

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

SCHERING CORPORATION)
2000 Galloping Hill Road)
Kenilworth, New Jersey 07033)

and)

MERCK & CO., INC.)
2000 Galloping Hill Road)
Kenilworth, New Jersey 07033)

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 Schering Corporation and Merck & Co., Inc. (collectively, "Schering")
for their 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. 7,304,078 ("the '078 Patent," attached as the Exhibit) seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '078 Patent be changed from 358 days to 697 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 Procedure 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) 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 28 U.S.C. § 2401 and 35 U.S.C. § 154(b)(4)(A) by application of the doctrine of equitable tolling.

THE PARTIES

6. Plaintiff Schering Corporation is a corporation organized under the laws of New Jersey, having a principal place of business at 2000 Galloping Hill, Kenilworth, New Jersey, NJ 07033.

7. Plaintiff Merck & Co., Inc. is a corporation organized under the laws of New Jersey, having a principal place of business at 2000 Galloping Hill, Kenilworth, New Jersey, NJ 07033.

8. Defendant David Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office ("PTO" or "Agency"),

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

9. Samuel Chackalamannil, William J. Greenlee, Yuguang Wang, Wenxue Wu, Enrico P. Veltri, and Yan Xia are the co-inventors of the invention claimed in U.S. patent application number 10/412,982 (“the ’982 application”) entitled “Thrombin Receptor Antagonists,” which issued as the ’078 patent on December 4, 2007. The ’078 patent is directed to heterocyclic-substituted tricyclic compounds of a specified formula and pharmaceutically acceptable salts thereof. Compositions comprising the claimed heterocyclic-substituted tricyclic compounds are useful in the treatment of disease states afflicting the cardiovascular system, including - but not limited to - thrombosis, atherosclerosis, restenosis, hypertension, angina pectoris, arrhythmia, and heart failure.

10. Plaintiff Schering is the assignee of the ’078 Patent, as evidenced by the assignment document recorded at Reel 014976, Frame 0150 in the PTO.

11. 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.”

12. 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).

13. The Director made a determination of patent term adjustment pursuant to 35 U.S.C. § 154(b)(3) and issued the '078 patent reflecting that determination.

14. 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

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

16. The patent term adjustment for the '078 Patent, as determined by the Director under 35 U.S.C. § 154(b) and indicated on the face of the '078 Patent, is 358 days. (*See Ex. at 1*). The determination of this 358 day patent term adjustment is in error because the PTO failed to properly account for delays that occurred before the date that was three years after the actual filing date of the '982 application, pursuant to 35 U.S.C. § 154(b). The correct patent term adjustment for the '078 Patent is 697 days.

17. The '982 Patent application was filed April 14, 2003, and claims the benefit of priority of U.S. provisional application number 60/373,072, filed April 16, 2002. The '982 application issued as the '078 Patent on December 4, 2007.

18. Under 35 U.S.C. § 154(b)(1)(A), the total number of days attributable to PTO examination delay ("A Delay") is 564 days.

a. The PTO was due to issue a first action on the merits on or before June 15, 2004, the date that is fourteen months after the date on which the '982 application was filed (April 14, 2003). However, the PTO did not mail the first action on the merits pursuant to 35 U.S.C. § 132 until August 24, 2005. Accordingly, 436 days of term credit are due to compensate for the PTO's failure to issue an Office Action no later than 14 months after the filing date of the '078 Patent.

b. Likewise, the PTO must respond to an Applicant's reply to an Agency communication made under 35 U.S.C. § 132 not later than four months after the date on which the reply was filed. Here, Applicant filed a response to a Restriction Requirement/Election of Species on September 21, 2005, but the PTO did not respond with its non-final Office Action until May 5, 2006, 104 days after the four month response period had passed. Thus, 104 days of term must be added to compensate for the PTO's delay in mailing its response to Applicant's Election of Species.

c. In addition, the PTO was obligated to issue the '078 Patent within 4 months after the date that the issue fee was paid. Applicant paid the issue fee on July 10, 2007, and all requirements for issuance were met. The PTO should have issued the '078

Patent on November 11, 2007, but did not do so until December 4, 2007, thus incurring an additional 24 days of delay.

d. Thus, **564 days** (436 days + 104 + 24 days) of term adjustment are required to compensate for the **A Delay** attributable to PTO examination inaction.

19. Under 35 U.S.C. § 154(b)(1)(B), the number of days attributable to PTO's failure to issue the '078 Patent within three (3) years of application pendency ("B Delay") is 599 days. This figure is calculated as the number of days between the date that was three years after the date on which the '982 application was filed (*i.e.*, April 14, 2003) and the date that the '078 Patent was issued (*i.e.*, December 4, 2007). The period beginning on April 15, 2006 (the day after the date that is three years after April 14, 2003) and ending on December 4, 2007, totals 599 days. However, Applicant filed a Request for Continued Examination under 35 U.S.C. § 132(b) on April 9, 2007, which triggered a period excluded from the PTO's obligation to issue a patent within three-years of the filing of the '982 application. Therefore, the 240-day period beginning on April 9, 2007, and running through December 4, 2007 (the day the '078 Patent issued) must be subtracted from the 599 days of delay, resulting in a total of **359 days** of **B Delay**.

