

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

Syntonix Pharmaceuticals, Inc.)
9 Fourth Avenue,)
Waltham, MA 02451)

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)
Madison Building East, Rm. 10B20)
600 Dulany Street, Alexandria, VA 22314)

Defendant.)

COMPLAINT

Plaintiff, Syntonix Pharmaceuticals, Inc., for its complaint against the Honorable Jon. W. Dudas, states as follows:

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 7,404,956 (“the ’956 patent”) seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the ’956 patent be changed from 423 days to at least 752 days.

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 Syntonix Pharmaceuticals, Inc. is a corporation organized under the laws of Massachusetts, having a principal place of business at 9 Fourth Street, Waltham, MA 02451.

7. 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 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

8. Robert Peters, Adam Mezo, Daniel Rivera, Alan Bitonti, and Susan Low are the inventors of U.S. patent application number 10/841,250 (“the ’250 application”) entitled “Immunoglobulin Chimeric Monomer-Dimer Hybrids,” which was issued as the ’956 patent on July 29, 2008. The ’956 patent claims compositions comprising a single biologically active molecule linked to an immunoglobulin constant region. The ’956 patent is attached as Exhibit A.

9. Plaintiff Syntonix Pharmaceuticals Inc is the assignee of the ’956 patent, as evidenced by the assignment documents recorded in the PTO.

10. 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.”

11. 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).

12. The Director made a determination of patent term adjustment pursuant to 35 U.S.C. § 154(b)(3) and issued the ’956 patent reflecting that determination.

13. 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

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

15. The patent term adjustment for the ’956 patent, as determined by the Director under 35 U.S.C. § 154(b) and indicated on the face of the ’956 patent, is 423 days. (*See* Ex. A at

1.) The determination of this 423 day patent term adjustment is in error because the PTO failed to properly account for the delays that occurred before the date that was three years after the actual filing date of the '250 application, pursuant to 35 U.S.C. § 154(b)(1)(A). The correct patent term adjustment for the '956 patent is at least 752 days.

16. The '250 application was filed on May 6, 2004, and issued as the '956 patent on July 29, 2008.

17. Under 35 U.S.C. § 154(b)(1)(A), the number of days attributable to PTO examination delay ("A Delay") is 329 days.

18. Under 35 U.S.C. § 154(b)(1)(B), the number of days between the date that was three years after the actual filing date of the '250 application (*i.e.*, May 6, 2007) and the date that the '956 patent was granted (*i.e.*, July 29, 2008) ("B Delay") is 450 days.

19. Under 35 U.S.C. § 154(b)(2)(C), the number of days of applicant delay is 27 days.

20. 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 overlap between the "A Delay" period and the "B Delay" period in the prosecution of the '956 patent (*i.e.*, the period of "A Delay" that occurred between May 6, 2007 and July 29, 2008) is 0 days.

21. The '956 patent is not subject to a disclaimer of term. Thus the period of patent term adjustment is not limited under 35 U.S.C. § 154(b)(2)(B).

22. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is the sum of the "A Delay" and "B Delay" ($329 + 450 = 779$ days) reduced by the number of days of applicant delay (27 days) for a net adjustment of 752 days.

23. The Director erred in the determination of patent term adjustment by treating the entire period of PTO examination delay, and not only the period of PTO examination delay that occurred after the date that was three years after the actual filing date of the '250 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 329 days, rather than the correct number of 0 days, and arrived at a net patent term adjustment of 423 days.

24. 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. In accordance with *Wyeth*, the patent term adjustment for the '956 patent is properly determined to be 752 days, as set forth above.

25. The Director's determination that the '956 patent is entitled to only 423 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

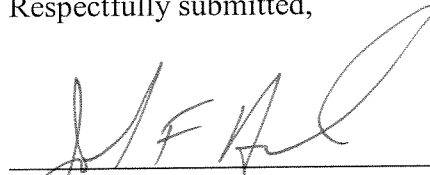
Wherefore, Plaintiff demands judgment against Defendant and respectfully requests that this Court enter Orders:

A. Changing the period of patent term adjustment for the '956 patent term from 423 days to 752 days and requiring the Director to extend the term of the '956 patent to reflect the 752 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: January 16, 2009

Respectfully submitted,



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