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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
(ALEXANDRIA DIVISION)

2013 APR 22 P 4: 07

CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

<p>BIONICHE LIFE SCIENCES, INC.,</p> <p style="text-align: center;">Plaintiff,</p> <p style="text-align: center;">v.</p> <p>Hon. TERESA STANEK REA, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office,</p> <p style="text-align: center;">Defendant.</p>
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Civil Action No: 1:13 CV 491
LO/JFA

COMPLAINT

Plaintiff Bioniche Life Sciences, Inc. ("Bioniche"), by its undersigned attorneys, for its Complaint against Director of the United States Patent and Trademark Office Teresa Stanek Rea, alleges as follows:

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 8,293,745 ("the '745 Patent," attached hereto as Exhibit A) seeking judgment, pursuant to 35 U.S.C. §154(b)(4)(A), that the patent term adjustment conferred by the United States Patent and Trademark Office ("USPTO") for the '745 Patent be changed from 623 days to 1744 days.

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

PARTIES

3. Bioniche is a Canadian company having a principal place of business at 231 Dundas Street East, Belleville, Ontario K8N 1E2. Bioniche is the owner by assignment of all right, title, and interest in and to the '745 Patent.

4. Defendant Teresa Stanek Rea (the "Director") is the Under Secretary of Commerce for Intellectual Property and Director of the USPTO, acting in her official capacity. The Director is the head of the USPTO and is responsible for superintending or 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 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 judicial district under 35 U.S.C. §154(b)(4)(A).

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

BACKGROUND FACTS

8. Bioniche is the assignee of the '745 Patent, as evidenced by assignment documents recorded at the USPTO. The entire right, title, and interest to the '745 Patent, including the right to sue and recover for past infringement thereof, is assigned to and is owned by Bioniche. Bioniche is therefore the real party in interest in this case.

9. Under 35 U.S.C. §154(a)(2), a successful patent applicant is entitled to a 20-year patent term beginning on the date its application was first filed with the USPTO. Because this

period starts to run with the filing of the application rather than with the grant of the patent, any administrative delay by the USPTO in processing of an application reduces the applicant's effective patent term.

10. To prevent such administrative delays from causing unfair losses of patent protection, 35 U.S.C. §154(b) requires that the Director of the USPTO grant a patent term adjustment ("PTA") 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. Accordingly, the USPTO must grant successful applicants upward adjustments of their patent terms to compensate for three categories of processing delay by the USPTO. Those three categories, set forth in 35 U.S.C. §154(b)(1)(A), (B), and (C) are known as "A delays," "B delays," and "C delays," respectively. Only B delays are at issue in this case.

12. B delays occur when the USPTO fails to issue a patent within 3 years of the filing of the patent application, excluding certain specified periods of delay. 35 U.S.C. §154(b)(1)(B). The statute provides for a day-for-day patent term adjustment to compensate for any B delays: "the term of the patent shall be extended by 1 day for each day after the end of that 3-year period until the patent is issued." *Id.*

13. Under 35 U.S.C. §132(b), an applicant may make a request for continued examination ("RCE") after the prosecution of an application is closed. 37 C.F.R. §1.114.

14. The dispute in this case concerns the proper interpretation of the statute governing B delays when an applicant has filed an RCE more than three years after the application was filed.

15. In particular, the USPTO has taken the position that 35 U.S.C. §154(b)(1)(B) allows the USPTO to reduce the PTA by the time attributable to an RCE when the RCE is filed after the expiration of the three-year guarantee period specified by the statute.

16. This Court rejected the USPTO's interpretation of 35 U.S.C. §154(b)(1)(B) in *Exelixis, Inc. v. Kappos*, No. 1:12cv96, 2012 U.S. Dist. LEXIS 157762 (E.D. Va. Nov. 1, 2012) ("*Exelixis I*"). In *Exelixis I*, the Court granted summary judgment against the USPTO, holding that the USPTO's PTA calculation methodology was erroneous as a matter of law and inconsistent with the plain and unambiguous language of 35 U.S.C. §154(b)(1)(B). *Id.* at *20-21. Specifically, in *Exelixis I*, the Court held that 35 U.S.C. §154(b)(1)(B) "clearly provides no basis for any RCE's to reduce PTA; instead, RCE's operate only to toll the three year guarantee deadline, if, and only if, they are filed within three years of the application filing date." *Id.* at *20 (emphasis added). *But see Exelixis, Inc. v. Kappos*, No. 1:12cv574, 2013 WL 314754 (E.D. Va. Jan. 28, 2013) ("*Exelixis II*") (finding that an RCE filing at any time will reduce B-delay PTA available under the statute).

