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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC., Plaintiff, v. GATE PHARMACEUTICALS (a Division of Teva Pharmaceuticals USA, Inc.), TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No. 08-4058(SRC)(MAS) **FIRST AMENDED COMPLAINT** *Document electronically filed.*

Plaintiff Hoffmann-La Roche Inc. for its First Amended Complaint against Gate Pharmaceuticals (a division of Teva Pharmaceuticals USA, Inc.), Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd., alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug and Patent Laws of the United States, Titles 21 and 35, respectively. Plaintiff Hoffmann-La Roche Inc. brings this action to enforce its patent rights covering Boniva® Ibandronate Sodium 150 mg tablets, the first bisphosphonate drug approved in the United States for once-monthly dosing to treat osteoporosis. ("Boniva® Once-Monthly").

PARTIES

2. Plaintiff Hoffmann-La Roche Inc. ("Roche") is a company organized and existing under the laws of the State of New Jersey with its principal place of business at 340 Kingsland Street, Nutley, New Jersey, 07110.

3. On information and belief, Defendant Gate Pharmaceuticals ("Teva's Gate Division") is an unincorporated division of Defendant Teva Pharmaceuticals USA, Inc. Teva's Gate Division lists its mailing address as 1090 Horsham Road, PO Box 1090, North Wales, Pennsylvania, 19454-1090.

4. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation having its corporate offices and principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, 19454-1090.

5. On information and belief, Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business at 5 Basel Street, Petach Tikva 49131, Israel.

6. Gate Pharmaceuticals (a division of Teva Pharmaceuticals USA, Inc.), Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd. are collectively referred to hereafter as "Teva."

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

8. On information and belief, Defendant Teva USA is in the business of preparing generic prescription pharmaceuticals that it distributes in New Jersey and throughout the United States. On further information and belief, Teva USA is conducting business within this District, including from facilities located at 8 Gloria Lane, Suite 10, Fairfield, New Jersey, 07004.

9. On information and belief, this Court has personal jurisdiction over Teva USA and Teva's Gate Division by virtue of, among other things, (1) Teva USA's presence in New Jersey, (2) the fact that Teva USA has registered to do business in New Jersey, (3) the fact that Teva USA has registered with the New Jersey Department of Health and Senior Services as a Drug or Medical Device Manufacturing or Wholesale Drug or Medical Device Business, and (4) Teva USA's systematic and continuous contacts with New Jersey.

10. On information and belief, this Court has personal jurisdiction over Teva Ltd. by virtue of, among other things, (1) the fact that Teva Ltd. directly, or through its wholly-owned subsidiaries, manufactures, markets and sells generic drugs throughout the United States and within this District, (2) Teva USA is a wholly-owned subsidiary of Teva Ltd., (3) Teva USA acts as the agent of Teva Ltd., and (4) the acts of Teva's Gate Division and Teva USA complained of herein were done at the direction of, with the authorization, cooperation, participation and assistance of, and for the benefit of, Teva Ltd.

11. Teva has invoked this Court's jurisdiction and subjected itself to this Court's jurisdiction in over sixty cases as plaintiff or defendant.

12. On information and belief, Gate Pharmaceuticals (a division of Teva Pharmaceuticals USA, Inc.), Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd. have previously consented to personal jurisdiction in this District in several cases as plaintiffs and defendants, including a pending related action filed in this District, Hoffmann-La Roche Inc. v. Gate Pharmaceuticals (a division of Teva Pharmaceuticals USA, Inc.), Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd., Civ. No. 07-4285 (SRC)(MAS).

13. On information and belief, this Court has personal jurisdiction over Teva by virtue of, *inter alia*, the facts alleged in paragraphs 8-12 above.

14. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b).

STATEMENT OF FACTS

15. This action arises because of Teva's efforts to gain approval from the United States Food and Drug Administration ("FDA") to market a generic version of Roche's Boniva® Once-Monthly drug product prior to the expiration of Roche's patent rights covering it. The FDA approved Roche's Boniva® Once-Monthly drug product for marketing in the United States under Plaintiff Roche's New Drug Application ("NDA") No. 21-455, pursuant to section 505(b) of the Federal Food Drug and Cosmetics Act ("FFDCA"), 21 U.S.C. § 355(b).

16. With the passage of the Hatch-Waxman Act in 1984, the FFDCA provisions regarding the generic drug approval process were amended in several important respects. One provision requires innovator drug companies to submit patent information to the FDA "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). The FDA then publishes the submitted patent information in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). Whenever a new patent is issued, the innovator drug company must submit the patent information to the FDA not later than thirty days after the patent was issued. 21 U.S.C. § 355(c)(2). The FDA publishes new patent information in updates to the Orange Book.

