IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Civil Action No. 1:15-CV-10

COMPLAINT

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 Mylan Pharmaceuticals Inc. ("Mylan") 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. Defendant Mylan is a corporation organized and existing under the laws of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

NATURE OF THE ACTION

5. This is a civil action concerning United States Patent No. 6,087,380 ("the '380 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, Mylan develops, 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 Mylan because of, *inter alia*, its incorporation under the laws of the State of West Virginia, and because it maintains its principal place of business in the State of West Virginia.

10. Upon information and belief, Mylan has previously admitted that this Court has personal jurisdiction over it. *See Astrazeneca AB v. Mylan Pharms. Inc.*, No. 14-94 (IMK) (N.D. W.Va. Oct. 6, 2014), D.I. No. 17, ¶¶ 10, 11, 13.

BACKGROUND

11. BIPI is the holder of New Drug Application ("NDA") No. 22-512, by which the United States Food and Drug Administration ("FDA") first granted approval for 75 mg

and 150 mg dabigatran etexilate mesylate capsules. The dabigatran etexilate mesylate capsules described in BIPI's NDA are prescribed, *inter alia*, to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Boehringer sells these capsules in the United States under the trade name "PRADAXA®."

12. BIPKG owns the '380 patent, which was duly and legally issued on July 11, 2000, and is titled "Disubstituted Bicyclic Heterocycles, the Preparations and the Use Thereof as Pharmaceutical Compositions." BII and BIPI have an exclusive license under the '380 patent in the United States from BIPKG. A copy of the '380 patent is attached as Exhibit A.

CLAIM FOR RELIEF

13. Plaintiffs reallege paragraphs 1-12 as if fully set forth herein.

14. Mylan filed with the FDA Abbreviated New Drug Application ("ANDA") No. 208067, which included a certification with respect to the '380 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 75 mg and 150 mg dabigatran etexilate mesylate capsules ("Mylan's ANDA products") prior to the expiration of that patent.

15. On or about December 8, 2014, Mylan sent a letter ("Mylan's Notice Letter") to BIPI, BIPKG, BII, and Boehringer Ingelheim Corporation in which Mylan represented that it had filed an ANDA for Mylan's ANDA products, including the certification with respect to the '380 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

16. This action is being commenced within 45 days of the receipt of Mylan's Notice Letter.

17. Because Mylan 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 '380 patent, and a drug the use of which is claimed in the '380 patent, before its expiration, Mylan has infringed the '380 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

18. Plaintiffs are entitled to a declaration that, if Mylan commercially manufactures, uses, sells, offers to sell, and/or imports any of Mylan's ANDA products, or induces or contributes to any such conduct, it would further infringe the '380 patent pursuant to 35 U.S.C. § 271(a), (b), and/or (c).

19. The commercial manufacture, use, sale, offer to sell, and/or importation of Mylan's ANDA products, if approved by the FDA, prior to the expiration of the '380 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '380 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 Mylan's ANDA No. 208067 be a date that is not earlier than the expiration date of the '380 patent, or any later expiration of exclusivity for the '380 patent to which Boehringer is or may become entitled.

20. Upon information and belief, Mylan was aware of the existence of the '380 patent, and was aware that the filing of its ANDA and certification with respect to the '380 patent constituted an act of infringement of that patent.

21. Mylan's statement of the factual and legal bases for its opinion regarding the invalidity of the '380 patent contained in Mylan's Notice Letter is devoid of any objective good-faith basis in either the facts or the law.

22. Plaintiffs will be irreparably harmed by Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at

law.

STATEMENT REGARDING PRIOR-FILED SUIT

23. Boehringer previously filed, on December 15, 2014, an action in The District of New Jersey seeking to enjoin Mylan, as well as Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., and Alkem Laboratories, Ltd., from infringing the '380 patent. That action has been assigned Civil Action No. 3:14-cv-07811-MLC-TJB ("the D.N.J. Action"). The D.N.J. Action is assigned to Judge Mary L. Cooper.

24. In the D.N.J. Action, Boehringer alleged that the District Court for the District of New Jersey has personal jurisdiction over Mylan with regard to Boehringer's claim of patent infringement.

25. Judicial economy would be promoted, and Boehringer's choice of forum respected, if the claim related to Boehringer's action for infringement of the'380 patent is addressed by Judge Cooper in the District of New Jersey.

26. Mylan did not contest personal jurisdiction in New Jersey for the purpose of a Hatch-Waxman Act litigation in the matter of *Warner Chilcott Company, LLC v. Mylan Inc.*, No. 13-6560 (JAP)(TJB) (D.N.J. May 20, 2014), D.I. No. 19, ¶ 9.

27. Before the filing of this action, Mylan refused to consent to personal jurisdiction in New Jersey for the purpose of the D.N.J. Action.

28. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), a patent owner has 45 days from receipt of an ANDA Notice Letter to file suit in order to perfect its statutory right to a stay of FDA approval of an ANDA pending resolution of litigation regarding the submission of such ANDA. Boehringer filed this action as a further protective measure with regard to this statutory right in light of Mylan's refusal to consent to personal jurisdiction in New Jersey in the D.N.J.

Action. Boehringer expects that personal jurisdiction will be maintained in the District of New Jersey and that the action will proceed in that forum. In that circumstance, this action would be unnecessary and will be voluntarily dismissed without prejudice in favor of continued prosecution of the D.N.J. Action, transferred to the District of New Jersey for consolidation with the D.N.J. Action, or subject to such other non-substantive disposition that would ensure maintenance of Boehringer's rights pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment be entered that Mylan has infringed the '380 patent by submitting ANDA No. 208067;

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 Mylan, 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 '380 patent, including any exclusivities or extensions;

D. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Mylan's ANDA No. 208067 be a date that is not earlier than the expiration date of the '380 patent, or any later expiration of exclusivity of the '380 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: January 21, 2015

Respectfully submitted,

By: /s/ James F. Companion

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