

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

**FILED**

**JAN 29 2010**

**Clerk, U.S. District and  
Bankruptcy Courts**

NOVARTIS AG, Lichstrasse 35  
CH-4056, Basel, Switzerland

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  
Dulany Street, Alexandria, VA 22314

Defendant.

Case: 1:10-cv-00164  
Assigned To : Collyer, Rosemary M.  
Assign. Date : 1/29/2010  
Description: General Civil

**COMPLAINT**

Plaintiff Novartis AG, for their complaint against the Honorable David Kappos, state as follows:

**NATURE OF THE ACTION**

1. This is an action by applicants of United States Patent Nos. 7,569,337 (the “337 patent”) seeking review of the denial of the correct patent term adjustments for this patent by the defendant Director of the United States Patent and Trademark Office (“PTO”). Plaintiff is seeking a judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the ‘337 patent be changed from 640 days to 1257 days.

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

### **THE PARTIES**

3. Plaintiff Novartis AG is a corporation organized under the laws of Switzerland, having a principal place of business at Lichstrasse 35, CH-4056, Basel, Switzerland.

4. Defendant David Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the 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.

### **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 APPLICABLE TO ALL COUNTS**

8. Yves Auberson is the inventor of patent application number 10/506,381 (“the ‘381 application”), which issued as the ‘337 patent. The ‘337 patent is attached hereto as Exhibit A.

9. Plaintiff Novartis AG is the assignee of the '337 patent, as evidenced by records recorded in the PTO, and is the real party in interest in this case.

10. Section 154 of 35 U.S.C. 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 calculating the patent term adjustment, the Director has to 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).

12. 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.”

### **FIRST CLAIM FOR RELIEF**

13. The allegations of paragraphs 1-12 are incorporated in this claim for relief as if fully set forth.

14. The patent term adjustment for the '337 patent, as determined by the defendant under 35 U.S.C. § 154(b), and listed on the face of the '337 patent, is 640 days. (See Ex. A at p. l). The determination of the 640 day patent term adjustment is in error in that pursuant to 35 U.S.C. § 154(b)(1)(A) and § 154(b)(1)(B), the PTO failed to allow an adjustment for the sum of time for each delay under § 154(b)(1)(A) and § 154(b)(1)(B), to the extent that the delay for each

occurs on different days such that those days do not overlap. The correct patent term adjustment for the '337 patent is 1257 days.

15. The '381 application was filed on September 2, 2004 and issued as the '337 patent on August 4, 2009.

16. Under 35 U.S.C. § 154(b)(1)(A), the following periods of time are attributable to PTO examination delay:

- a. A period of 642 days under 35 U.S.C. § 154(b)(1)(A)(i) due to failure by the PTO to mail an action under 35 U.S.C. § 132 not later than 14 months after the actual filing date of the application (*i.e.*, by November 2, 2005).
- b. A period of 89 days under 35 U.S.C. § 154(b)(1)(A)(ii) due to the failure by the PTO to respond to a reply under section 132 within 4 months after the date on which the reply was filed ("4 Month Examination Delay").
- c. Thus, the total period of PTO examination delay under 35 U.S.C. § 154(b)(1)(A) is 731 days, which is the period of 14 Month Delay (*i.e.*, 642 days) and the period of 4 Month Examination Delay (*i.e.*, 89 days).

17. Under 35 U.S.C. § 154(b)(1)(B), the plaintiffs are entitled to an additional adjustment of the term of the '337 patent of a period of 702 days, which is the number of days the issue date of the '337 patent exceeds three years from the filing date of the application ("Three Year Delay"). The Three Year Delay for the '337 patent corresponds to the period of time from September 2, 2007 (*i.e.*, three years after the filing date) to August 4, 2009 (*i.e.*, the patent grant date).

18. 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 subsections shall not exceed the actual number of days the issuance of the patent was delayed.” Of the delays attributable to the PTO for the ‘337 patent, only the 89 day period of the 4 Month Examination Delay from March 2, 2009 to May 30, 2008 overlap with the Three Year Delay period (September 2, 2007 to August 4, 2009). This overlapping period is not included in the adjustment sought by plaintiffs.

19. Thus, the total period of PTA delay is 1344 days, which is the sum of the period of PTA examination delay (731 days) and the period of the Three Year Delay (702 days) reduced by the period of overlap (89 days).

20. Under 35 U.S.C. § 154(b)(2)(C), the total period of PTA delay is reduced by the period of applicant delay, which is 87 days as determined by the PTO.

21. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is 1257 days, which is the difference between the total period of PTA delay (1344 days) and the period of applicant delay (87 days).

22. On October 2, 2009, patentees timely filed a Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. § 1.705(d) (“Request for Reconsideration”) for the ‘337 patent, requesting that they be granted a corrected final patent term adjustment of 1249 days.<sup>1</sup> The Request for Reconsideration was dismissed on December 22, 2009.

23. On January 29, 2010, patentees filed a Second Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. § 1.705(d) (“Second Request for Reconsideration”) for the ‘337 patent, requesting that they be granted a corrected final patent term adjustment of 1257

---

<sup>1</sup> Patentee in the Request for Reconsideration inadvertently entered the filing Date as September 6, 2004 and not September 2, 2004. Therefore, the Patentee’s calculation of Patent Term Adjustment was incorrect by eight (8) days. Patentees have since corrected this error in the Second Request for Reconsideration.

days and in compliance with the decision by the Court of Appeals for the Federal Circuit in *Wyeth v. Dudas*. The Second Request for Reconsideration is currently pending before the PTO.

24. The '337 patent is not subject to a terminal disclaimer.

25. The defendant's denial of the full patent term adjustment of 1257 days under 35 U.S.C. § 154(b) for the '337 patent is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.


WHEREFORE, Plaintiffs respectfully pray that this Court:

26. Issue an Order changing the period of patent term adjustment for the '337 patent term from 640 days to 1257 days and requiring defendant to alter the terms of the '337 patent to reflect the 1257 day patent term adjustment.

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

Dated: January 29, 2010

Respectfully Submitted,

A handwritten signature in black ink, appearing to read 'John R. Fuisz', is written over a horizontal line. A checkmark is visible to the right of the signature.

John R. Fuisz (DC Bar No.: 439698) ✓  
1455 Pennsylvania Avenue, NW  
Suite 400  
Washington, DC 20004  
Phone: (202) 621-1889  
Fax: (202) 621-1844

*Attorneys for Plaintiff Novartis AG*

*Of Counsel*

Paul D. Strain

Dean L. Fanelli

Thomas A. Haag

Fanelli Strain & Haag PLLC

1455 Pennsylvania Avenue, NW

Suite 400

Washington, DC 20004

Phone: (202) 621-1840

Fax: (202) 621-1844

*Attorneys for Plaintiff Novartis AG*