

FILED

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

2014 APR 29 P 4: 22

CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

ROXANE LABORATORIES, INC.,

Plaintiff,

v.

HON. MICHELLE K. LEE,
Deputy Under Secretary of Commerce for
Intellectual Property and Deputy Director of
the United States Patent and Trademark Office;
and

UNITED STATES PATENT AND
TRADEMARK OFFICE

Defendants.

Civil Action No.: 3:14-cv-313 (HEH)

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Roxane Laboratories, Inc. ("Roxane"), for its Complaint against the Deputy Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office and the United States Patent and Trademark Office ("USPTO"), alleges as follows:

NATURE OF THE ACTION

1. This is an action for declaratory judgment seeking to vacate the USPTO's decision to revive U.S. Patent Application No. 09/709,829 (the "'829 Application"), which later issued as U.S. Patent No. 7,364,752 (the "'752 Patent"). A copy of the '752 Patent is attached as Exhibit A.

2. The USPTO's decision to revive the '829 Application was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.

JURISDICTION AND VENUE

3. This action arises under the Administrative Procedure Act (“APA”), 5 U.S.C. §§ 701-706 and the Patent Act, 35 U.S.C. §§ 1-376.

4. This Court has jurisdiction and is authorized to issue the relief sought under 28 U.S.C. §§ 1331, 1338(a), 1361, 2201-2202, and/or 5 U.S.C. §§ 701-706.

5. Venue is proper in this district under 35 U.S.C. § 1(b) and 28 U.S.C. § 1391(e).

THE PARTIES

6. Roxane is a corporation organized and existing under the laws of the State of Nevada, with its principal place of business at 1809 Wilson Road, Columbus, Ohio 43288.

7. The USPTO is a federal agency within the United States Department of Commerce. The USPTO is located at 600 Dulany St., Alexandria, Virginia 22314.

8. Michelle K. Lee is the Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office. Ms. Lee is being sued in her official capacity.

THE '829 APPLICATION AND THE '752 PATENT

9. The '829 Application was submitted to the USPTO on November 10, 2000.

10. On February 20, 2002, the USPTO issued a non-final rejection of all the pending claims of the '829 Application. Applicants responded to the non-final rejection on August 26, 2002, amending the claims of the '829 Application.

11. On January 17, 2003, the USPTO issued a final rejection of all pending claims of the '829 Application. Applicants did not timely respond to the final rejection, and on September 30, 2003, the USPTO issued a Notice of Abandonment. The Notice of Abandonment stated that,

“On September 23, 2003, Attorney Kalim Fuzail confirmed that Applicants would be submitting a petition to revive in this application.”

12. On September 6, 2005, Applicants filed a Petition to Revive the '829 Application, along with a Notice of Appeal of the final rejection. The Petition stated that the, “application became abandoned because the failure to prosecute was an unintentional delay. The entire delay in filing the required reply from the due date until the filing of this petition was unintentional 37 C.F.R. § 1.137(b)(3).”

13. Under the “Showing” section of the Petition to Revive, Applicants stated:

Because this petition is more than 1 year after the date of abandonment of the application, applicant additionally submits further information as to when applicant (or applicant’s representative) first became aware of the abandonment of the application, and a showing as to how the delay in discovering the abandoned status of the application occurred despite the exercise of due care or diligence on the part of the applicant (or applicant’s representative). 62 Fed. Reg. 53,131, 53,159 (Oct. 10, 1997); Section 711.03(c), MPEP, 8th Edition, Rev. 2).

This application became abandoned on September 30, 2003 for failure to timely file a proper reply to the Office Letter mailed on January 17, 2003. The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR §1.137(b) was unintentional. Applicant’s representative first discovered that this application became abandoned when the present application was included in her docket after the previous Applicant’s representative left the company in May 2005.

14. On information and belief, the delay by Applicants in responding to the final rejection was not unintentional.

15. On February 10, 2006, the USPTO granted the Petition to Revive the '829 Application under 37 C.F.R. 1.137(b). The USPTO mailed a Notice of Allowance on December 19, 2007, and the '752 Patent issued on April 29, 2008, naming Abbott Laboratories (“Abbott”) as Assignee. (Ex. A at 1.)

16. Thereafter, on May 22, 2008, Applicants filed a Request for Reconsideration of Patent Term Adjustment, informing the USPTO that they believed the patent term adjustment calculation of 688 days was in error. The USPTO reviewed the application file history, including the abandonment and petition to revive, and concluded that the patent term adjustment should have been 9 days. A certificate of correction issued on January 6, 2009.

17. On information and belief, the '752 Patent is currently assigned to and owned by AbbVie Inc ("AbbVie").

ROXANE'S ANDA AND THE OHIO LITIGATION

18. Roxane is a pharmaceutical company that develops and markets generic equivalents of branded drug products.

19. On December 20, 2010 Roxane submitted Abbreviated New Drug Application ("ANDA") No. 202573 to the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version of Abbott's Norvir® tablets, which are approved by the FDA in combination with other antiretroviral agents for the treatment of HIV-1 infection.

