.S.C. § 371) to April 8, 2008, the date the first non-final Office Action was mailed by the PTO, which equals 540 days. The PTO later delayed the issuance of the '922 patent from March 2, 2009, to July 22, 2009, adding another 40 days to the A Delay calculus. The **A Delay** due to PTO examination inaction is therefore calculated as: 540 + 40 = **580** days.

18. Under 35 U.S.C. § 154(b)(1)(B), the number of days attributable to PTO's failure to issue the '922 patent within three (3) years of application pendency ("B" Delay) is 381 days. This figure is calculated as the number of days between the date that was three years after the date national stage commenced for the '290 application (*i.e.*, July 25, 2005) and the date that the '922 patent was granted (*i.e.*, August 11, 2009). The period beginning on July 26, 2008 (the day after the date that is three years after July 25, 2005) and ending on August 11, 2009 totals **381** days of **B Delay**.

19. Under 35 U.S.C. § 154(b)(2)(C), the number of days of patent term adjustment is limited by the number of days applicant failed to engaged in reasonable efforts to conclude prosecution of the '290 application. Applicant was deemed to have been non-diligent for the submission of two Information Disclosure Statements for seven (7) days from April 28, 2008, until April 15, 2008, and for thirty-six (36) days from September 24, 2008, to October 1, 2008, totaling **Applicant delay** of **43** days.

20. 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." The A Delay accumulated as follows:

July 25, 2005 to April 8, 2008: 540 days

March 2, 2009 to August 11, 2009: 40 days

Total A Delay: 540 + 40 + 580 days

The B Delay accumulated as follows:

July 26, 2008 to August 11, 2009: 381 days

As evidenced above, the period of A Delay and the period of B Delay **overlap** (i.e. occur on the same calendar day) for a total of **40** days, from March 2, 2009 to August 11, 2009.

21. The '922 patent is not subject to a disclaimer of term.

22. 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 (580 + 381 = 961 days) reduced by the number of days of overlap (40 days), further reduced by the period of applicant delay (43 days), for a net patent term adjustment of **878** days.

23. 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 '290 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 341 days, rather than correctly determining that there was only a limit of 40

concurrent calendar days of overlap under 35 U.S.C. § 154(b)(2)(A), and arrived at an incorrect net patent term adjustment of 537 days.

24. 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. The *Wyeth* Court held that the Director has incorrectly applied the statute by 1) treating the period of B Delay as commencing upon the filing of the patent for overlap calculations, as opposed to calculating the B Delay only after the PTO has failed to issue a patent within three years, and 2) only allowing patentees the longer of an A Delay or a B Delay, but not both. This construction by the District Court was recently upheld on appeal. *Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir. Jan. 7, 2010). In accordance with *Wyeth*, the patent term adjustment for the '922 patent is properly determined to be 878 days, as explained above.

25. The Director's determination that the '922 patent is entitled to only 537 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

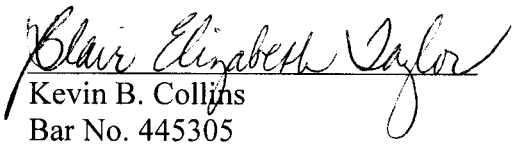
Wherefore, Plaintiff demands judgment against Defendant and respectfully requests that this Court enter Orders:

A. Changing the period of patent term adjustment for the '922 patent term from 537 days to 878 days and requiring the Director to extend the term of the '922 patent to reflect the 878 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 5, 2010

Respectfully submitted,



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