

FILED

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

2013 JUN 21 P 4: 50

CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

KREMERS URBAN
PHARMACEUTICALS INC.

Plaintiff,

v.

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

and

UNITED STATES PATENT AND
TRADEMARK OFFICE

Defendants.

Civil Action No. 3:13cv399

JRS

COMPLAINT

Plaintiff Kremers Urban Pharmaceuticals Inc. (“Kremers”), for its Complaint against Defendants the United States Patent and Trademark Office (“PTO”) and Theresa Stanek Rea in her capacity as the Under Secretary of Commerce for Intellectual Property and Acting Director of the PTO, hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action under the Administrative Procedures Act, 5 U.S.C. §§ 701 et seq. (“APA”), for a declaration setting aside the PTO’s September 24, 1999 revival of abandoned Application Serial No. 08/903,755 (the “755 application”), which application ultimately issued as U.S. Patent No. 6,469,035 (the “035 patent”), and further for a declaration that the ‘035

patent is invalid in its entirety because it was abandoned during prosecution and the PTO's revival of the '755 application was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

2. This action is not a facial challenge to the PTO's regulation pertaining to revival of abandoned patent applications, 37 CFR § 1.137(b). Rather, this action challenges the PTO's application of that regulation in the specific facts and circumstances set forth below.

PARTIES

3. Plaintiff Kremers Urban Pharmaceuticals Inc. ("Kremers") is an Indiana corporation with its principal place of business at 902 Carnegie Center, Suite 360 in Princeton, New Jersey 08540.

4. Defendant the United States Patent and Trademark Office ("PTO") is a federal agency within the United States Department of Commerce. The PTO is located at 600 Dulany Street, Alexandria, Virginia 22314.

5. Defendant Teresa Stanek Rea (the "Director") is the Under Secretary of the United States Department of Commerce and Acting Director of the PTO. The Director's office is located at 600 Dulany Street, Alexandria, Virginia 22314. The Director is sued in her official capacity. References to the Director herein refer both to her and to her official predecessors as the context requires. References to the PTO herein refer to the defendants collectively.

JURISDICTION AND VENUE

6. This action arises under the Administrative Procedure Act ("APA"), 5 U.S.C. §§701-706 and 35 U.S.C. § 133.

7. This Court has jurisdiction and is authorized to issue the relief sought under 28 U.S.C. §§ 1331, 1389(a), 1361, 2201-2202, and/or 5 U.S.C. §§701-706.

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

THE DELAWARE PATENT INFRINGEMENT ACTION

9. On information and belief, AbbVie, Inc. is a corporation organized and existing under the laws of the State of Illinois, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

10. On information and belief, AbbVie Respiratory LLC is a limited liability corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

11. AbbVie, Inc. and AbbVie Respiratory LLC are herein referred to collectively as “AbbVie”.

12. AbbVie holds New Drug Application (“NDA”) No. 20-0381 by which the FDA granted approval for the marketing and sale of certain niacin extended-release tablets, which AbbVie markets in the United States under the trade name “NIASPAN®”.

13. The FDA’s official publication of approved drugs (the “Orange Book”) lists, among others, U.S. Pat. Nos. 6,080,428 (the “‘428 patent”) and 6,469,035 (the “‘035 patent”) as purportedly covering limited therapeutic uses of NIASPAN®.

14. On information and belief, AbbVie is the owner by assignment of the ‘428 and ‘035 patents.

15. In late 2012, Abbott Laboratories purportedly changed its name to AbbVie, Inc. and Abbott Respiratory LLC purportedly changed its name to AbbVie Respiratory LLC.

16. Abbott Laboratories and Abbott Respiratory LLC are herein referred to collectively as “Abbott.”

17. Kremers is a pharmaceutical company that, among other things, applies for FDA approval for generic versions of brand pharmaceutical products.

