

FILED

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
Alexandria Division**

2012 DEC -7 P 3:56

CLERK OF DISTRICT COURT
ALEXANDRIA, VIRGINIA

THE REGENTS OF THE UNIVERSITY OF)
CALIFORNIA)
1111 Franklin Street, 12th Floor)
Oakland, CA 94607)

Plaintiff,)

v.)

HON. DAVID J. KAPPOS)
In His Official Capacity As Under Secretary of)
Commerce for Intellectual Property and)
Director of the United States Patent and)
Trademark Office.)
Office of the General Counsel,)
United States Patent and Trademark Office)
P.O. Box 14557, Arlington, VA 22215)
Madison Building East, Room 10B20)
600 Dulany Street, Alexandria, VA 22314.)

Defendant.)

Civil Action No. 1:12cv 1410

LMB/JFA

COMPLAINT

Plaintiff, the Regents of the University of California (“Regents”), for this complaint against the Defendant Honorable David Kappos in his official capacity as the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, state as follows:

NATURE OF THE ACTION

1. This is an action by the exclusive assignee of United States Patent No. 8,197,872 (“the ‘872 patent”) for review of the determination by Defendant pursuant to 35 U.S.C. § 154, of

the patent term accorded the '872 patent. Plaintiff seeks a judgment pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment of the '872 patent be changed from 631 days to at least 848 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 Regents is a corporation organized under the laws of California, having a principal place of business at 1111 Franklin Street, 12th Floor, Oakland, CA 94607.

4. Defendant David Kappos ("the Director") 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 and performing all duties required by law with respect to the granting and issuing of patents. The Director is designated by statute as the official responsible for determining the period of patent term adjustment 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 by Plaintiff 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 the Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 9, 125 Stat. 361 (2011).

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

BACKGROUND

8. Regents of the University of California is the owner by assignment of all right,

title and interest in the '872 patent, as evidenced by the face of the '872 patent and records recorded in the PTO at Reel/Frame 022009/0592. As such, Regents is the real party in interest in this case.

9. David A. Mills, Carlito B. Lebrilla, Riccardo Locascio, Milady Ninonuevo, J. Bruce German, and Samara Freeman are the inventors of the claims of U.S. patent application number 12/121,683 ("the '683 application"), filed on May 15, 2008, entitled "Human Milk Oligosaccharides To Promote Growth Of Beneficial Gut Bacteria," which issued on June 12, 2012, as the '872 patent. A copy of the '872 patent is attached hereto as Exhibit A.

10. On January 19, 2011, the PTO mailed its first notification regarding the '683 application under 35 U.S.C. § 132.

11. On August 4, 2011, the PTO mailed a Final Rejection of the '683 application. The mailing date of the Final Office Action was after May 15, 2011, over three years from the filing date of the '683 application.

12. Plaintiff filed an Amendment, Declaration under 37 C.F.R. § 1.131 with Exhibits A-D and a Request for Continued Examination ("RCE") under 35 U.S.C. § 132(b) on November 9, 2011.

13. On February 17, 2012, the PTO mailed a Notice of Allowance and Fees Due for the '683 application (the "Notice of Allowance"). Included in the Notice of Allowance was a Determination of Patent Term Adjustment ("PTA") wherein the PTO indicated that the PTA to date for the '683 application was 478 days.

14. On May 14, 2012, Regents paid the issue fee for the '683 application.

15. On May 23, 2012, the PTO mailed an Issue Notification for the '683 application wherein the Determination of Patent Term Adjustment indicated the PTA for the '683

application was 631 days.

16. The '872 patent issued on June 12, 2012 and is not subject to a terminal disclaimer.

PATENT TERM GUARANTEE

17. 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.”

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

19. The Director made a determination of patent term adjustment pursuant to 35 U.S.C. § 154(b)(3) and on June 12, 2012, the '872 patent issued with a patent term adjustment of 631 days listed on the face of the patent.

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.”

CLAIMS FOR RELIEF

COUNT ONE

(Patent Term Adjustment under 35 U.S.C. § 154)

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

22. The patent term adjustment for the '872 patent, as determined by the Director under 35 U.S.C. § 154(b), and listed on the face of the '872 patent, is 631 days. (*See* Ex. A at 1). The determination of the 631 days is in error because the PTO failed to properly account for the additional 217-day period from when Plaintiff filed the RCE to the date of issuance. *See* PTO calculation of PTA from PAIR "Patent Term Adjustments", attached as Exhibit B.

23. The '683 application was filed on May 15, 2008, and issued as the '872 patent on June 12, 2012.

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

- a. A single period of 553 days, from July 15, 2009 to January 19, 2011, due to failure by the PTO to mail an action under 35 U.S.C. § 132 not later than fourteen months after the actual filing date of the application.

