David E. De Lorenzi, Esq.
Sheila F. McShane, Esq.
**GIBBONS, P.C.**
One Gateway Center
Newark, New Jersey 07102-5310
Telephone No.: (973) 596-4743
Facsimile No.: (973) 639-6235

Mark E. Waddell, Esq.
**LOEB & LOEB LLP**
345 Park Avenue
New York, New York 10154-1895
Telephone No.: (212) 407-4000
*Attorneys for Plaintiff*

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

| | | |
|---|---|---|
| HOFFMANN-LA ROCHE INC., | : | |
| Plaintiff, | : | |
| v. | : | Civil Action No. 08-4053 (SRC)(MAS) |
| APOTEX INC. and APOTEX CORP., | : | **FIRST AMENDED COMPLAINT** |
| Defendants. | : | *Document electronically filed.* |

Plaintiff Hoffmann-La Roche Inc. for its First Amended Complaint against Apotex Inc. and Apotex Corp., 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 Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

4. On information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2400 N. Commerce Parkway, Suite 400, Weston, Florida, 33326.

5. Apotex Inc. and Apotex Corp. are collectively referred to hereafter as "Apotex."

## 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), 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

7. On information and belief, Apotex Inc. develops and manufactures generic drugs for sale and use in the United States and exports some of its pharmaceutical products for sale in the State of New Jersey.

8. On information and belief, Apotex Corp. is the United States marketing and sales affiliate for Apotex Inc. and 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" N.J.S.A. 24:6B.

9. On information and belief, Apotex has maintained continuous and systematic contacts with the State of New Jersey.

10. On information and belief, both Apotex Inc. and Apotex Corp. have previously consented to personal jurisdiction in this District in several cases as plaintiffs and defendants, including two pending related actions filed in this District, Hoffmann-La Roche Inc. v. Apotex Inc. and Apotex Corp., Civ. No. 07-4417 (SRC)(MAS) and Hoffmann-La Roche Inc. v. Apotex Inc. and Apotex Corp., Civ. No. 08-3065 (SRC)(MAS).

11. On information and belief, this Court has personal jurisdiction over Apotex by virtue of, *inter alia*, the facts alleged in paragraphs 7-10.

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

## STATEMENT OF FACTS

13. This action arises because of Apotex's 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"). 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.

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 on or about August 14, 2008.

16. 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).

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, Apotex has filed ANDA No. 78-948 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 August 2, 2007, Roche received a letter signed by Bernard C. Sherman, Ph.D., P.Eng., Chairman and CEO of Apotex Inc. purporting to be a notice of Apotex'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 for Roche's Boniva® Once-Monthly drug product. (Apotex's "First Paragraph IV Notice").

20. Apotex's First Paragraph IV Notice to Roche stated Apotex's intention to seek approval to market a generic copy of Roche's Boniva® Once-Monthly drug product prior to expiration of two Roche patents listed in the Orange Book, namely U.S. Patent No. 7,192,938

("the '938 Patent"), expiring May 6, 2023, and U.S. Patent No. 6,294,196 ("the '196 Patent"), expiring October 7, 2019. Notwithstanding the United States Patent and Trademark Office's grant of patent protection to Roche, Apotex asserted in its First Paragraph IV Notice that these patents are invalid, unenforceable, or would not be infringed.

21. On September 14, 2007, Roche filed an action for patent infringement of each of the '938 and '196 Patents in Hoffmann-La Roche Inc. v. Apotex Inc. and Apotex Corp., Civ. No. 07-4417 (SRC)(MAS), which action is currently pending before this Court.

22. On or about May 12, 2008, Roche received a letter signed by Bernice Tao, Director of Regulatory Affairs for Apotex Inc. purporting to be a second notice of Apotex'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 another of Roche's patents that is currently listed in the Orange Book for Roche's Boniva® Once-Monthly drug product - U.S. Patent No. 4,927,814 ("the '814 Patent"), expiring March 17, 2012. (Apotex's "Second Paragraph IV Notice").

23. Apotex's Second Paragraph IV Notice to Roche states Apotex's intention to seek approval to market a generic copy of Roche's Boniva® Once-Monthly drug product prior to expiration of the '814 Patent on March 17, 2012. Notwithstanding the United States Patent and Trademark Office's grant of patent protection to Roche, Apotex asserts in its Second Paragraph IV Notice that this patent is invalid, unenforceable, or would not be infringed.

24. On June 18, 2008, Roche filed an action for patent infringement of the '814 Patent in Hoffmann-La Roche Inc. v. Apotex Inc. and Apotex Corp., Civ. No. 08-3065 (SRC)(MAS) (consolidated with Civ. No. 07-4417), which actions are currently pending before this Court.

25. On or about November 28, 2008, Roche received a letter from Bernice Tao, Director, U.S. Regulatory Affairs for Apotex, Inc., purporting to be a notice of Apotex's Paragraph IV certification required by 21 U.S.C. § 355(j)(2)(B), with respect to Roche's '957 patent that is currently listed in the Orange Book. (Apotex's "Third Paragraph IV Notice").

26. Apotex's Third Paragraph IV Notice to Roche states Apotex'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, Apotex asserts in its Paragraph IV Notice that the '957 patent is invalid, unenforceable, or would not be infringed.

27. Apotex'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 Apotex with respect to the subject matter of Apotex's purported ANDA and Roche's patent identified in Apotex's Paragraph IV Notice.

**COUNT ONE**

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

29. 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.

30. 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.

31. 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.

32. 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.

33. 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).

34. On information and belief, Apotex 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 Apotex's ANDA.

35. Additionally, healthcare providers administering and/or patients using Apotex's proposed generic copy of Boniva® Once-Monthly within the United States in the manner and for the indications described in Apotex'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 Apotex's proposed generic copy of Boniva® Once-Monthly in a method claimed in Roche's '957 Patent will occur with Apotex's inducement and with Apotex's intent, knowledge, and encouragement.

36. Apotex has committed an act of infringement of the '957 Patent that creates a justiciable case or controversy between Roche and Apotex. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex committed an act of infringement by filing an ANDA with a Paragraph IV certification that seeks FDA marketing approval for Apotex'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.

37. 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 Apotex's ANDA be a date which is not earlier than the May 6, 2023 expiration date of the '957 Patent.

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

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

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

## RELIEF SOUGHT

**WHEREFORE**, Plaintiff requests:

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

B) A judgment that Apotex 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 Apotex'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 Apotex's ANDA No. 78-948 be a date that is not earlier than the expiration date for the '957 Patent;

D) A judgment that Apotex would infringe and induce infringement of Roche's '957 Patent upon marketing of Apotex's generic copy of Boniva® Once-Monthly 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 Apotex 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 Boniva® Once-Monthly identified in this 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 Apotex under 35 U.S.C. § 285; and

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

Dated: December 12, 2008

Respectfully submitted,

David E. De Lorenzi, Esq.
Sheila F. McShane, Esq.
**GIBBONS, P.C.**
One Gateway Center
Newark, New Jersey 07102-5310
Telephone No.: (973) 596-4743
Facsimile No.: (973) 639-6235

By: s/ David E. De Lorenzi
Attorneys for Plaintiff

Of Counsel:
Mark E. Waddell, Esq.
**LOEB & LOEB LLP**
345 Park Avenue
New York, New York 10154-1895
Telephone No.: (212) 407-4000
Facsimile No.: (212) 407-4990