20. On April 10, 2012, Abbott sued Roxane in the District Court for the District of Delaware, alleging that the generic product described in Roxane's ANDA No. 202573 infringes certain Abbott patents that allegedly cover Norvir®, including the '752 Patent. *See AbbVie Inc. v. Roxane Labs., Inc.*, No. 1:12-cv-00457-RGA-CJB, D.I. 1.

21. The next day, Abbott filed an Amended Complaint in its Delaware lawsuit against Roxane asserting two additional patents that allegedly cover Norvir®. *See AbbVie Inc. v. Roxane Labs., Inc.*, No. 1:12-cv-00457-RGA-CJB, D.I. 8.

22. On August 29, 2012, Abbott moved to substitute its related company AbbVie as named Plaintiff in the Delaware lawsuit against Roxane because the asserted patents, including

the '752 Patent, had been assigned to AbbVie. *See AbbVie Inc. v. Roxane Labs., Inc.*, No. 1:12-cv-00457-RGA-CJB, D.I. 34. This motion was granted on June 18, 2013. *See id.* at D.I. 65.

23. On June 28, 2013, AbbVie's Delaware lawsuit against Roxane was transferred to the U.S. District Court for the Southern District of Ohio, where it is currently pending before Judge Michael H. Watson. *See AbbVie Inc. v. Roxane Labs., Inc.*, No. 2:13-cv-00645-MHW-NMK.

REVIEWABILITY AND STANDING

24. Agency action is presumptively subject to judicial review under the APA. USPTO orders affecting the revival of abandoned patent applications and issuance of patents stemming from these wrongfully-revived applications have been reviewed by district courts. *See, e.g., New York Univ. v. Autodesk, Inc.*, 466 F. Supp. 2d 563, 565 (S.D.N.Y. 2006).

25. Roxane has standing to bring this action because it has been sued for infringement of the '752 Patent, which was improperly issued by the USPTO following an improper revival of the '829 Application.

26. But for the USPTO's improper revival of the '829 Application and improper issuance of the '752 Patent, that Patent would not be asserted against Roxane.

27. Accordingly, Roxane falls within the "zone of interests" to be protected or regulated by the applicable statutes, *e.g.*, 5 U.S.C. § 701 *et. seq.* and 35 U.S.C. § 371, and otherwise satisfies the constitutional and other prerequisites for standing to challenge the USPTO's improper decisions. *See, e.g., Centigram Comm'n Corp. v. Lehman*, 862 F. Supp. 113,117 n. 9 (E.D. Va. 1994); *Ass'n for Melocular Pathology v. USPTO*, 653 F.3d 1329 (Fed. Cir. 2011).

28. Roxane has no other adequate forum in which to raise this issue, as it is foreclosed from asserting the defense of “improper revival” in the pending lawsuit in Ohio. *See Aristocrat Techs. Austral. Pty Ltd. v. Int'l Game Tech.*, 543 F.3d 657, 663 (Fed. Cir. 2008) (“[W]e hold that improper revival may not be asserted as a defense in an action involving the validity or infringement of a patent.”).

29. Accordingly, the USPTO’s improper issuance of the ’752 Patent based in part upon its improper revival of the ’829 Application constitutes “final agency action for which there is no other adequate remedy in a court” and properly is subject to judicial review under the APA.

30. Further, there is an actual controversy between the parties within the meaning of 28 U.S.C. § 2201.

COUNT 1

31. Roxane reasserts and realleges paragraphs 1-31 as if fully set forth herein.

32. The USPTO improperly revived the ’829 Application even though the Applicants delay in responding was not “unintentional.” The ’752 Patent was thus improperly issued.

33. An actual and justiciable controversy exists between the parties with respect to the ’752 Patent. Roxane is entitled to a declaratory judgment that the ’752 Patent is invalid, unenforceable, and/or without legal effect.

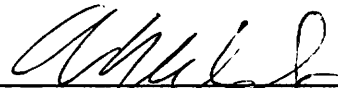
RELIEF REQUESTED

WHEREFORE, Plaintiff respectfully requests that the Court:

a. Issue a declaratory judgment or other Order holding that Roxane has standing to challenge the USPTO’s revival of the ’829 Application and issuance of the ’752 Patent;

- b. Issue a declaratory judgment or other order holding that the '752 Patent was improperly issued following the improper revival of the '829 Application, and the '752 Patent is invalid, unenforceable and/or without legal effect;
- c. Award Roxane its costs and reasonable attorneys' fees; and
- d. Grant any other relief deemed appropriate by the Court.

Dated: April 29, 2014



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