

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

SOLVAY PHARMACEUTICALS GmbH  
Hans-Boeckler Allee 20, 30173 Hannover,  
Germany,

Plaintiff,

v.

HON. JON W. DUDAS,  
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,  
10B20, Madison Building East, 600 Dulany  
Street, Alexandria, VA 22314,

Defendant.

Civil Action No. \_\_\_\_\_

**COMPLAINT**

Plaintiff Solvay Pharmaceuticals GmbH (“Solvay”), for its complaint against the Honorable Jon W. Dudas, states as follows:

**NATURE OF THE ACTION**

1. This is an action by Solvay, the applicant and owner of United States Patent No. 7,381,729 (“the ‘729 patent”) for review of the determination by Defendant, pursuant to 35 U.S.C. § 154(b)(3)(B), of the patent term adjustment of the ‘729 patent. Plaintiff seeks a judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the ‘729 patent be changed from 534 days to 633 days.

2. This action arises under 35 U.S.C. § 154(b)(4)(A) and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

### **THE PARTIES**

3. Plaintiff Solvay is a company organized under the laws of the Federal Republic of Germany, with its principal place of business at Hans-Boeckler Allee 20, Hannover, Germany.

4. Defendant Jon W. Dudas 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 PTO and is responsible for superintending or performing all duties required by law with respect to the granting and issuing of patents, and is designated by statute as the official responsible for determining the period of patent term adjustments under 35 U.S.C. § 154(b)(3)(B).

### **JURISDICTION AND VENUE**

5. 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.

6. Venue is proper in this district by virtue of 35 U.S.C. § 154(b)(4)(A).

7. This Complaint is being timely filed in accordance with 35 U.S.C. § 154(b)(4)(A).

### **FACTS**

8. Plaintiff Solvay is the assignee of all right, title and interest in the ‘729 patent, as evidenced by records on deposit with the PTO, and is the real party in interest in this case.

9. Axel Pahl, Timo Heinrich, Emil Finner, Bernd-Martin Luitjens, Jan Zorgdrager, and Pieter C. Verveer are the inventors of patent application number 10/828,650 (“the ‘650 application”).

10. The '650 application was filed on April 21, 2004, and issued as the '729 patent on June 3, 2008. The '729 patent is attached as Exhibit A.

11. On October 11, 2006, the PTO mailed the first notification under 35 U.S.C. § 132 ("the First Office Action") as to the '650 application.

12. On July 30, 2007, Plaintiff filed with the PTO a first and only request for continued examination ("the RCE") of the '650 application.

13. On September 10, 2007, the PTO mailed a Notice of Allowance and Fees Due for the '650 application. Included in the Notice of Allowance and Fees Due was a Determination of Patent Term Adjustment in which the PTO indicated that the patent term adjustment to date for the '650 application was 477 days.

14. On December 7, 2007, Plaintiff paid the issue fee for the '650 application, thereby satisfying all outstanding requirements for issuance of a patent therefrom.

15. On December 7, 2007, Plaintiff also filed with the PTO an Application for Patent Term Adjustment requesting that the PTO change its patent term adjustment to include an additional 100 days. On March 31, 2008, the PTO held in abeyance a decision on Plaintiff's Application for Patent Term Adjustment pending the issuance of the '729 patent.

16. The '729 patent issued on June 3, 2008, indicating a patent term adjustment of 534 days, evidently reflecting the additional 57-day delay in issuing the patent beyond four months after the date on which Solvay had paid the issue fee and all outstanding requirements were satisfied, pursuant to 35 U.S.C. § 154(b)(1)(A)(iv).

17. On June 25, 2008, Plaintiff filed a Request for Reconsideration of the December 7, 2007 Application for Patent Term Adjustment, renewing its request that the PTO change its

patent term adjustment calculation for the '729 patent. The PTO dismissed Plaintiff's Request for Reconsideration on September 30, 2008.

18. 35 U.S.C. § 154(b) requires that patent terms be adjusted to compensate for failures of the PTO to take certain actions on patent applications within designated time limits. 35 U.S.C. § 154(b)(3) requires the Director of the PTO to determine the patent term adjustment for each patent.

19. In calculating the patent term adjustment, the Director must take into account PTO delays under 35 U.S.C. § 154(b)(1), any overlapping periods in the PTO delays under 35 U.S.C. § 154(b)(2)(A), and any applicant delays under 35 U.S.C. § 154(b)(2)(C).

20. Under 35 U.S.C. § 154(b)(4)(A), "[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 the grant of the patent. Chapter 7 of title 5 shall apply to such action."