17. In compliance with that statutory obligation, Plaintiff Roche has submitted patent information to the FDA in connection with its NDA No. 21-455 for Roche's Boniva® Once-Monthly drug product, and the FDA has published same in the Orange Book on or about August 14, 2008.

18. The Hatch-Waxman Act further amended the FFDCA to permit generic drug companies to gain approval of generic copies of innovator drugs (also called the "reference drug" or "listed drug") by referencing studies performed by the innovator, without having to expend the same considerable investment in time and resources. Thus, generic drug companies are permitted to file what is referred to as an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355(j). When filing an ANDA, generic drug companies are required, *inter alia*, to review the patent information that the FDA listed in the Orange Book for the reference drug and make a statutory certification (commonly called "patent certification") with respect to same. This statutory patent certification is mandatory with respect to any patent which claims the listed drug or which claims a use for such listed drug for which the generic drug company is seeking approval and for which information is required to be filed under 21 U.S.C. §§ 355(b) or (c).

19. The generic drug company may state that it does not seek FDA approval to market its generic drug product prior to patent expiration (a "Paragraph III certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(III). Alternatively, the generic drug company may seek FDA approval to market its generic drug product prior to patent expiration by stating in its ANDA that it challenges whether the listed patent is "invalid or will not be infringed ..." (commonly called a 'Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

20. On information and belief, Teva, by and through Teva's Gate Division, has filed ANDA No. 78-999 with the FDA seeking approval to market a 150 mg generic copy of Roche's Boniva® Once-Monthly drug product prior to expiration of Roche's patent rights.

21. On or about July 27, 2007, Roche received a letter from Dr. Paul H. Fackler, Vice President, Research & Development, of Teva USA and Teva's Gate Division, purporting to be a notice of Teva's filing of an ANDA seeking to market a generic copy of Roche's Boniva® Once-Monthly drug product and allegedly containing a Paragraph IV certification required by 21 U.S.C. § 355(j)(2)(B)(i) and (ii), with respect to two of Roche's patents that are currently listed in the Orange Book. (Teva's "Paragraph IV Notice").

22. Teva's Paragraph IV Notice to Roche states Teva's intention to seek approval to market a generic version of Roche's Boniva® Once-Monthly drug product prior to expiration of two of Roche's patents listed in the Orange Book, namely U.S. Patent No. 7,192,938, expiring May 6, 2023, and U.S. Patent No. 6,294,196, expiring October 7, 2019. Notwithstanding the United States Patent and Trademark Office's grant of patent protection to Roche, Teva asserts in its Paragraph IV Notice that these patents are invalid, unenforceable, or would not be infringed.

23. On September 7, 2007, Roche filed an action for patent infringement of both of the '938 and '196 Patents in Hoffmann-La Roche Inc. v. Gate Pharmaceuticals (a division of Teva Pharmaceuticals USA, Inc.), Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd., Civ. No. 07-4285 (SRC)(MAS), which action is currently pending before this Court.

24. On or about September 15, 2008, Roche received a letter from Deborah A. Jaskot, Vice President, Regulatory Affairs for Gate Pharmaceuticals, a Division of Teva Pharmaceuticals USA, Inc., purporting to be a notice of Teva's Paragraph IV certification required by 21 U.S.C. § 355(j)(2)(B)(i) and (ii), with respect to Roche's '957 patent that is currently listed in the Orange Book. (Teva's "Paragraph IV Notice").

25. Teva's Paragraph IV Notice to Roche states Teva's intention to seek approval to market a generic version of Roche's Boniva® Once-Monthly drug product prior to expiration of Roche's patent listed in the Orange Book, namely U.S. Patent No. 7,410,957, expiring May 6, 2023. Notwithstanding the United States Patent and Trademark Office's grant of patent protection to Roche, Teva asserts in its Paragraph IV Notice that the '957 patent is invalid, unenforceable, or would not be infringed.

26. Teva's efforts to seek FDA approval to market a generic copy of Roche's Boniva® Once-Monthly drug product prior to expiration of Roche's patent creates a justiciable controversy between Roche and Teva with respect to the subject matter of Teva's purported ANDA and Roche's patent identified in Teva's Paragraph IV Notice.

