Michael R. Girffinger, Esq.
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 Plaintiffs

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC. and GENENTECH, INC., Plaintiffs, v. ORCHID CHEMICALS & PHARMACEUTICALS LTD., ORCHID HEALTHCARE (a Division of Orchid Chemicals & Pharmaceuticals Ltd.), ORCHID PHARMACEUTICALS INC., and ORGENUS PHARMA INC. Defendants.	Civil Action No. 07-4582 (SRC)(MAS) Civil Action No. 08-4051 (SRC)(MAS) Civil Action No. 10-4050 (SRC)(MAS) (consolidated with 07-4582 for all purposes) **FIRST AMENDED COMPLAINT** *Document Electronically Filed*

Plaintiffs Hoffmann-La Roche Inc. and Genentech, Inc. (collectively "Plaintiffs") for its First Amended Complaint against Orchid Chemicals & Pharmaceuticals Ltd., Orchid Healthcare (a Division of Orchid Chemicals & Pharmaceuticals Ltd.), Orchid Pharmaceuticals Inc., and Orgenus Pharma 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. Plaintiffs bring 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. Plaintiff Genentech, Inc. ("Genentech") is a company organized and existing under the laws of the State of Delaware with its principal place of business at 1 DNA Way, South San Francisco, California 94080. Genentech is an exclusive licensee of the patents identified herein and commercializes the Boniva® Ibandronate Sodium 150 mg tablets.

4. On information and belief, Defendant Orchid Chemicals & Pharmaceuticals Ltd. (hereafter "Orchid Ltd.") is an Indian public limited liability company organized and existing under the laws of India, having a place of business at Orchid Towers, #313, Valluvar Kottam High Road, Nungambakkam, Chennai - 600 034, Tamil Nadu, India. On further information and belief, Orchid Ltd. is registered to do business in the State of New Jersey and maintains a business address at 700 Alexander Park, Suite 104, Princeton, New Jersey, 08540.

5. On information and belief, Defendant Orchid Healthcare (a Division of Orchid Chemicals & Pharmaceuticals Ltd.) (hereafter "Orchid Healthcare") is an unincorporated division of Orchid Ltd., having a place of business at Plot Nos. B3 - B6 & B 11 - B14, SIPCOT Industrial Park, Irungattukottai, Kancheepuram District – 602 105, India.

6. On information and belief, Defendant Orchid Pharmaceuticals Inc. ("Orchid Inc.") is a Delaware corporation with a registered agent at 2711 Centerville Road, Suite 400, Wilmington, Delaware, 19808. On information and belief, Orchid Inc. is a wholly owned subsidiary of Orchid Ltd.

7. On information and belief, Defendant Orgenus Pharma Inc. ("Orgenus") is a New Jersey corporation with its principal place of business at 700 Alexander Road, Suite 104, Princeton, New Jersey, 08540. On information and belief, Orgenus is a subsidiary of Orchid Ltd. On further information and belief, Orgenus acts as the United States agent of Orchid Ltd. and Orchid Healthcare.

8. Orchid Ltd., Orchid Healthcare, Orgenus, and Orchid Inc. are collectively referred to hereafter as "Orchid."

JURISDICTION AND VENUE

9. 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.

10. On information and belief, Orchid Ltd. directly, or through its subsidiaries and affiliates, manufactures, markets and sells generic drugs throughout the United States and in this Judicial District.

11. On information and belief, this Court has personal jurisdiction over Orchid by virtue of, among other things, (1) Orchid's presence in New Jersey, (2) the fact that Orchid has registered to do business in New Jersey, (3) the fact that Orchid has previously consented to jurisdiction in this Judicial District, including the pending related actions, Hoffmann-La Roche Inc. v. Orchid Chemicals & Pharmaceuticals Ltd., Orchid Healthcare, Orchid Pharmaceuticals Inc., and Orgenus Pharma Inc., Civil Action Nos. 07-4582 (SRC)(MAS) and 08-4051 (SRC)(MAS), (4) the acts of Orchid Healthcare complained of herein were done at the direction of, with the authorization, cooperation, participation and assistance of, and for the benefit of Orchid Ltd., Orgenus, and Orchid Inc., and (5) Orchid's systematic and continuous contacts with the State of New Jersey.

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 Orchid's efforts to gain approval from the United States Food and Drug Administration ("FDA") to market a generic version of the Boniva® Once-Monthly drug product prior to the expiration of the patent rights covering it. The FDA approved the Boniva® Once-Monthly drug product for marketing in the United States under 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, Roche has submitted patent information to the FDA in connection with its NDA No. 21-455 for the Boniva® Once-Monthly drug product, and the FDA has published the same in the Orange Book.

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, Orchid has filed ANDA No. 78-998 with the FDA seeking approval to market a 150 mg generic copy of the Boniva® Once-Monthly drug product prior to expiration of the patent rights.

19. On or about August 13, 2007, Roche received a letter signed by Dr. Billa Praveen Reddy of Orchid Healthcare purporting to be a notice of Orchid's filing of an ANDA seeking to market a generic copy of the 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 patents that are currently listed in the Orange Book for the Boniva® Once-Monthly drug product (Orchid's "Paragraph IV Notice").