18. By letter dated April 18, 2012 (“the Notice Letter”), Kremers notified Abbott that Kremers’ ANDA No. 203899 includes a certification under Section 505(j)(2)(A)(vii)(IV) (“Paragraph IV” certification) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(A)(vii)(IV)) seeking approval to engage in the commercial manufacture, use, and sale of 500 mg and 1000 mg dosage strengths of generic niacin extended-release tablets before the expiration of the ‘428 patent and the ‘035 patent.

19. On June 1, 2012, Abbott brought suit in the U.S. District Court for the District of Delaware (the “Delaware Action”) against Kremers for infringement of the ‘428 and ‘035 patents under 35 U.S.C. § 271(e)(2)(A), for Kremers’ ANDA submission and Paragraph IV certification. The official caption of the Delaware Action has since changed to reflect the purported name change from Abbott to AbbVie.

20. The Delaware Action is civil action number 12-703-SLR, and is currently pending before Judge Sue L. Robinson.

ABANDONMENT AND PURPORTED REVIVAL OF THE ‘755 APPLICATION

21. The ‘755 application, which ultimately issued as the ‘035 patent, was filed on July 31, 1997. The prosecution history of the ‘755 application, which includes a copy of the ‘035 patent, is attached hereto as **Exhibit A**.

22. On June 18, 1998, Examiner James H. Reamer of the PTO issued a non-final Office Action rejecting all 20 pending claims in the ‘755 application. (Exh. A, KUP112-117).

23. The June 18, 1998 Office Action provided the following notice: “A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is

longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).” (Exh. A, KUP113).

24. No response was submitted prior to the 3-month deadline or during the potential extended period of time to respond.

25. On April 1, 1999, Examiner Reamer issued a communication comprising an “Interview Summary” and a “Notice of Abandonment”. (Exh. A, KUP118-120).

26. The April 1, 1999 Interview Summary provided that Examiner Reamer had a personal interview with the Applicant’s representative, Mr. Kevin Hansbro (PTO Reg. No. 38,485), on March 30, 1999. (Exh. A, KUP119). Mr. Hansbro worked for Jenkins and Gilcrest, P.C. (*See, e.g.*, Exh. A, KUP111).

27. According to the April 1, 1999 Interview Summary, an “Agreement was reached” and the Examiner’s comments under the words, “Description of the general nature of what was agreed to if an agreement was reached, or any other comments,” were: “Confirmed abandonment of the application.” (Exh. A, KUP119).

28. The April 1, 1999 Interview Summary further states: “A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW.” (*Id.*).

29. The prosecution history of the ‘755 application did not include the Applicant’s summary of the March 30, 1999 interview between Examiner Reamer and Mr. Hansbro. Nor did the Applicant or its representatives directly challenge or otherwise explicitly address the contents of the April 1, 1999 Interview Summary.

30. The April 1, 1999 Notice of Abandonment states that the application was abandoned in view of “applicant’s failure to timely file a proper response to the Office letter mailed on Jun 18, 1998.” The Notice of Abandonment further indicates that “No response has been received.” (Exh. A, KUP120).

31. On April 28, 1999, the Applicant, through its representative Peter J. Manso (PTO Reg. No. 32,264) filed with the PTO a “PETITION TO REVIVE ABANDONED APPLICATION UNDER 37 CFR § 1.137(b)”. (Exh. A, KUP129-130). Like Mr. Hansbro, Mr. Manso worked for Jenkins & Gilchrist, P.C. at that time. (Exh. A, KUP130).

32. The April 28, 1999 Petition to Revive alleged as follows: “The above-identified application was unintentionally allowed to go abandoned on March 23, 1999 for failure to timely file a response to the Office Action. Applicant hereby respectfully petitions to revive the above-identified application under 37 CFR § 1.137(b).” (Exh. A, KUP129).

33. The April 28, 1999 Petition to Revive included a “Statement Concerning Unintentional Abandonment,” in which the Applicant, through its representative, stated the following: “Applicant respectfully submits that the above-identified application was unintentionally abandoned. The entire delay in filing the required reply from the due date for the reply until the filing of the grantable petition was unintentional.” (Exh. A, KUP129-130).

