

FILED

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA**

2012 DEC 17 P 3:28

CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

INTREXON CORPORATION,

1750 Kraft Drive
Suite 1400
Blacksburg, Virginia 24060

Plaintiff,

v.

HON. DAVID KAPPOS,

Under Secretary of Commerce for Intellectual
Property and Director of the United States
Patent and Trademark Office,

P.O. Box 1450
Alexandria, VA 22313

and

401 Dulany Street
Alexandria, Virginia 22314

Office of General Counsel, United States
Patent and Trademark Office,

P.O. Box 15667,
Arlington, Virginia 22215

and

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

Defendant.

Civil Action No.:

1:12cv1451

LMB/JFA

COMPLAINT

Plaintiff Intrexon Corporation, for its Complaint against the Honorable David Kappos, in his official capacity as Under Secretary of Commerce for Intellectual Property and as Director of the United States Patent and Trademark Office (the "Director"), alleges as follows:

NATURE OF THE ACTION

1. Intrexon owns the entire right, title, and interest in and to U.S. Patent No. 8,236,556 (“the ’556 patent”), entitled “Method of Modulating Gene Expression Using An Ecdysone Receptor-Based Inducible Gene Expression System.” The named inventors of U.S. Patent Application No. 11/841,597 (“the ’597 application”) are Marianna Zinovjevna Kapitskaya and Subba Reddy Palli. The ’597 application issued as the ’556 patent on August 7, 2012. A true and correct copy of the ’556 patent is attached to this Complaint as Exhibit A.

2. This is an action by Intrexon for review of the Director’s wrongful determination of the patent-term adjustment for the ’556 patent, incorrectly set at zero days, pursuant to 35 U.S.C. § 154(b)(3)(B). Intrexon seeks a judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent-term adjustment for the ’556 patent be changed from zero days to 551 days.

3. 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

4. Intrexon is a Virginia corporation, organized under the laws of the Commonwealth of Virginia, with its principal place of business at 1750 Kraft Drive, Suite 1400, Blacksburg, Virginia 24060.

5. The Director 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

6. This Court has subject matter jurisdiction over this action and is authorized to issue the requested relief 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.

7. Venue is proper in this district pursuant to 35 U.S.C. § 154(b)(4)(A).

8. This Complaint is timely filed within 180 days of the grant of the '556 patent in accordance with 35 U.S.C. § 154(b)(4)(A).

**LEGAL FRAMEWORK FOR
CALCULATING PATENT-TERM ADJUSTMENTS**

9. Section 154 of Title 35 of the United States Code requires the Director of the United States Patent and Trademark Office (“USPTO”) to grant a patent-term adjustment in accordance with the provisions of section 154(b). Under, 35 U.S.C. § 154(b)(3)(D), “[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.”

10. In calculating the patent-term adjustment, the Director is required to take into account USPTO delays under 35 U.S.C. § 154(b)(1), any overlapping periods in the USPTO delays under 35 U.S.C. § 154(b)(2)(A), and any applicant delays under 35 U.S.C. § 154(b)(2)(C).

11. 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 Eastern District of Virginia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action.”

CLAIM FOR RELIEF

12. The allegations of paragraphs 1-11 above are repeated and re-alleged as if set forth fully herein.

A. The Director's Inaccurate Calculation For The Patent-Term Adjustments.

13. The patent-term adjustment for the '556 patent, as determined by the Director under 35 U.S.C. § 154(b) and stated on the face of the '556 patent, is zero days. *See* Exhibit A at 1. The Director's determination of the zero-day patent-term adjustment is wrong because the Director ignored the requirement set forth in 35 U.S.C. § 154(b)(1)(B) to account properly for the delays that occurred three years after the actual filing date of the '597 application.

B. The Correct Calculation For The Patent-Term Adjustments.

14. The correct patent-term adjustment for the '556 patent is 551 days. The '597 application was filed on August 20, 2007, and later issued as the '556 patent on August 7, 2012.

1. The "A Delay Period"

15. Under 35 U.S.C. § 154(b)(1)(A), the number of days attributable to the USPTO examination delay ("A Delay") is 94 days due to the USPTO's failure to adhere to 35 U.S.C. § 132 and 1) mail an office action within 14 months of the date on which the '597 application was filed and 2) mail a response to a reply under section 132 within four months. In this case, the A Delay period consists of the 84 days from October 20, 2008 (14 months after August 20, 2007, the filing date of the '597 application) to January 12, 2009 (the mailing date of the Restriction/Election Requirement) and 10 days from October 11, 2009 (4 months after June 11, 2009, the filing date of the Response to Election/Restriction) to October 21, 2009 (the mailing date of a Non-Final Rejection).

