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

Of Counsel:
Mark E. Waddell, Esq.
Warren MacRae, Esq.
Juliette J. Everhard, Esq.
LOEB & LOEB LLP
345 Park Avenue
New York, New York 10154-1895
Telephone No.: (212) 407-4000
Facsimile No.: (212) 407-4990
Attorneys for Plaintiff

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Hoffmann-La Roche Inc. for its Complaint against 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 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.

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

5. Teva USA and Teva Ltd. are collectively referred to hereafter as "Teva."

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, 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.

8. On information and belief, this Court has personal jurisdiction over Teva USA by virtue of, among other things, (1) Teva USA's presence in New Jersey, (2) the fact that Teva USA is registered to do business in New Jersey, (3) the fact that Teva USA is 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.

9. 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 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.

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

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

STATEMENT OF FACTS COMMON TO ALL COUNTS

12. 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).

13. 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").

14. 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.

15. 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") 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.

16. 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).

17. On information and belief, Teva has filed ANDA No. 79-000 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.

18. On or about July 27, 2007, Roche received a letter from Dr. Paul H. Fackler, Vice President, Research & Development of Teva USA, 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").

19. 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 Roche 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.

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

COUNT ONE

21. Plaintiff Roche alleges paragraphs 1 through 20 above as if set forth again.

22. On March 20, 2007, the United States Patent and Trademark Office duly and legally issued Bauss *et al.*, U.S. Patent No. 7,192,938 ("the '938 Patent") to Plaintiff Roche. A true and correct copy of the '938 Patent is attached hereto as **Exhibit A**.

23. As noted above, Boniva® Once-Monthly is the first bisphosphonate drug approved in the United States for monthly dosing to treat osteoporosis. This FDA approved method of use is protected by Roche's '938 Patent.

24. Plaintiff Roche is the assignee of the '938 Patent and owns all rights, title and interest in the '938 Patent, including all rights needed to bring this action in Plaintiff Roche's own name.

25. The '938 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, Teva included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with its ANDA alleging that the '938 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.

27. Healthcare providers administering and/or patients using Teva's proposed generic version of Boniva® Once-Monthly within the United States in the manner and for the indications described in Teva's ANDA will be direct infringers of Roche's '938 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 version of Boniva® Once-Monthly in the methods claimed in Roche's '938 Patent will occur at Teva's behest and with Teva's intent, knowledge, and encouragement.

28. Teva has committed an act of infringement of the '938 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 '938 Patent. This Court has subject matter jurisdiction with respect to this action to declare Roche's rights under the '938 Patent.

29. 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 '938 Patent.

30. Plaintiff Roche is further entitled to a declaration that, if Teva commercially manufactures, uses, offers for sale or sells Teva's proposed generic version of Boniva® Once-Monthly within the United States, imports Teva's proposed generic version of Boniva® Once-Monthly into the United States, or induces or contributes to such conduct, Teva would further infringe the '938 Patent under 35 U.S.C. § 271(a), (b) and/or (c).

31. 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.

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

COUNT TWO

33. Plaintiff Roche alleges paragraphs 1 through 32 above as if set forth again.

34. 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 B**. The composition of Roche's Boniva® Once-Monthly drug product is protected by Roche's '196 Patent.

35. 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.

36. 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).

37. On information and belief, Teva 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 Teva's ANDA.

38. According to Teva's Paragraph IV Notice to Roche, Teva disputes whether the composition of Teva's proposed generic copy of Roche's Boniva® Once-Monthly drug product would infringe the '196 Patent.

39. Teva purported to include an "Offer of Confidential Access" to its ANDA along with its Paragraph IV Notice sent to Roche. The Federal Food Drug and Cosmetics

Act, 21 U.S.C. § 355(j)(5)(C)(i)(III), specifies that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

40. Teva's Offer of Confidential Access to Roche restricted disclosure to Roche's outside counsel and certain of their staff.

41. Soon after receipt of Teva's purported Offer of Confidential Access, outside counsel for Roche requested that Teva amend its Offer of Confidential Access to permit in-house counsel for Roche to gain access to the relevant portions of Teva's ANDA defining the composition of Teva's proposed generic copy of Roche's Boniva® Once-Monthly drug product.

42. After Teva refused Roche's request, Roche's outside counsel asked that Teva reconsider and permit access solely by Roche's Chief Patent Counsel. Teva again refused.

43. Thus, no Roche client representative has been permitted to review information concerning Teva's proposed generic copy of Roche's Boniva® Once-Monthly drug product beyond that which is set forth in Teva's Paragraph IV Notice itself. That Paragraph IV Notice does not specify the composition of Teva's proposed generic copy of Roche's Boniva® Once-Monthly drug product. Consequently, through no fault of its own, Roche has not been able to analyze the basis, if any, for Teva's assertion that its proposed generic product would not infringe the '196 Patent.

44. Under the terms of Teva's Offer of Confidential Access, Roche's outside counsel are permitted solely to advise Roche whether or not to bring an action for infringement of the '196 Patent. In addition, Roche's outside counsel are precluded from advising Roche of any information derived from Teva that forms the basis for that advice. Roche disputes the restrictions imposed by Teva and will seek entry of a protective order permitting Roche's in-house counsel access to Teva's proposed product composition whereby Roche may evaluate the basis, if any, for Teva's Paragraph IV Notice concerning Roche's '196 Patent.

45. Teva has committed an act of infringement of the '196 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 '196 Patent. This Court has subject matter jurisdiction with respect to this action to declare Roche's rights under the '196 Patent.

46. If this Court determines that Teva's generic copy of Roche's Boniva® Once-Monthly drug product would infringe the '196 Patent, then 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 October 7, 2019 expiration date of the '196 Patent.

47. Moreover, on information and belief, Roche is entitled to a declaration whether, if Teva commercially manufactures, uses, offers for sale or sells Teva's

proposed generic version of Boniva® Once-Monthly within the United States, imports Teva's proposed generic version of Boniva® Once-Monthly into the United States, or induces or contributes to such conduct, Teva would further infringe the '196 Patent under 35 U.S.C. § 271(a), (b) and/or (c).

48. 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.

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

RELIEF SOUGHT

WHEREFORE, Plaintiff requests:

A) A judgment and decree that the '938 and '196 Patents are valid and enforceable;

B) A judgment that Teva infringed Roche's '938 and '196 Patents 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 those patents;

C) A judgment that Teva would infringe and induce infringement of Roche's '938 and '196 Patents upon marketing of Teva's generic version of Boniva® Once-Monthly after grant of FDA approval and during the unexpired terms of Roche's '938 and '196 Patents;

D) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Teva's ANDA No. 79-000 be a date that is not earlier than the expiration date for the last to expire of the '938 and '196 Patents.

E) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) 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 version of Boniva® Once-Monthly identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '938 or '196 Patents, prior to patent expiration;

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

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

Dated: September 7, 2007

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.
Warren MacRae, Esq.
Juliette J. Everhard, Esq.
LOEB & LOEB LLP
345 Park Avenue
New York, New York 10154-1895
Telephone No.: (212) 407-4000
Facsimile No.: (212) 407-4990