IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES and ABBOTT RESPIRATORY LLC,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
KREMERS URBAN PHARMACEUTICALS, INC.	)	
Defendant.	)	

COMPLAINT

Plaintiffs Abbott Laboratories and Abbott Respiratory LLC (collectively, "Abbott"), for their Complaint against Defendant Kremers Urban Pharmaceuticals, Inc. ("Kremers") hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent Nos. 6,080,428 ("the '428 patent"), and 6,469,035 ("the '035 patent"), arising under the patent laws of the United States, Title 35, United States Code §§ 271 and 281. This action relates to Abbreviated New Drug Application ("ANDA") No. 203899 filed by Kremers with the U.S. Food and Drug Administration ("FDA") for approval to market 500 mg and 1000 mg niacin extended release tablets, which are generic versions of the 500 mg and 1000 mg forms of Abbott's NIASPAN® drug product.

PARTIES

2. Abbott Laboratories 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.

3. Abbott Respiratory LLC ("Abbott Respiratory") is a limited liability corporation organized and existing under the laws of the State of Delaware, with its principle place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

4. Upon information and belief, 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.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

6. This Court has personal jurisdiction over Kremers because it has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of, a tortious act of patent infringement in filing ANDA No. 203899 that has led to foreseeable harm and injury to Abbott Respiratory, a Delaware corporation, and Abbott Laboratories, a corporation actively engaged in business in Delaware.

7. This Court also has personal jurisdiction over Kremers because it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Kremers has had persistent,

systematic and continuous contacts with Delaware, DEL. CODE ANN. tit. 10, § 3104(c)(4), as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

8. Upon information and belief, Kremers will manufacture, market, and/or sell within the United States the generic 500 mg and 1000 mg niacin extended release tablets described in Kremers's ANDA No. 203899 if FDA approval is granted. If ANDA No. 203899 is approved, the generic 500 mg and 1000 mg niacin extended release tablets charged with infringing the patents-in-suit, would, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by persons in Delaware, all of which would have a substantial effect on Delaware.

9. Kremers has agreed to subject itself to the jurisdiction of this Court by agreeing to be joined as a defendant in *Pfizer Inc. et al v. Kremers Urban LLC et al*., Civil Action No. 1:09-cv-00924-LPS (D. Del.).

PATENTS IN SUIT

10. Abbott Respiratory is the owner by assignment of the '428 patent, entitled "Nicotinic Acid Compositions for Treating Hyperlipidemia and Related Methods Therefor," which the U.S. Patent and Trademark Office duly and legally issued on June 27, 2000. A true and correct copy of the '428 patent is attached hereto as **Exhibit A**. The claims of the '428 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '428 patent with respect to NIASPAN®, with the right to sue for and obtain equitable relief and damages for infringement of the '428 patent.

11. Abbott Respiratory is the owner by assignment of the '035 patent, entitled "Methods of Pretreating Hyperlipidemic Individuals with a Flush Inhibiting Agent Prior to the

Start of Single Daily Dose Nicotinic Acid Therapy to Reduce Flushing Provoked by Nicotinic Acid," which the U.S. Patent and Trademark Office duly and legally issued on October 22, 2002. A true and correct copy of the '035 patent is attached hereto as **Exhibit B**. The claims of the '035 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '035 patent with respect to NIASPAN®, with the right to sue for and obtain equitable relief and damages for infringement of the '035 patent.

12. Abbott Laboratories is the holder of New Drug Application ("NDA") No. 20-0381 by which the FDA granted approval for the marketing and sale of 500 mg, 750 mg, and 1000 mg strength niacin extended-release tablets, which Abbott markets in the United States under the trade name "NIASPAN®". The formulation and dosing of NIASPAN® are covered by certain claims of the '428 patent and '035 patent. The FDA's official publication of approved drugs (the "Orange Book") includes NIASPAN® together with the '428 patent and the '035 patent.

INFRINGEMENT BY KREMERS

13. By letter dated April 18, 2012 ("the Notice Letter"), Kremers notified Abbott that Kremers's ANDA No. 203899 includes a certification under Section 505(j)(2)(A)(vii)(IV) 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. Upon information and belief, Kremers intends to engage in the commercial manufacture, use, and sale of generic niacin extended-release tablets promptly upon receiving FDA approval to do so.

14. By filing ANDA No. 203899, Kremers has necessarily represented to the FDA that its generic niacin extended-release tablets have the same active ingredient as NIASPAN®, have the same route of administration, dosage form, and strengths as NIASPAN®, and are bioequivalent to NIASPAN®.

15. This Complaint is being filed before the expiration of the forty-five days from the date Abbott received the Notice Letter.

COUNT I (INFRINGEMENT OF THE '428 PATENT)

16. Each of the preceding paragraphs 1 to 15 is incorporated as if fully set forth herein.

17. Kremers's submission of ANDA No. 203899 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release tablets prior to the expiration of the '428 patent constitutes infringement of one or more of the claims of the '428 patent under 35 U.S.C. § 271(e)(2)(A).

18. Upon FDA approval of Kremers's ANDA No. 203899, Kremers will further infringe the '428 patent by making, using, offering to sell, and selling generic niacin extended-release tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

19. Upon information and belief, Kremers had actual and constructive knowledge of the '428 patent prior to filing ANDA No. 203899 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '428 patent.

20. If Kremers's infringement of the '428 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II (INFRINGEMENT OF THE ’035 PATENT)

21. Each of the preceding paragraphs 1 to 20 is incorporated as if fully set forth herein.

22. Kremers’s submission of ANDA No. 203899 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release tablets prior to the expiration of the ’035 patent constitutes infringement of one or more of the claims of the ’035 patent under 35 U.S.C. § 271(e)(2)(A).

23. Upon FDA approval of Kremers’s ANDA No. 203899, Kremers will further infringe the ’035 patent by making, using, offering to sell, and selling generic niacin extended-release tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

24. Upon information and belief, Kremers had actual and constructive knowledge of the ’035 patent prior to filing ANDA No. 203899 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the ’035 patent.

25. If Kremers’s infringement of the ’035 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Abbott prays that this Court grant the following relief:

a) A judgment that one or more claims of the ’428 patent and the ’035 patent are infringed by Kremers’s submission of ANDA No. 203899, and that Kremers’s making, using, offering to sell, or selling in the United States, or importing into the United States, of 500 mg and

1000 mg dosage strengths of generic niacin extended-release tablets will infringe one or more claims of the ’428 patent and the ’035 patent;

b) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 203899 shall be a date which is not earlier than the latest expiration date of the ’428 patent and the ’035 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled;

c) An order permanently enjoining Kremers, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States of 500 mg and 1000 mg dosage strengths of generic niacin extended-release tablets until after the latest expiration date of the ’428 patent and the ’035 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled;

d) Damages or other monetary relief to Abbott if Kremers engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of 500 mg and 1000 mg dosage strengths of generic niacin extended-release tablets prior to the latest expiration date of the ’428 patent and the ’035 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled.

e) Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

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