20. Under 35 U.S.C. § 154(b)(2)(C), the number of days of patent term adjustment is limited by the number of days that an Applicant failed to engaged in reasonable efforts to conclude prosecution on the merits.

a. Here, the Applicant filed an Information Disclosure Statement ("IDS") on November 23, 2005, following the filing of a Response to Election of Species on September 21, 2005. Pursuant to 37 C.F.R. § 1.704(c)(8), the 63-day period between the

initial response filed on September 21, 2005, and the filing of the IDS is deducted from the total adjustment of term due the '078 Patent.

b. Applicant filed a Reply after Non-final Action under 37 C.F.R. § 1.111 on August 7, 2006, which was two days after the requisite period of three months for responding to an Office Action under 35 U.S.C. § 154(b)(2)(C)(ii) had passed, adding two days to the Applicant's Delay.

c. Applicant then filed a second IDS on September 12, 2006, after filing the August 7, 2006, Reply after Non-final Action, thereby adding 36 days to the Applicant Delay calculus.

d. A Notice of Allowance was mailed on January 10, 2007. Applicant later filed a Request to Correct Inventorship on March 20, 2007, which under 35 U.S.C. § 154(b)(2)(C)(iii) and 37 C.F.R. §1.704(c)(10) incurred a 105-day period of Delay until a second Notice of Allowance issued on July 2, 2007.¹

e. The sum of Applicant actions (63 + 2 + 36 + 105) constitutes an **Applicant Delay of 206 days.**

21. 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 ...

¹ The Applicant filed a third IDS on June 20, 2007, following the submission of a Request for Continued Examination on April 9, 2007. However, because the 72-day period from June 20, 2007, until the issuance of the patent overlaps the period of additional term that is already excluded from the PTO's B Delay due to the filing of the Request for Continued Examination, this period is not included in the Applicant's Delay calculus to avoid double counting.

shall not exceed the actual number of days the issuance of the patent was delayed.” The A Delay accumulated as follows:

June 15, 2004 to August 24, 2005: 436 days

September 21, 2005 to May 5, 2006: 104 days

November 11, 2007 to December 4, 2007: 24 days

The B Delay period accumulated as follows:

April 15, 2006 to December 4, 2007: 599 days

As evidenced above, the period of A Delay and the period of B Delay overlap (*i.e.* occur on the same calendar day) between a) April 15, 2006, and May 5, 2006, (20 days) and b) November 11, 2007, and December 4, 2007 (24 days). However, the 24-day period from November 11, 2007, and December 4, 2007, was deducted from the potential additional term during the B Delay calculation, and is not deducted again in the overlap calculus to avoid double counting. Thus, the **overlap** calculation is **20 days**.

22. The '078 patent is not subject to a disclaimer of term.

23. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and § 154(b)(2) is the sum of the A Delay and B Delay ($564 + 359 = 923$ days) reduced by the number of days of A Delay and B Delay overlap (20 days), further reduced by the period of Applicant Delay (206 days) for a net patent term adjustment of **697 days**.

24. 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 '992

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 339 days, rather than correctly determining that there were only 20 concurrent calendar days of overlap under 35 U.S.C. § 154(b)(2)(A), and arrived at an incorrect net patent term adjustment of 358 days.

25. 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, for the purposes of overlap calculations, as commencing upon the filing date, as opposed to calculating the B Delay only after the PTO has failed to issue a patent within three years of filing, 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 by the United States Court of Appeals for the Federal Circuit (“Federal Circuit”). *Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir. Jan. 7, 2010). In accordance with *Wyeth*, the patent term adjustment for the ’078 Patent is properly determined to be 697 days, as explained above.

26. On information and belief, prior to the issuance of the Federal Circuit’s decision in *Wyeth*, the Director refused to calculate the patent term adjustment figure in the manner set forth above in this Complaint. Over a period of years, the PTO steadfastly adhered to its erroneous interpretation that applicants were only entitled under the statute to the longer of either an A Delay or a B Delay period. Schering was induced by the PTO’s conduct and pronouncements into believing that the law did not permit it to obtain additional patent term for both an A Delay and a B Delay, and relied to its detriment on the PTO’s representations that any attempt at further recalculation would be futile. The Federal Circuit’s contrary determination in

Wyeth - and the PTO's decision not to appeal this decision to the United States Supreme Court - resulted in a recent change of law governing the adjustment of patent term under 35 U.S.C. § 154. This change of law constitutes an extraordinary circumstance triggering the application of the doctrine of equitable tolling to the filing of this Complaint.

27. The Director's determination that the '078 Patent is entitled to only 358 days of patent term adjustment is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law by, *inter alia*, violating the Administrative Procedure Act, or is in excess of statutory jurisdiction, authority, or limitation. No public harm arises from the timing of the filing of this Complaint. Schering, acting with clean hands, timely acted after monitoring the progress of the *Wyeth* case through the PTO's decision not to seek further review by the United States Supreme Court and the Federal Circuit's mandating of the case. Furthermore, the filing of this Complaint results in no immediate prejudice to third parties, as the additional period sought will not take effect until the end of the existing term of the '078 Patent - which is currently over 12 years from now.

PRAYER FOR RELIEF

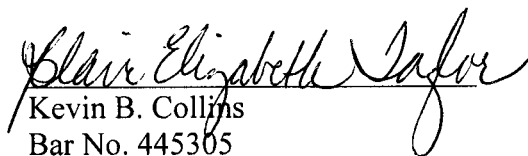
Wherefore, Schering demands judgment against Defendant and respectfully requests that this Court enter Orders:

A. Changing the period of patent term adjustment for the '078 Patent term from 358 days to 697 days and requiring the Director to extend the term of the '078 Patent to reflect the 697 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: March 1, 2011

Respectfully submitted,

A handwritten signature in cursive script that reads "Blair Elizabeth Taylor". The signature is written in black ink and is positioned above the printed name and contact information.

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