#### **CLAIM FOR RELIEF**

21. The allegations of paragraphs 1-20 are incorporated in this claim for relief as if fully set forth herein.

22. The currently challenged patent term adjustment for the '729 patent, as determined by the Defendant under 35 U.S.C. § 154(b), and listed on the face of the '729 patent, is 534 days. (*See* Ex. A at p.1). This determination of the 534-day patent term adjustment is in error in that it fails to include an adjustment, as required by 35 U.S.C. § 154(b)(1)(B), for the time from three years after the filing date of the '650 application to the date the patent issued, not including the period of time following Plaintiff's request for continued examination (*i.e.*, not including the period of time between the filing of the RCE and the grant of the '729 patent). The

number of days in the period from April 21, 2007 (three years after the filing date of the ‘650 application) until July 29, 2007 (the day before the filing of the RCE) is 99 days. Therefore, the correct patent term adjustment for the ‘729 patent, including both the 534-day period determined by the PTO and this 99-day additional adjustment under 35 U.S.C. § 154(b)(1)(B), is 633 days.

23. Under 35 U.S.C. § 154(b)(1)(A), Plaintiff is entitled to an adjustment of the term of the ‘729 patent of 534 days, the number of days attributable to PTO examination delay (“A Delay”). The A Delay period consists of the following:

a. A period of 477 days pursuant to 35 U.S.C. § 154(b)(1)(A)(i) due to the PTO’s failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the actual filing date of the application. This period consists of the length of time from June 21, 2005 (14 months after the filing date of the ‘650 application) to October 11, 2006 (the mailing date of the First Office Action).

b. A period of 57 days pursuant to 35 U.S.C. § 154(b)(1)(A)(iv) due to the PTO’s failure to issue the ‘729 patent within four months after the date the issue fee was paid. This period consists of the length of time from April 7, 2008 (four months after the date the issue fee was paid) to June 3, 2008 (the date the ‘729 patent issued).

24. Under 35 U.S.C. § 154(b)(1)(B), Plaintiff is entitled to an additional adjustment of the term of the ‘729 patent of 99 days, the number of days attributable to the PTO’s “failure . . . to issue a patent within 3 years after the actual filing date of the [‘650] application,” but not including “any time consumed by continued examination of the application requested by the applicant under section 132 (b)” (“B Delay”). The B Delay period therefore consists of the period commencing April 21, 2007 (three years after the filing date of the ‘650 application) until

the issue date of the '729 patent, excluding the period between July 29, 2007 (the day before the filing date of the RCE) and June 3, 2008 (the issue date of the '729 patent).

25. 35 U.S.C. § 154(b)(2)(A) states that “to the extent . . . periods of delay attributable to grounds specified in paragraph [154(b)(1)] overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” For the '729 patent, none of the A Delay period overlaps with the B Delay period. Therefore, there is no period of overlap to be excluded from the determination of patent term adjustment for the '729 patent under 35 U.S.C. § 154(b)(2)(A).

26. Thus the total period of PTO delay is 633 days, the sum of the period of A Delay (534 days) and the period of B Delay (99 days).

27. As determined by the Defendant, there was no period of applicant delay under 35 U.S.C. § 154(b)(2)(C) that would reduce the period of PTO delay.

28. Accordingly, the correct patent term adjustment for the '729 patent under 35 U.S.C. §§ 154(b)(1) and (2) is 633 days.

29. Defendant's determination that the period of the patent term adjustment for the '729 patent is only 534 days, his failure to include in the patent term adjustment the 99 days required by 35 U.S.C. § 154(b)(1)(B) and his refusal to reconsider the patent term adjustment of the '729 patent are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

30. Moreover, Defendant's determination that the period of the patent term adjustment for the '729 patent is only 534 days is in conflict with this Court's judgment in Wyeth v. Dudas, Civ. Action No. 1:07-cv-01492-JR, 2008 WL 4445642 (D.D.C. Sept. 30, 2008),

which explains the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b).

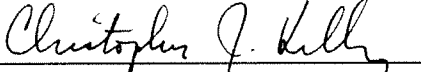
WHEREFORE, Plaintiff respectfully prays that this Court:

A. Issue an Order changing the period of patent term adjustment for the '729 patent from 534 days to 633 days, and requiring Defendant to alter the term of the '729 patent to reflect the 633-day patent term adjustment; and

B. Grant such other and further relief as the nature of the case may admit or require and as may be just and equitable.

Respectfully submitted,

Dated: November 26, 2008

  
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