

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

PURAC BIOCHEM B.V. )  
Arkelsedijk 46 )  
P.O. Box 21 )  
4200 AA Gorinchem )  
The Netherlands )

Plaintiff, )

v. )

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

HON. JON W. DUDAS )  
Under Secretary of Commerce for Intellectual )  
Property and Director of the United States )  
Patent and Trademark Office )  
Madison Building )  
600 Dulany Street )  
Alexandria, VA 22314 )

Defendant. )

**COMPLAINT**

Plaintiff PURAC Biochem B.V., for its complaint against defendant the Honorable Jon W. Dudas, states as follows:

1. This is an action by the owner of United States Patent No. 7,410,556 seeking review of inaccurate and erroneous patent term adjustment calculations made by the United States Patent & Trademark Office ("PTO"). Specifically, this is an action by Plaintiffs under 35 U.S.C. § 154(b)(4)(A) seeking a judgment that the patent term adjustment of 386 days calculated by the PTO for the '556 patent should be corrected to 949 days.
2. This action arises under 35 U.S.C. § 154 and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

## I. THE PARTIES

3. Plaintiff PURAC Biochem B.V. (“PURAC”) is a company operating under the laws of The Netherlands. PURAC is located at Arkelsedijk 46, P.O. Box 21, 4200 AA Gorinchem, The Netherlands.
4. Defendant Jon W. Dudas is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office. Defendant is sued in his official capacity.

## II. JURISDICTION AND VENUE

5. This Court has jurisdiction over this action and is authorized to issue the requested relief to Plaintiffs 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 pursuant to 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).

## III. BACKGROUND

8. The ‘556 patent issued to Hendrik Martinus Winkelaar; Jan Van Breugel; Camprubi Vila; Margarita; Jose Maria Vidal Lancis on August 12, 2008, based on patent application number 10/130,990 which entered the national stage under 35 U.S.C. § 371 October 1, 2002. The ‘556 patent is attached hereto as Exhibit A.
9. Plaintiff PURAC is the assignee of the ‘556 patent, as evidenced by records recorded in the PTO, and is the real party in interest in this case. PURAC is a division of CSM NV, a

company operating under the laws of The Netherlands. CSM NV is located at P.O. Box 349, 1000 AH Amsterdam, Nienoord 13, 1112 XE Diemen, The Netherlands

10. When the USPTO issued the '556 patent on August 12, 2008, it erroneously calculated the entitled patent term adjustment for the '556 patent as 386 days. Had the USPTO calculated the entitled patent term adjustment properly, the '556 patent would be entitled to 949 days of patent term adjustment.
11. The errors in the USPTO's patent term adjustment calculations are detailed in a recent order from the U.S. District Court for the District of Columbia in an action titled *Wyeth v. Dudas*, Civil Action No. 07-1492 (D.D.C. Sept. 30, 2008) where the Court granted summary judgment against the USPTO, holding that the USPTO's patent term adjustment calculation methodology was erroneous as a matter of law and inconsistent with the Patent Statute. The *Wyeth v. Dudas* opinion is attached as Exhibit B.
12. The correct patent term adjustment methodology identified in the prior *Wyeth v. Dudas* action governs the USPTO's calculation of patent term adjustment for Plaintiff's '556 patent.

#### **IV. COUNT I: U.S. PATENT NO. 7,410,556**

13. Plaintiff incorporates by reference the allegations in paragraphs 1-12 above, as if fully set forth herein.
14. During prosecution of the '556 patent, the patent owner accrued 654 days of patent term adjustment under 35 USC § 154(b)(1)(A), and accrued 563 days of patent term adjustment under 35 USC 154(b)(1)(B).

15. Under the PTO's interpretation of 35 USC § 154, all PTA accrued under 35 U.S.C. § 154(b)(1)(A) and all PTA accrued under 35 USC § 154(b)(1)(B) inherently overlaps and, thus, it has been the PTO position that a patent holder is only eligible for the larger of these two amounts of PTA, 654 days. For the '556 patent, the PTO erroneously limited the patent term adjustment for the '556 patent to 386 days (*see* calculation in paragraph 21, below), as shown on the face of the '556 patent.
16. In view of a recent decision from the this Court (*Wyeth v. Dudas*, Civil Action No. 07-1492 (JR)), all days on which 35 USC 154(b)(1)(A) or 35 USC 154(b)(1)(B) apply should accrue patent term adjustment for the '556 patent.
17. Each day from the day after December 1, 2003 (14 months from the National Stage Entry) through to the issuance of a Non-Final Office Action on September 15, 2005 qualify for patent term adjustment under 35 U.S.C. § 154(b)(1)(A), a total of 654 days.
18. Furthermore, each day from the day after October 1, 2005 (3 years from meeting all 35 USC 371 Requirements on National Stage entry of PCT application PCT/NL2000/000865) through to the filing of a Request for Continued Examination on April 17, 2007, qualify for patent term adjustment under 35 U.S.C. § 154(b)(1)(B), a total of 563 days.
19. Under the interpretation of this Court (*Wyeth v. Dudas*, Civil Action No. 07-1492 (JR)), these periods do no not overlap, and the total PTO prosecution delay is accordingly  $563 + 654 = 1,217$  days.

20. Plaintiff agrees with the PTO's holding of a total applicant prosecution delay of 268 days under 35 USC 154(b)(2)(B) or (C).
21. Under the PTO's interpretation, the PTO had calculated an erroneous patent term adjustment of  $654-268 = 386$  days.
22. It is accordingly believed that the overall PTA accrued by the patent holder is  $1,217 - 268 = 949$  days, and the patent holder accordingly requests  $949-386 = 563$  **ADDITIONAL days** of Patent Term Adjustment.

WHEREFORE, Plaintiff respectfully prays that this Court:

- A. Issue an Order changing the period of patent term adjustment for the '556 patent term from 386 days to 949 days and requiring Defendant to alter the terms of the '556 patent to reflect the 949 days of actual patent term adjustment due the '556 patent.
- B. Grant such other and further relief as the nature of the case may admit or require and as may be just and equitable.

Dated: December 1, 2008

Respectfully submitted,



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