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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

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HOFFMANN-LA ROCHE INC.,	:	Civil Action No. _____
	:	
Plaintiff,	:	COMPLAINT FOR PATENT
	:	INFRINGEMENT
v.	:	
	:	
ACTAVIS ELIZABETH LLC	:	
and ACTAVIS INC.,	:	<i>Document Electronically Filed</i>
	:	
Defendants.	:	
	:	

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Plaintiff Hoffmann-La Roche Inc. for its Complaint against Actavis Elizabeth LLC and Actavis Inc., 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 Actavis Elizabeth LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 200 Elmora Avenue, Elizabeth, New Jersey, 07207. On further information and belief, Actavis Elizabeth LLC is a wholly-owned subsidiary of Actavis Inc.

4. On information and belief, Defendant Actavis Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 14 Commerce Drive, Suite 301, Cranford, New Jersey 07016.

JURISDICTION AND VENUE

5. 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.

6. On information and belief, Actavis Elizabeth LLC and Actavis Inc. are in the business of developing and manufacturing generic drug products.

7. On information and belief, Actavis Elizabeth LLC and Actavis Inc. conduct business in the State of New Jersey and sell various drug products in the United States including in the State of New Jersey.

8. On information and belief, Actavis Elizabeth LLC and Actavis Inc. have maintained continuous and systematic contacts with the State of New Jersey.

9. On information and belief, Actavis Elizabeth LLC and Actavis Inc. have previously consented to personal jurisdiction in this District in several cases as defendants.

10. On information and belief, this Court has personal jurisdiction over Actavis Elizabeth LLC and Actavis Inc based on their presence in and continuous and sytematic contacts with the State of New Jersey.

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

12. Actavis Elizabeth LLC and Actavis Inc. are collectively referred to hereafter as “Actavis.”

STATEMENT OF FACTS

13. This action arises because of Actavis’ efforts to gain approval from the United States Food and Drug Administration (“FDA”) to market a generic copy 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).

14. With the passage of the Hatch-Waxman Act in 1984, the FFDCA provisions with respect to 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”).

15. 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.

16. The Hatch-Waxman Act further amended the FDCA to permit generic drug companies to gain approval of generic copies of innovator drugs (also called the "reference 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 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.

17. 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).

18. On information and belief, Actavis has filed ANDA No. 90-129 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.

19. On or about April 2, 2008, Roche received a letter signed by Jasmine Shah, Vice President, Regulatory Affairs of Actavis Inc. purporting to be a notice of Actavis' 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 one of Roche's patents that is currently listed in the Orange Book for Roche's Boniva® Once-Monthly drug product. (Actavis' "Paragraph IV Notice").

20. Actavis' Paragraph IV Notice to Roche states Actavis' intention to seek approval to market a generic copy of Roche's Boniva® Once-Monthly drug product prior to expiration of one of Roche's patents listed in the Orange Book, namely 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, Actavis asserts in its Paragraph IV Notice that this patent is invalid, unenforceable, or would not be infringed.

21. Actavis' 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 Actavis with respect to the subject matter of Actavis' purported ANDA and the Roche patent identified in Actavis' Paragraph IV Notice.

COUNT ONE

22. Plaintiff Roche alleges paragraphs 1 through 21 above as if set forth again.

23. On September 25, 2001, the United States Patent and Trademark Office duly and legally issued Gabel *et al.*, U.S. Patent No. 6,294,196 ("the '196 Patent"). A true and correct copy of the '196 Patent is attached hereto as **Exhibit A**. The composition of Roche's Boniva® Once-Monthly drug product is protected by Roche's '196 Patent.

24. Plaintiff Roche is the assignee of the '196 Patent and owns all rights, title and interest in the '196 Patent, including all rights needed to bring this action in Plaintiff Roche's own name.

25. The '196 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).

26. On information and belief, Actavis included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with its ANDA alleging that the ‘196 Patent is invalid or will not be infringed by the manufacture, use, or sale of the generic copy of Boniva® Once-Monthly covered by Actavis’ ANDA.

27. Actavis has committed an act of infringement of the ‘196 Patent that creates a justiciable case or controversy between Roche and Actavis. Pursuant to 35 U.S.C. § 271(e)(2)(A), Actavis committed an act of infringement by filing an ANDA with a Paragraph IV certification that seeks FDA marketing approval for Actavis’ generic copy of Roche’s Boniva® Once-Monthly drug product prior to expiration of Roche’s ‘196 Patent. This Court has subject matter jurisdiction with respect to this action to declare Roche’s rights under the ‘196 Patent.

28. 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 Actavis’ ANDA be a date that is not earlier than the expiration date for the last to expire of the ‘196 Patent or any other patent listed in the Orange Book for Boniva® Once-Monthly.

29. Plaintiff Roche is further entitled to a declaration that, if Actavis commercially manufactures, uses, offers for sale or sells Actavis’ generic copy of Boniva® Once-Monthly within the United States, imports Actavis’ generic copy of Boniva® Once-Monthly into the United States, or induces or contributes to such conduct, Actavis would further infringe the ‘196 Patent under 35 U.S.C. § 271(a), (b) and/or (c).

30. Plaintiff Roche will be irreparably harmed by Actavis’ infringing activities unless those activities are enjoined by this Court. Plaintiff Roche does not have an adequate remedy at law.

31. This is an exceptional case and Roche is entitled to an award of reasonable attorney fees from Actavis.

RELIEF SOUGHT

WHEREFORE, Plaintiff requests:

- A) A judgment and decree that the '196 Patent is valid and enforceable;
- B) A judgment that Actavis infringed Roche's '196 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the aforesaid ANDA with a Paragraph IV Certification seeking to market Actavis' generic copy of Boniva® Once-Monthly prior to the expiration of the '196 Patent;
- C) A judgment that Actavis would infringe and induce infringement of Roche's '196 Patent upon marketing of Actavis' generic copy of Boniva® Once-Monthly after grant of FDA approval and during the unexpired term of Roche's '196 Patent;
- D) An Order pursuant to 35 U.S.C. § 271 (e)(4)(A) that the effective date of any FDA approval of Actavis' ANDA No. 90-129 be a date that is not earlier than the expiration date for the last to expire of the '196 Patent or any other patent listed in the Orange Book for Boniva® Once-Monthly.
- E) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Actavis 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 generic copy of Boniva® Once-Monthly identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '196 Patent, prior to patent expiration;
- F) An award of attorneys fees from Actavis under 35 U.S.C. § 285;

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

Dated: May 16, 2008

Respectfully submitted,

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