34. Contemporaneously with the April 28, 1999 Petition to Revive, the Applicant filed an Amendment, which included substantive responses to the June 18, 1998 Office Action rejections. (Exh. A, KUP131-153).

35. On September 24, 1999, the PTO mailed a “decision on the petition under 37 C.F.R. § 1.137(b), filed April 28, 1999, to revive the above-identified application.” (“September

24, 1999 Petition Decision”). (Exh. A, KUP154). The Petition Decision granted the Applicant’s Petition to Revive the ‘755 application. (*Id.*).

36. In addition, the Petition Decision stated: “This application became abandoned for failure to timely reply within three months to the Office action mailed June 18, 1998. A response was due on or before September 18, 1998. Accordingly, this application became abandoned on September 19, 1998. A Notice of Abandonment was mailed on April 1, 1999.” (*Id.*).

37. The September 24, 1999 Petition Decision correctly acknowledges that the application became abandoned on September 19, 1998 and that a Notice of Abandonment was mailed on April 1, 1999. However, the Petition Decision omitted any mention of the Interview Summary memorializing the March 30, 1999 personal interview between Examiner Reamer and Mr. Hansbro, wherein Mr. Hansbro explicitly agreed with the Examiner that the ‘755 application was indeed abandoned. (*See Id.*).

38. The September 24, 1999 Petition Decision further omitted the fact that the prosecution history contained no statement by the Applicant or its representative(s) challenging or otherwise contradicting the substance of the April 1, 1999 Interview Summary. (*See Id.*).

39. The September 24, 1999 Petition Decision was addressed to Peter J. Manso at the firm Ackerman, Senterfitt & Edison, P.A. of Fort Lauderdale FL. (*Id.*).

40. After a series of subsequent communications between the PTO and the Applicant, the ‘035 patent issued on October 22, 2002. (Exh. A, KUP3).

**REVIEWABILITY AND KREMERS’
STANDING TO CHALLENGE THE PTO’S ORDERS**

41. This Court has held that PTO orders reviving abandoned patent applications are presumptively subject to judicial review under the APA. *Exela Pharma Sciences, LLC v.*

Kappos, 2012 U.S. Dist. LEXIS 118998, at *6-13 (E.D. Va.) (O’Grady, J.), dismissed on other grounds by 2012 U.S. Dist. LEXIS 181435 (E.D. Va., Dec. 21, 2012).

42. The APA prohibits agency action which is “arbitrary, capricious an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. §706(2)(A); accord, *New York University v. Autodesk, Inc.*, 495 F.Supp.2d 369, 372-373 (S.D.N.Y. 2007) (“Under the [APA] ..., this Court must hold unlawful and set aside PTO actions found to be arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law.”).

43. Furthermore, the APA prohibits agency action which is “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.” *Id* § (C).

44. APA Section 702 provides a party “suffering legal wrong because of agency action,” with the right of judicial review.

45. AbbVie’s assertion of the ‘035 patent against Kremers in the Delaware Action constitutes a legal wrong resulting from agency action. That is, but for the PTO’s improper revival of the ‘755 application and consequential improper issuance of the ‘035 patent, AbbVie could not have asserted the ‘035 patent against Kremers.

46. The two patents-in-suit in the Delaware Action are the ‘428 patent and the ‘035 patent. According to the FDA Orange Book, the ‘428 patent purportedly expires on May 27, 2017, while the ‘035 patent purportedly expires on March 15, 2018. Thus, even if Kremers succeeds on the merits with respect to the ‘428 patent in the Delaware Action, the ‘035 patent stands to prevent Kremers from launching generic NIASPAN® until after March 15, 2018, if Kremers does not succeed on the merits against the ‘035 patent in the Delaware Action.

47. Moreover, the time and expense that Kremers has invested and is likely to continue to invest in challenging the ‘035 patent is a harm in and of itself – a harm that Kremers

would not be suffering had the PTO not wrongly granted the April 28, 1999 Petition to Revive and subsequently issued the '035 patent.