2. *The “B Delay Period”*

16. Under 35 U.S.C. § 154(b)(1)(B), Intrexon is entitled to an additional adjustment of the term of the '556 patent for the number of days attributable to the USPTO's "failure . . . to issue a patent within 3 years after the actual filing date of the application in the United States" ("B Delay"). *See also* 37 C.F.R. § 1.703(b). The B Delay period consists of the period commencing August 20, 2010 (three years after the filing date of the '597 application), until August 7, 2012 (the issue date of the '556 patent). The B Delay is 718 days.

3. *Appropriate Deductions and Limitations*

17. Under 35 U.S.C. § 154(b)(2)(C), the number of days of applicant delay is 261 days. The Director calculated that the applicant delay was 248 days. The Director, however, did not include the 13-day time period between January 21, 2010 (applicant filed a timely reply to a non-final office action, 3 months from the office action) and February 3, 2010 (applicant filed an Information Disclosure Statement) as applicant delay. Pursuant to 35 U.S.C. § 154(b)(2)(C)(iii), "[t]he Director shall proscribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application." 37 C.F.R. § 1.704(8) states that a "[c]ircumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application also include the following circumstances . . . [s]ubmission of a supplemental reply or other paper, . . . after a reply has been filed." Because the applicant filed an Information Disclosure Statement 13 days after the applicant's reply to a non-final office action, this delay should be included as part of the applicant delay. Thus, the total applicant delay is 261 days.

18. 35 U.S.C. § 154(b)(2)(A) states that "to the extent that 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 ’556 patent, there was no overlap between the periods of Office delay under 35 U.S.C. §§ 154(b)(1)(A) and 154(b)(1)(B). Therefore, in the absence of an overlap period, zero days should be excluded from the determination of patent-term adjustment for the ’556 patent.

19. 35 U.S.C. § 154(b)(2)(B) states that “[n]o patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.” The ’556 patent is not subject to a terminal disclaimer. Thus, 35 U.S.C. § 154(b)(2)(B) does not restrict the patent-term adjustment of the ’556 patent.

4. *Applying the Formula Correctly*

20. The patent-term adjustment under 35 U.S.C. § 154(b)(1) is the sum of the “A Delay” and “B Delay” ($94 + 718 = 812$) reduced by the number of days for applicant delay (261 days) and overlap days (0 days) ($812 - 261 = 551$).

21. Accordingly, the correct patent-term adjustment for the ’556 patent is 551 days.

5. *The Director’s Calculations Ignore This Court’s Holding On The Correct Way to Calculate Patent-Term Adjustments.*

22. The Director’s determination that the period of patent-term adjustment for the ’556 patent is zero days conflicts with this Court’s judgment in *Exelixis, Inc. v. Kappos*, No. 1:12-cv-00096, ECF No. 29, (E.D. Va. Nov. 1, 2012). The Director erred in the determination of patent-term adjustment by not including the time after applicant filed a Request for Continued Examination.

23. In *Exelixis*, this Court explained the proper construction of the provisions of 35 U.S.C. § 154(b) for patent-term adjustment. In accordance with *Exelixis*, the patent-term adjustment for the ’556 patent is properly determined to be 551 days, as set out above.

24. The Director's determination that the '556 patent is entitled to zero days of patent-term adjustment is arbitrary, capricious, an abuse of discretion, not in accordance with the law, and in excess of statutory jurisdiction, authority, or limitation.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Intrexon respectfully prays that this Court:

A. Issue a Judgment changing the period of patent-term adjustment for the '556 patent from zero days to 551 days and requiring the Director to alter the term of the '556 patent to reflect the 551-day patent-term adjustment; and

B. Award Intrexon any further relief that this Court may deem appropriate.

Respectfully submitted,

INTREXON CORPORATION

Date: December 17, 2012

By:

A handwritten signature in black ink, appearing to read 'B. Pickard', written over a horizontal line.

Byron L. Pickard (VSB No. 42786)

Email: bpickard@skgf.com

K. Courtney Macdonald (VSB No. 77014)

Email: cmacdonald@skgf.com

STERNE, KESSLER, GOLDSTEIN & FOX PLLC

1100 New York Avenue, NW

Washington, D.C. 20005-3934

Telephone No.: (202) 371-2600

Facsimile No.: (202) 371-2540

Attorneys for Plaintiff

Of Counsel:

Rob W. Esmond

Email: resmond@skgf.com

Grant E. Reed

Email: gereed@skgf.com

STERNE, KESSLER, GOLDSTEIN & FOX PLLC

1100 New York Avenue, NW

Washington, D.C. 20005-3934

Telephone No.: (202) 371-2600

Facsimile No.: (202) 371-2540

Attorneys for Plaintiff