COUNT ONE

27. Plaintiff Roche alleges paragraphs 1 through 26 above as if set forth again.

28. On August 12, 2008, the United States Patent and Trademark Office duly and legally issued Bauss *et al.*, U.S. Patent No. 7,410,957 ("the '957 Patent") to Plaintiff Roche. A true and correct copy of the '957 Patent is attached hereto as **Exhibit A**. The '957 Patent was issued from U.S. Patent Application Serial No. 10/430,007, filed May 6, 2003, and is related to the '938 Patent, which issued on March 20, 2007.

29. Roche's '957 Patent discloses and claims, *inter alia*, a method of treating osteoporosis by commencing treatment by orally administering to a subject in need of such treatment, on a single day, a first dose in the form of a tablet, wherein the tablet comprises an amount of a pharmaceutically acceptable salt of ibandronic acid that is equivalent to about 150 mg of ibandronic acid and continuing the treatment by orally administering, once monthly

on a single day, a tablet comprising an amount of a pharmaceutically acceptable salt of ibandronic acid that is equivalent to about 150 mg of ibandronic acid.

30. Plaintiff Roche is the assignee of the '957 Patent and owns all rights, title and interest in the '957 Patent, including all rights needed to bring this action in Plaintiff Roche's own name.

31. Roche's '957 Patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by Roche engaged in the manufacture, use, or sale of Roche's Boniva® Once-Monthly drug product.

32. The '957 Patent is listed in the Orange Book, maintained by the FDA, as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1).

33. On information and belief, Teva has provided a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '957 Patent is invalid or will not be infringed by the manufacture, use, or sale of the generic copy of Boniva® Once-Monthly covered by Teva's ANDA.

34. Additionally, healthcare providers administering and/or patients using Teva's proposed generic copy of Roche's Boniva® Once-Monthly drug product within the United States in the manner and for the indications described in Teva's ANDA will be direct infringers of Roche's '957 Patent under 35 U.S.C. § 271(a). On information and belief, the healthcare providers' and/or patients' infringing use of Teva's proposed generic copy of Roche's Boniva®

Once-Monthly drug product in a method claimed in Roche's '957 Patent will occur with Teva's inducement and with Teva's intent, knowledge, and encouragement.

35. Teva has committed an act of infringement of the 957 Patent that creates a justiciable case or controversy between Roche and Teva. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva committed an act of infringement by filing an ANDA with a Paragraph IV certification that seeks FDA marketing approval for Teva's generic copy of Roche's Boniva® Once-Monthly drug product prior to expiration of Roche's '957 Patent. This Court has subject matter jurisdiction with respect to this action to declare Roche's rights under the '957 Patent.

36. Plaintiff Roche is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for Teva's ANDA be a date which is not earlier than the May 6, 2023 expiration date of the '957 Patent.

37. Plaintiff Roche is entitled to a declaration that, if Teva commercially manufactures, uses, offers for sale or sells Teva's proposed generic copy of Roche's Boniva® Once-Monthly drug product within the United States, imports Teva's proposed generic copy of Roche's Boniva® Once-Monthly drug product into the United States, or induces or contributes to such conduct, Teva would infringe the '957 Patent under 35 U.S.C. § 271.

38. Plaintiff Roche will be irreparably harmed by Teva's infringing activities unless those activities are enjoined by this Court. Plaintiff Roche does not have an adequate remedy at law.

39. This is an exceptional case and Roche is entitled to an award of reasonable attorneys fees from Teva.

RELIEF SOUGHT

WHEREFORE, Plaintiff requests:

A) A judgment and decree that the '957 Patent is valid and enforceable;

B) A judgment that Teva infringed Roche's '957 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the aforesaid ANDA with a Paragraph IV Certification seeking to market Teva's generic version of Boniva® Once-Monthly prior to the expiration of the '957 patent;

C) An Order pursuant to 35 U.S.C. § 271(e)(4) that the effective date of any FDA approval of Teva's ANDA No. 78-999 be a date that is not earlier than the expiration date for the '957 Patent;

D) A judgment that Teva would infringe and induce infringement of Roche's '957 Patent upon marketing of Teva's generic copy of Roche's Boniva® Once-Monthly drug product after grant of FDA approval and during the unexpired term of Roche's '957 Patent;

E) A permanent injunction pursuant to 35 U.S.C. § 271 restraining and enjoining Teva and its officers, agents, servants and employees, and those persons in active concert or participation with any of 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 proposed generic copy of Roche's Boniva® Once-Monthly drug product identified in this First Amended Complaint, and any other product that infringes or induces or contributes to the infringement of the '957 Patent, prior to the expiration date of the '957 Patent;

F) An award of attorneys fees from Teva under 35 U.S.C. § 285; and

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

Dated: September 24, 2008

Respectfully submitted,

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