48. Accordingly, the Delaware Action and the PTO's wrongful granting of the April 28, 1999 Petition to Revive have caused Kremers to suffer an injury in fact, thus conferring standing on Kremers to bring this action under the APA. See *Exela Pharma*, 2012 U.S. Dist. LEXIS 118998, at *7-8 ("Here, there could be no infringement action without the PTO's allegedly improper revival decision.").

49. Significantly, Kremers 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 Delaware Action. See *Aristocrat Techs. Austl. Pty Ltd. V. Int'l Game Tech.*, 543 F. 3d 657, 663 (Fed. Cir. 2008) ("[I]mproper revival may not be asserted as a defense in an action involving the validity or infringement of a patent.").

50. This Court has held that while *Aristocrat* bars a party from challenging the validity of a patent *defensively* in an infringement action, the same party may assert a claim in this District under the APA against the PTO, alleging error in the agency's decision making process. *Exela Pharma*, 2012 U.S. Dist. LEXIS 118998, at *11-13 ("[I]f the Plaintiffs here are prevented from challenging the agency's actions, it is unlikely that any other party would be positioned to do so. The Court finds no support for the PTO's apparent proposition that certain agency actions should remain entirely unchecked.").

51. Accordingly, the PTO's improper revival and consequential improper issuance of the '035 patent, constitute "final agency action for which there is no other adequate remedy in a court" and properly is subject to judicial review under the APA.

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

COUNT I: AGENCY ACTION NOT IN ACCORDANCE WITH REGULATIONS

53. Each of the preceding paragraphs 1 to 52 is incorporated as if fully set forth herein.

54. Under 35 U.S.C. § 133, a patent application is deemed abandoned when an applicant “fail[s] ... to prosecute the application within six months” of any PTO action with respect to the application, unless the applicant shows “that such delay was unavoidable.”

55. In addition to the “unavoidable delay” standard set forth in 35 U.S.C. § 133, under 35 U.S.C. § 41(a)(7), the Director may accept a petition “for the revival of an unintentionally abandoned application for a patent.”

56. Pursuant to 35 U.S.C. § 41(a)(7), the PTO promulgated 37 C.F.R. § 1.137(b), which states in pertinent part:

If the delay in reply by applicant or patent owner was unintentional, a petition may be filed pursuant to this paragraph to revive an abandoned application ... A grantable petition pursuant to this paragraph must be accompanied by:

... (3) A statement that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to this paragraph was unintentional.

57. While the statutory maximum amount of time allowed to respond to a PTO office action is six months, 35 U.S.C. § 133 gives discretion to the Director to require that an applicant respond to an office action within a “shorter time, [but] not less than thirty days.”

58. The Director has directed examiners to set a shortened period of three months to reply to any Office action on the merits. MPEP § 710.02(b)¹.

59. As required by the Director, Examiner Reamer set a shortened period of three months to reply to the June 18, 1998 Office Action. (Exh. A, KUP113).

60. Thus, the Applicant was required to reply to the June 18, 1998 Office Action by or before September 18, 1998, unless the Applicant submitted a reply and petition for extension of time prior to the six month statutory deadline under 35 U.S.C. § 133.

61. The Applicant failed to reply to the June 18, 1998 Office Action within three months of the date of that Office Action.

62. Additionally, the Applicant failed to reply to the June 18, 1998 Office Action within the six month statutory deadline mandated by 35 U.S.C. § 133.

63. Thus, according to the September 24, 1999 Petition Decision, the '755 application became abandoned on September 19, 1998 for failure to reply timely within three months to the June 18, 1998 Office Action. (Exh. A, KUP154).

64. Mr. Manso's representation in the April 28, 1999 Petition to Revive that the application "was unintentionally allowed to go abandoned on March 23, 1999 for failure to timely file a response to the Office Action," (Exh. A, KUP129) directly contradicts the PTO's position that the application was abandoned as of September 19, 1998. Yet in its September 24, 1999 Petition Decision, the PTO made no mention of this contradiction.

