

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

\_\_\_\_\_  
SCHERING CORPORATION )  
2000 Galloping Hill Road )  
Kenilworth, NJ 07033 )

and )

MERCK & CO., INC. )  
2000 Galloping Hill Road )  
Kenilworth, NJ 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, state as follows:

**NATURE OF THE ACTION**

1. This is an action by the assignee of United States Patent No. 7,612,058 ("the '058 patent," attached as Exhibit A) seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '058 patent be changed from 899 days to 1374 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 Schering Corporation is a corporation organized under the laws of New Jersey, having a principal place of business at 2000 Galloping Hill Road, Kenilworth, 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 Road, Kenilworth, 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"), 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. Wing-Kee Philip Cho is the inventor of the invention claimed in U.S. patent application number 10/998,400 (“the ’400 application”) entitled “Methods for Inhibiting Sterol Absorption,” which issued as the ’058 patent on November 3, 2009. The ’058 patent is directed to methods of treating disease states such as vascular conditions, diabetes, and obesity by administering to a mammal a pharmaceutical composition containing acetamide and pharmaceutical excipients. The ’058 patent is attached hereto as Exhibit A.

10. Plaintiff Schering Corporation is the assignee of the ’058 patent, as evidenced by the assignment document recorded at Reel 013903, Frame 0904 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 '058 patent reflecting that determination. The patent Applicant filed a Patent Term Adjustment Petition under 37 C.F.R. § 1.705(b) on April 7, 2009, which was dismissed as premature because the '058 patent claims had been allowed, but the patent had not yet issued. On December 22, 2009, Applicant filed a Request for Reconsideration of Patent Term Adjustment in the PTO, attached as Exhibit B. That Request has yet to be acted upon by the PTO.

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 '058 patent, as determined by the Director under 35 U.S.C. § 154(b) and indicated on the face of the '058 patent, is 899 days. (*See Ex. A at 1*). The determination of this 899 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 '400 application, pursuant to 35 U.S.C. § 154(b)(1)(B). The correct patent term adjustment for the '058 patent is 1374 days.

17. The '400 patent application was filed November 29, 2004, as a divisional application of U.S. Patent number 7,030,106 filed on May 1, 2002, which is a divisional application of U.S. patent application number 10/057,323, filed on January 25, 2002. The '400 patent application claims the benefit of priority of U.S. provisional application number 60/264,396, filed January 26, 2001 and U.S. provisional application number 60/323,839, filed September 21, 2001. The '400 application issued as the '058 patent on November 3, 2009.

18. Under 35 U.S.C. § 154(b)(1)(A), the total number of days attributable to PTO examination delay ("A Delay") is 1675 days. The PTO was due to issue a first action on the merits on or before January 29, 2006, the date that is fourteen months after the date on which the '400 application was filed (November 29, 2004). However, the PTO did not mail the first action on the merits pursuant to 35 U.S.C. § 132 until July 1, 2008. Accordingly, 884 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 '058 patent. Moreover, the issue fee was paid for the '058 patent on April 9, 2009. By PTO Rules, the '058 patent should have issued no later than four months after the date on which the issue fee was paid and all outstanding requirements were satisfied, which was August 29, 2009. See 37 C.F.R. § 1.702(a)(4). The PTO issued the '058 patent 86 days later, on November 3, 2009. Thus, an additional 86 days of term must be added to the A Delay calculus to compensate for the PTO's delay in issuing the '058 patent. Taken together, the '058 patent is due the sum of these two periods or  $884 + 86 = 970$  **days** of term 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 '058 patent within three (3) years of application pendency ("B Delay") is 705 days. This figure is calculated as the number of days between the date that was three years after

the date on which the '400 application was filed (*i.e.*, November 29, 2004) and the date that the '058 patent was issued (*i.e.*, November 3, 2009). The period beginning on November 30, 2007 (the day after the date that is three years after November 29, 2004) and ending on November 3, 2009, totals **705 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 applicant failed to engaged in reasonable efforts to conclude prosecution of the '400 application. The Applicant was deemed to have been non-diligent by the PTO for the submission of a Request for a Refund. The Applicant filed this Request for a refund because the Agency improperly double-charged the Applicant for a Terminal Disclaimer fee. The Request for Refund was submitted on October 30, 2008, prior to the January 1, 2009, mailing of the Notice of Allowance for the '400 application. According to 37 C.F.R. § 1.704(c)(10), a request for a refund is among the papers which the PTO can characterize as a "failure to engage" prosecution, but only if the refund request is mailed after the Notice of Allowance has been given or mailed. Here, the Request for Refund preceded the mailing of the Notice of Allowance and, therefore, the "failure to engage" label does not apply. Thus, the PTO shortchanged the '058 patent by 35 days of term because of this refund error.

21. Furthermore, the PTO counted an amendment submitted under 37 C.F.R. § 1.312 as a source of Applicant Delay, decreasing the term of the '058 patent by an additional 36 days. This amendment was submitted by the Applicant to correct errors contained in the Examiner's Amendment and Statements for Reasons of Allowance included in the Notice of Allowance dated January 9, 2009. The Examiner corrected this oversight in his Response to Amendment under § 1.312 mailed March 20, 2009. According to 37 C.F.R. § 1.704(c)(10), the submission of an amendment correcting an error or omission in an examiner's reasons for

allowance or in a Notice of Allowance is not considered to be a failure to engage in reasonable efforts to conclude processing or examination of a patent application. Yet the PTO reduced the term of the '058 patent for precisely this reason. The PTO erred by debiting the term adjustment due the '058 patent by 35 days (request for refund) + 36 days (Rule 312 Amendment) for a total of 71 days, when the period of **Applicant Delay** is actually **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.” The A Delay accumulated as follows:

January 29, 2006 to July 1, 2008: 884 days

August 29, 2009 to November 3, 2009: 86 days

Total A Delay:  $884 + 86 = 970$  days

The B Delay accumulated as follows:

November 30, 2007 to November 3, 2009: 705 days

As evidenced above, the period of A Delay and the period of B Delay **overlap** (i.e. occur on the same calendar day), specifically for 86 days from August 29, 2009 to November 3, 2009, and for 215 days from November 30, 2007 to July 1, 2008. Thus, the **overlap** calculus is the sum of 86 days + 215 days for a total of **301 days**.

23. The '058 patent is not subject to a disclaimer of term.

24. 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 ( $970 + 705 = 1675$  days) reduced by the

number of days of overlap (301 days), further reduced by the period of Applicant Delay (0 days), for a net patent term adjustment of **1374 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 '400 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 705 days, rather than correctly determining that there was only a limit of 301 concurrent calendar days of overlap under 35 U.S.C. § 154(b)(2)(A), and arrived at an incorrect net patent term adjustment of 899 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. 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 '058 patent is properly determined to be 1374 days, as explained above.

27. The Director's determination that the '058 patent is entitled to only 899 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**

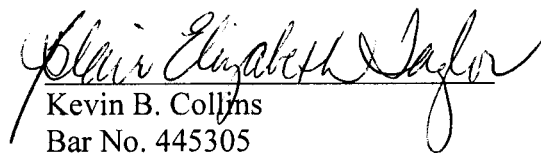
Wherefore, Schering demands judgment against Defendant and respectfully requests that this Court enter Orders:

A. Changing the period of patent term adjustment for the '058 patent term from 899 days to 1374 days and requiring the Director to extend the term of the '058 patent to reflect the 1374 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: April 30, 2010

Respectfully submitted,



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