25. Under 35 U.S.C. § 154(b)(1)(B), Regents is also entitled to additional patent term adjustment of the '872 patent of a period of 394 days, which is the number of days beyond three years after the actual filing date of the '683 application (*i.e.*, May 15, 2011) until issuance of the patent on June 12, 2012 ("B Delay").

26. 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.” There is no overlap between the delays attributable to the PTO (“A Delay”) for the ‘872 patent and the three year delay (“B Delay”) period in the patent term adjustment sought by the Plaintiff.

27. The total period of PTO delay is 947 days, which is the sum of the period of PTO examination delay (“A Delay,” 553 days) and the period of the Three Year Delay (“B Delay,” 394 days).

28. Under 35 U.S.C. § 154(b)(2)(C), the total period of PTO delay is reduced by the number of days of applicant delay which is determined as 99 days as follows for the ‘872 patent:

- a. A period of 62 days, from April 19, 2011 to June 20, 2011, due to failure of applicants’ timely response to the PTO’s action within three months (*i.e.*, PTO action mailed on January 19, 2011).
- b. A period of 8 days, from June 20, 2011 to June 28, 2011, due to applicants’ submission of a supplemental response (Information Disclosure Statement) after a reply was initially filed in response to the PTO’s action (*i.e.*, Applicant response to PTO action filed June 20, 2011).
- c. A period of 5 days, from November 4, 2011 to November 9, 2011, due to failure of applicants’ timely response to the PTO’s action within three months (*i.e.*, PTO action mailed on August 4, 2011).
- d. A period of 24 days, inclusive, between February 27, 2012 to March 21, 2012, for applicants’ submission of an Amendment under 37 C.F.R. 1.312 after the mailing of a Notice of Allowance under 35 U.S.C. 151

and the PTO response to the Amendment mailed on March 21, 2012.

- e. Thus, the total period of applicant delay under 35 U.S.C. § 154(b)(2)(C) is 99 days which is the sum of the periods of 62 days, 8 days, 5 days, and 24 days.

29. Accordingly, the correct patent term adjustment to which the Plaintiff is entitled under 35 U.S.C. § 154(b)(1) and (2) is 848 days, which is the difference between the total period of PTO delay (947 days) and the period of applicant delay (99 days).

30. The '872 patent is not subject to a terminal disclaimer. Thus the period of patent term adjustment is not limited under 35 U.S.C. § 154(b)(2)(B).

31. The Director erred in the determination of patent term adjustment for the '872 patent by stopping the accrual of the PTO "B Delay" period on November 8, 2011. The date the PTO's calculation of PTA used the recorded filing date of the RCE¹, instead of stopping the accrual of PTO "B Delay" on the date the '872 patent issued. Thus, the Director incorrectly calculated a patent term adjustment for the '872 patent as 631 days. By this erroneous calculation, the Director has deprived the Plaintiff of the full patent term adjustment to which they are entitled under the applicable statutes (calculated above as 848 days).

32. 35 U.S.C. § 154(b)(1)(B), entitled "Guarantee of no more than 3-year pendency," states that "if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States... the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued." Exceptions for the "1 day for each

¹ This date in error since the RCE was filed on 11/9/2011. Plaintiff did not file a Request for Reconsideration under 37 C.F.R. 1.705(d) within the two-month from issue date period to cite the one-day discrepancy, and thus is not disputing this one-day discrepancy.

day” extension include “any time consumed by continued examination of the application requested by the applicant under section 132(b).”

33. The PTO interprets the 35 U.S.C. § 154(b)(1)(B) “any time consumed by continued examination of the application requested by the applicant under section 132(b),” exception for one-for-one day to apply to RCE filings, regardless of whether they were filed before or after the three years post-filing date. This interpretation is explicit by the PTO and can be found within the “Patent Laws, Regulations, Policies & Procedures” section within an article regarding the 1999 American Inventor’s Protection Act (AIPA) entitled “Patent Term Guarantee Overview” (http://www.uspto.gov/patents/law/aipa/pta/patent_term_guarantee.jsp) (See Exhibit C). The PTO’s article states “Although filing a request for continued examination (RCE) under 35 U.S.C. § 132(b) and 37 CFR § 1.114 cuts off any additional patent term adjustment due to failure of the USPTO to issue a patent within three years, an applicant may continue to accrue patent term adjustment for events after the filing of the RCE.”

34. This Court recently held that the PTO’s patent term adjustment interpretation of 35 U.S.C. § 154(b)(1)(B) is erroneous with respect to RCEs filed after three years of application pendency. In *Exelixis, Inc. v. Kappos*, Case No. 1:12cv96 (E.D. Va. November 1, 2012) 2012 U.S. Dist. LEXIS 157762, the Court points out that 35 U.S.C. § 154(b)(1)(B)

...does not address the filing of an RCE after the expiration of the three year clock. To be sure, the provision makes clear that the clock is tolled for the processing of an RCE filed before the three year clock runs out, but the provision does not refer to or mention RCE's filed after the three year clock has run. Instead, subparagraph (B) makes clear that once the three year clock has run, PTA is to be awarded on a day for day basis regardless of subsequent events.