17. Bioniche respectfully submits that the methodology identified in the *Exelixis I* action is the correct PTA methodology that should govern the USPTO's calculation of PTA for Bioniche's '745 Patent.

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

THE COUNT: U.S. PATENT NO. 8,293,745

19. The allegations of paragraphs 1-18 are incorporated in this claim for relief as if fully set forth.

20. Phillippe Riviere, Marc Riviere, and Stephanie Reader are the inventors of U.S. Patent Application No. 11/228,982 (“the ’982 application”), entitled “Use of Imatinib to Treat Liver Disorders and Viral Infections.” The ’982 application was filed on September 14, 2005. Pursuant to 35 U.S.C. §154(b)(1)(B), the ’982 application was guaranteed to issue by September 14, 2008, but did not. On September 22, 2009, while the ’982 application was still pending, and after the three-year period, the applicants filed with the USPTO an RCE of the ’982 application.

21. The ’982 application eventually issued as the ’745 Patent on October 23, 2012.

22. When the USPTO issued the ’745 Patent on October 23, 2012, it erroneously calculated the entitled PTA for the ’745 Patent as 623 days.

23. Under 35 U.S.C. §154(b)(1)(A) and according to the USPTO, Bioniche is entitled to an adjustment of the term of the ’745 Patent of a period of 682 days, which is the number of days attributable to A delay.

24. According to the USPTO, Bioniche is only entitled to a B delay adjustment of the term of the ’745 Patent of a period of 372 days (*i.e.*, only 372 days from September 14, 2008 to September 21, 2009).

25. The USPTO’s determination of the 623 day PTA is in error because it fails to include a correct adjustment, as required by 35 U.S.C. §154(b)(1)(B), for the time period from September 14, 2008 (three years after the filing date of the ’982 application) to October 23, 2012 (the date the ’745 Patent issued). There are 1500 days in between September 14, 2008 and October 23, 2012.

26. Under 35 U.S.C. §154(b)(1)(B) and the holding in *Exelixis I*, since an RCE was filed more than three years after the filing date of the '982 application (*i.e.* September 22, 2009), Bioniche is entitled to a total B delay adjustment of 1500 days.

27. Section 35 U.S.C. §154(b)(2)(A) states that “[t]o the extent . . . periods of [A and B delay] 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 a 12 day overlap of the A and B periods for the '745 Patent.

28. Section 35 U.S.C. §154(b)(2)(C) states that “[t]he period of adjustment of the term of a patent under paragraph (1) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” For the '745 Patent, the USPTO determined the period of applicants delay to be 426 days.

29. The correct PTA for the '745 Patent is 1744 days. The 1744 days includes the 682 day period determined by the USPTO attributed to A delays (*i.e.*, USPTO examination delay under 35 U.S.C. §154(b)(1)(A)) and the 1500 day period under 35 U.S.C. §154(b)(1)(B), less the 426 day period of applicants delay under 35 U.S.C. §154(b)(2)(C), minus the overlap of 12 days under 35 U.S.C. §154(b)(2)(A).

30. The Director's determination of only 623 days of PTA for the '745 Patent is arbitrary, capricious, an abuse of discretion, inconsistent with the language of 35 U.S.C. §154 and related rules, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation. The Director's determination of only 623 days is clearly incorrect in view of the holding in *Exelixis I*.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Bioniche prays that the Court:

- A. Issue an Order compelling the Director to change the amount of patent term adjustment for the '745 Patent from 623 days to 1744 days, and to issue an appropriate Certificate of Correction for the '745 Patent to reflect the 1744 day patent term adjustment; and
- B. Grant to Bioniche such other and further relief as the nature of the case may admit or require and as this Court deems just and proper.

Dated: April 22, 2013

Respectfully submitted,



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