IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively, "Boehringer" or "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively, "Teva" or "Defendants"), 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 Teva USA is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

5. Defendant Teva USA is a wholly owned subsidiary and agent of Defendant Teva Ltd.

6. Defendant Teva Ltd. is an Israeli corporation having a principal place of business at 5 Basel Street, Petah Tikva 49131, Israel.

NATURE OF THE ACTION

7. 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

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

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

10. Teva USA develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

11. Teva USA is subject to personal jurisdiction in this judicial district because, *inter alia*, it is a corporation organized and existing under the laws of the State of Delaware.

12. Upon information and belief, Teva USA regularly and continuously transacts business in this judicial district, including by selling and distributing pharmaceutical products in Delaware, either on its own or through its affiliates. Teva USA also purposefully avails itself of the rights and benefits under the laws of the State of Delaware, and has substantial and continuing contacts with the State.

13. Teva Ltd. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

14. This Court has personal jurisdiction over Teva Ltd. because, *inter alia*, Teva Ltd.: (1) intends to market, sell, and/or distribute Teva's ANDA products (as defined in Paragraph 21 *infra*) in this State; (2) holds Drug Master File ("DMF") No. 28118 for dabigatran etexilate mesylate USP, the active pharmaceutical ingredient in Teva's ANDA products; (3) controls Defendant Teva USA; (4) makes its generic drug products available in this State through Teva USA; (5) maintains a broad distributorship network within this State; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State.

15. Both Teva USA and Teva Ltd. have previously consented to personal jurisdiction in this Court. *See Millennium Pharms., Inc. v. Teva Pharms. USA, Inc.*, No. 14-93 (GMS) (D. Del. Jan. 22, 2014), D.I. No. 7, ¶ 10.

16. Both Teva USA and Teva Ltd. have previously taken advantage of the jurisdiction of this Court by affirmatively filing claims and counterclaims in other actions pending before this Court. *See Teva Pharms. USA, Inc. v. Synthon Pharms. Inc.*, No. 14-1419 (GMS) (D. Del. Nov. 18, 2014); *Teva Pharms. USA, Inc. v. Mylan Pharms. Inc.*, No. 14-1278 (GMS) (D. Del. Oct. 6, 2014); *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, No. 14-1171 (GMS) (D. Del. Sept. 10, 2014).

17. Alternatively, to the extent the above facts do not establish personal jurisdiction over Teva Ltd., this Court may exercise personal jurisdiction over Teva Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Teva Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Teva Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of personal jurisdiction over Teva Ltd. satisfies due process.

BACKGROUND

18. 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®."

19. 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

20. Plaintiffs reallege paragraphs 1-19 as if fully set forth herein.

21. Teva filed with the FDA ANDA No. 208057, 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 ("Teva's ANDA products") prior to the expiration of that patent.

22. On or about December 5, 2014, Teva USA sent a letter ("Teva USA's Notice Letter") to BIPI in which Teva USA represented that it had filed an ANDA for Teva'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.

23. Teva USA's Notice Letter did not provide complete and effective notice under 21 U.S.C. § 355(j)(2)(B)(iii) because Teva has not served notice to BIPKG.

24. This action is being commenced within 45 days of the receipt of Teva USA's Notice Letter.

25. Teva USA and Teva Ltd. are jointly and severally liable for any infringement of the '380 patent because, upon information and belief, Teva USA and Teva Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 208057 and the § 355(j)(2)(A)(vii)(IV) allegations to the FDA.

26. Because Teva 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, Teva has infringed the '380 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

27. Plaintiffs are entitled to a declaration that, if Teva commercially manufactures, uses, sells, offers to sell, and/or imports any of Teva'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).

28. The commercial manufacture, use, sale, offer to sell, and/or importation of Teva'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 Teva's ANDA No. 208057 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.

29. Upon information and belief, Teva 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.

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

31. Plaintiffs will be irreparably harmed by Teva'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

32. Boehringer previously filed, on December 15, 2014, an action in the District of New Jersey seeking to enjoin Teva USA and Teva Ltd., as well as Mylan Pharmaceuticals, Inc. 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.

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

34. 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.

35. Teva did not contest personal jurisdiction in New Jersey for the purpose of a Hatch-Waxman Act litigation in the matter of *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc..*, No. 14-06341 (MLC)(DEA) (D.N.J. May 20, 2014), D.I. No. 12, ¶ 9.

36. Before the filing of this action, Teva was asked to consent to personal jurisdiction in New Jersey for the purpose of the D.N.J. Action, but has not responded.

37. 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 Teva's silence regarding whether it will contest 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 Defendants Teva USA and Teva Ltd. have infringed the '380 patent by submitting Teva's ANDA No. 208057;

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 Defendants Teva USA and Teva Ltd., their 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 Teva's ANDA No. 208057 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;

E. An award of Plaintiffs' costs and expenses in this action; and

F. Such other and further relief as the Court may deem just and proper under the circumstances be ordered.

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January 16, 2015