In addition to the Court determining the PTO’s incorrect interpretation of 35 U.S.C. § 154(b)(1)(B) with regarding to RCEs filed after three years of an application’s pendency, it

points to the PTO's seemingly contradictory stance on the utility of an RCE as a "valuable tool" as well as its absence in 37 C.F.R. 1.704 regarding Applicant Delay periods for PTA, since

in essence, [the PTO] construed subparagraph (B) to punish the applicant for filing the RCE. Yet there is no basis for reading subparagraph (B) in this manner. Indeed, the PTO properly regards the RCE not as an occasion to punish the applicant, but as a "valuable tool in the patent prosecution process." Nor does the PTO list an RCE as one of 11 enumerated applicant delays.

The Court, in awarding summary judgment to *Exelixis*, concludes:

In sum, the plain and unambiguous language of subparagraph (B) requires that the time devoted to an RCE tolls the running of the three year clock if the RCE is filed within the three year period. And, put simply, RCE's have no impact on PTA if filed after the three year deadline has passed. The PTO's arguments to the contrary are not persuasive and, accordingly, the PTO's interpretation of subparagraph (B) must be set aside as "not in accordance with law" and "in excess of [its] statutory . . . authority" pursuant to 5 U.S.C. § 706(2)(A) and (C).

35. In its opinion in *Exelixis, Inc. v. Kappos*, Case No. 1:12cv96 (E.D. Va. November 1, 2012) 2012 U.S. Dist. LEXIS 157762, this Court explained the proper construction of the provisions of 35 U.S.C. § 154(b) for determining the patent term adjustment with regarding to RCEs filed after three years of application pendency. In accordance with *Exelixis*, the patent term adjustment for the '872 patent is properly determined to be 848 days, as set forth above.

36. The Director's determination that the '872 patent is entitled to only 631 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.

COUNT TWO

(Declaratory Judgment Under the Administrative Procedures Act,

5 U.S.C. § 702 et seq.)

37. The allegations of paragraphs 1-36 are incorporated in this claim for relief as if fully set forth herein.

38. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1), the regulatory subsection interpreting 35 U.S.C. § 154(b)(1)(B)(i), and its improper calculation of B Delay when determining PTA for the '872 patent were contrary to law.

39. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '872 patent are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A); contrary to Regents constitutional rights within the meaning of 5 U.S.C. § 706(2)(8); and in excess of statutory authority within the meaning of 5 U.S.C. § 706(2)(C).

40. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '872 patent were final agency actions that are reviewable by a district court in accordance with 5 U.S.C. § 704.

41. It is the belief of the Regents that there is no requirement to exhaust administrative remedies under this section. To the extent that any requirement may exist, Regents did not pursue such remedy because it would have been futile at the time. A Request for Reconsideration under 37 C.F.R. § 1.705(d) can be filed by a patent owner within 2 months of issuance. The '872 patent issued June 12, 2012, which set the deadline for filing such a Request as August 12, 2012. The Exelixis decision, on which the present complaint is based, was issued November 1, 2012. The Regents therefore did not contest the PTA in an administrative forum.

42. Regents has been afforded no adequate remedy at law for Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '872 patent.

43. Regents will suffer irreparable injury if 37 C.F.R. § 1.703(b)(1) is not invalidated and Defendant is not directed to recalculate PTA for the '872 patent.

44. There is an actual controversy between the parties within this Court's jurisdiction.

45. An order invalidating 37 C.F.R. § 1.703(b)(1) and directing Defendant to recalculate PTA for the '872 patent would not substantially injure any other interested parties, and the public interest will be furthered by invalidation of a regulatory subsection and recalculation of PTA that is contrary to law.

46. Regents is entitled to additional patent term for the '872 patent such that the 631 days of PTA granted by the PTO should be changed 848 days.

PRAYER FOR RELIEF

Wherefore, Plaintiff respectfully prays that this Court:

A. Issue an Order changing the period of patent term adjustment for the '872 patent from 631 days to 848 days, and requiring the Director to alter the term of the '872 patent to reflect the 848 day patent term adjustment;


B. Issue an Order requiring the Director to correct the front page of the '872 patent, issue an appropriate Certificate of Correction, and otherwise take action to reflect on the '872 patent the 848 day patent term adjustment; and

C. Grant such other and further relief as the Court deems just and equitable.

DATED: December 7, 2012

Respectfully submitted,

KILPATRICK TOWNSEND & STOCKTON LLP

By: 
STEPHEN E. BASKIN (VA Bar # 47567)
Suite 900
607 14th Street, NW
Washington , DC 20005-2018 USA
Telephone: (202) 508-5800
Facsimile: (202) 508-5858
Email: sbaskin@kilpatricktownsend.com

Attorney for Plaintiff
THE REGENTS OF THE UNIVERSITY OF
CALIFORNIA

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