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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Plaintiffs, v. KREMERS URBAN PHARMACEUTICALS INC., Defendant.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharmaceuticals, Inc. (together, "Boehringer" or

"Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant Kremers Urban Pharmaceuticals Inc. ("Kremers"), hereby allege as follows:

THE PARTIES

1. Plaintiff Boehringer Ingelheim Pharma GmbH & Co. KG ("BIPKG") is a limited partnership organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

2. Plaintiff Boehringer Ingelheim International GmbH ("BII") is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

3. Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

4. Upon information and belief, Defendant Kremers Urban Pharmaceuticals, Inc. ("Kremers") is a corporation organized and existing under the laws of the State of Indiana, having a principal place of business at 902 Carnegie Center, Suite 360, Princeton, New Jersey 08540.

NATURE OF THE ACTION

5. This is a civil action concerning United States Patent No. 6,015,577 ("the '577 patent"). This action arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

8. Upon information and belief, Kremers manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this Judicial District.

9. This Court has personal jurisdiction over Kremers based upon, *inter alia*, its having a place of business in this Judicial District and its connections with and sales in this Judicial District.

CLAIM FOR RELIEF

10. BIPI is the holder of New Drug Application ("NDA") No. 20-884, by which the United States Food and Drug Administration ("FDA") first granted approval for 200 mg extended-release dipyridamole / 25 mg acetylsalicylic acid ("aspirin") capsules. The dipyridamole/aspirin capsules described in BIPI's NDA are prescribed to reduce the risk of stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due to thrombosis. Boehringer sells these capsules in the United States under the tradename "AGGRENOX®."

11. BIPKG owns the '577 patent, which was duly and legally issued on January 18, 2000, and is titled "Pharmaceutical Compositions Containing Dipyridamole or Mopidamol and Acetylsalicylic Acid or the Physiologically Acceptable Salts Thereof, Processes for Preparing Them and Their Use in Treating Clot Formation." BII has an exclusive license under the '577 patent in the United States from BIPKG. BIPI has an exclusive license under the '577 patent from BII. A copy of the '577 patent is attached as Exhibit A.

12. Upon information and belief, Kremers filed with the FDA Abbreviated New Drug Application ("ANDA") No. 204552, which included a certification with respect to the '577 patent under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to engage in the manufacture, use, sale, offer for sale, and/or importation of 200 mg extended-release dipyridamole / 25 mg aspirin capsules ("the ANDA product") prior to the expiration of that patent.

13. On or about February 1, 2013, Kremers sent a letter ("Notice Letter") to BIPKG and Boehringer Ingelheim Corporation in which Kremers represented that it had filed an ANDA for the ANDA product, including the certification with respect to the '577 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

14. Kremers' Notice Letter did not provide complete and effective notice under 21 U.S.C. § 355(j)(2)(B)(iii) because Kremers has not served notice to any of the relevant Boehringer entities.

15. This action was commenced within 45 days of the date of the Kremers Notice Letter.

16. Because Kremers seeks approval of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a drug claimed in the '577 patent, and a drug the use of which is claimed in the '577 patent, before its expiration, Kremers has infringed the '577 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

17. Plaintiffs are entitled to a declaration that, if Kremers commercially manufactures, uses, sells, offers to sell, and/or imports any of the ANDA product, or induces or contributes to any such conduct, it would further infringe the '577 patent pursuant to 35 U.S.C. § 271(a), (b) and/or (c).

18. Upon information and belief, the commercial manufacture, use, sale, offer to sell, and/or importation of the ANDA product, if approved by the FDA, prior to the expiration of the '577 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '577 patent. Boehringer is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of Kremers' ANDA No. 204552 be a date that is not earlier than the expiration date of the '577 patent, or any later expiration of exclusivity for the '577 patent to which Boehringer is or may become entitled.

19. The Notice Letter does not dispute that claims 13-14, 16-18, and 20 of the '577 patent cover the ANDA product.

20. At least claims 13-14, 16-18, and 20 of the '577 patent encompass within their scope the ANDA product. The ANDA product would therefore literally infringe at least those claims.

21. Upon information and belief, Kremers was aware of the existence of the '577 patent, and was aware that the filing of its ANDA and certification with respect to the '577 patent constituted an act of infringement of that patent.

22. Kremers' statement of the factual and legal bases for its opinion regarding the invalidity of the '577 patent is devoid of any objective good-faith basis in either the facts or the law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment be entered that Kremers has infringed the '577 patent by submitting its ANDA;

B. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

C. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Kremers, its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the drugs or methods of administering drugs claimed in the '577 patent;

D. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Kremers' ANDA No. 204552 be a date that is not earlier than the expiration date of the '577 patent, or any later expiration of exclusivity for the '577 patent to which Plaintiffs are or may become entitled; and

E. Such other and further relief as the Court may deem just and proper.

Dated: March 14, 2013

Respectfully submitted,

By: s/ Charles M. Lizza

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