¹ The MPEP or "Manual of Patent Examining Procedure" is a reference the PTO publishes, setting forth the PTO's interpretation of pertinent statutes and case law. The MPEP also provides guidance on the PTO's internal operating procedures. The MPEP is not binding on courts, but may be given judicial notice to the extent it does not conflict with the statute. *In re Fisher*, 421 F.3d 1365, 1372 (Fed. Cir. 2005).

65. More importantly, however, the PTO accepted Mr. Manso's conclusory representations that the application "was unintentionally abandoned" and that "[t]he entire delay in filing the required reply from the due date for the reply until the filing of the grantable petition was unintentional," (Exh. A, KUP129-130) notwithstanding the April 1, 1999 Interview Summary's uncontroverted statement that the Applicant's representative had "confirmed abandonment of the application" in a March 30, 1999 personal interview between Examiner Reamer and the Applicant's representative. (Exh. A, KUP119).

66. Since the Applicant deliberately and expressly abandoned the '755 application, Mr. Manso's representations that the Applicant's delay and abandonment were unintentional, are facially false.

67. In view of the foregoing facts, the PTO's blanket acceptance of Mr. Manso's conclusory representations was arbitrary, capricious and clearly in violation of the PTO's own regulations as well as the statutes authorizing those regulations.

68. Accordingly, the '755 application should have remained abandoned, the '035 patent should have never issued and the '035 patent should have never been asserted against Kremers in the Delaware Action.

69. To be clear, Kremers does not allege that 37 C.F.R. § 1.137(b)² is facially invalid and/or exceeds the PTO's rulemaking authority.

70. Rather, Kremers challenges the PTO's September 24, 1999 Petition Decision as "arbitrary, capricious an abuse of discretion, or otherwise not in accordance with law" under 5 U.S.C. § 706(2)(A), and thus in violation of its own regulations as set forth in 37 CFR § 1.137(b).

² Again, this is the regulation authorizing the PTO to revive patent applications that were abandoned due to an applicant's failure to timely reply to a PTO communication, where the applicant purports that "the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition [to revive] was unintentional."

71. If the PTO's September 24, 1999 Petition Decision vis-à-vis the '755 application is not set aside and the '035 patent is permitted to remain in force, AbbVie will continue to leverage the '035 patent to try and prevent Kremers from entering the generic NIASPAN® market and continue to enforce the '035 patent in the Delaware Action, causing Kremers to suffer substantial and irreparable harm for which there is no remedy at law.

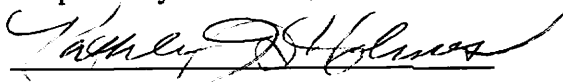
RELIEF REQUESTED

WHEREFORE, Plaintiff respectfully requests that the Court:

- a. Issue a declaratory judgment or other order holding that Kremers has standing to challenge the PTO's revival and issuance of the '035 patent;
- b. Issue a declaratory judgment or other order holding that the '755 application was improperly revived and, thus the '035 patent is invalid, unenforceable and/or without legal effect;
- c. Award Kremers its costs and reasonable attorneys' fees; and
- d. Grant other or further relief as may be deemed appropriate by the Court.

June 21, 2013

Respectfully submitted,



Kathleen J.L. Holmes (VSB #35219)
kholmes@holmesandcostin.com
Holmes & Costin, PLLC
5203 Lyngate Court, Suite B
Burke, VA 22015
Ph: (703) 260.6401
Fax: (703) 439-1873
*Counsel for Kremers Urban
Pharmaceuticals Inc.*

Of counsel:

David B. Gornish
Robert W. Stevenson

James J. Kozuch
CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.
1635 Market Street
Seven Penn Center – 12th Floor
Philadelphia, PA 19103
(215) 567-2010
dgornish@crbcp.com
rstevenson@crbcp.com
jjkozuch@crbcp.com
Attorneys for Kremers-Urban
Pharmaceuticals Inc.