20. Orchid's Paragraph IV Notice to Roche states Orchid's intention to seek approval to market a generic copy of the Boniva® Once-Monthly drug product prior to expiration of the two 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, Orchid asserted in its Paragraph IV Notice that these patents are invalid, unenforceable, or would not be infringed.

21. On September 25, 2007, Roche filed an action for patent infringement for each of the '938 and '196 Patents in Hoffmann-La Roche Inc. v. Orchid Chemicals & Pharmaceuticals Ltd., Orchid Healthcare, Orchid Pharmaceuticals Inc., and Orgenus Pharma Inc., Civ. No. 07-4582 (SRC)(MAS), which action is currently pending before this Court.

22. On or about October 14, 2008, Roche received a letter from Dr. B. Praveen Reddy, for Orchid Healthcare, purporting to be a notice of Orchid's Paragraph IV certification required by 21 U.S.C. § 355(j)(2)(B)(i) and (ii), with respect to U.S. Patent No. 7,410,957 ("the '957 patent") that is currently listed in the Orange Book. (Orchid's "Second Paragraph IV Notice").

23. Orchid's Second Paragraph IV Notice to Roche states Orchid's intention to seek approval to market a generic version of the Boniva® Once-Monthly drug product prior to expiration of the patent listed in the Orange Book, namely the '957 patent, expiring May 6, 2023. Notwithstanding the United States Patent and Trademark Office's grant of patent protection to Roche, Orchid asserts in its Second Paragraph IV Notice that the '957 patent is invalid or would not be infringed.

24. On August 12, 2008, Roche filed an action for patent infringement of the '957 Patent in Hoffmann-La Roche Inc. v. Orchid Chemicals & Pharmaceuticals Ltd., Orchid Healthcare, Orchid Pharmaceuticals Inc., and Orgenus Pharma Inc., Civ. No. 08-4051 (SRC)(MAS), which action is currently pending before this Court.

25. On or about June 24, 2010, Roche received a letter from Mr. Madhusudan Rao, for Orchid Healthcare, purporting to be a notice of Orchid's Paragraph IV certification required by 21 U.S.C. § 355(j)(2)(B)(i) and (ii), with respect to U.S. Patent No. 7,718,634 ("the '634 patent") that is currently listed in the Orange Book. (Orchid's "Third Paragraph IV Notice").

26. Orchid's Third Paragraph IV Notice to Roche states Orchid's intention to seek approval to market a generic version of the Boniva® Once-Monthly drug product prior to expiration of the patent listed in the Orange Book, namely the '634 patent, expiring May 6, 2023. Notwithstanding the United States Patent and Trademark Office's grant of patent protection to Roche, Orchid asserts in its Third Paragraph IV Notice that the '634 patent is invalid or would not be infringed.

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

COUNT ONE

28. Plaintiffs allege paragraphs 1 through 27 above as if set forth again.

29. On May 18, 2010, the United States Patent and Trademark Office duly and legally issued Bauss *et al.*, U.S. Patent No. 7,718,634 ("the '634 Patent") to Plaintiff Roche. A true and correct copy of the '634 Patent is attached hereto as **Exhibit A**. The '634 Patent was issued from U.S. Patent Application Serial No. 12/139,587, filed June 16, 2008, and is a continuation of the patent that matured into the '957 Patent, which issued on August 12, 2008.

30. The '634 Patent discloses and claims, *inter alia*, a method for treating or inhibiting postmenopausal osteoporosis in a postmenopausal woman in need of treatment or inhibition of postmenopausal osteoporosis by administration of a pharmaceutically acceptable salt of ibandronic acid, consisting essentially of orally administering to the postmenopausal woman, once monthly on a single day, a tablet comprising an amount of the pharmaceutically acceptable salt of ibandronic acid that is equivalent to about 150 mg of ibandronic acid..

31. Plaintiffs are the assignee or exclusive licensee of the '634 Patent and have all rights needed to bring this action.

32. The '634 Patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by Plaintiffs engaged in the manufacture, use, or sale of the Boniva® Once-Monthly drug product.

33. The '634 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, Orchid has provided a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '634 Patent is invalid or will not be infringed by the manufacture, use, or sale of the generic copy of the Boniva® Once-Monthly covered by Orchid's ANDA.

35. Additionally, healthcare providers administering and/or patients using Orchid's proposed generic copy of the Boniva® Once-Monthly drug product within the United States in the manner and for the indications described in Orchid's ANDA will be direct infringers of the

'634 Patent under 35 U.S.C. § 271(a). On information and belief, the healthcare providers' and/or patients' infringing use of Orchid's proposed generic copy of the Boniva® Once-Monthly drug product in a method claimed in the '634 Patent will occur with Orchid's inducement and with Orchid's intent, knowledge, and encouragement.

36. Orchid has committed an act of infringement of the '634 Patent that creates a justiciable case or controversy between Plaintiffs and Orchid. Pursuant to 35 U.S.C. § 271(e)(2)(A), Orchid committed an act of infringement by filing an ANDA with a Paragraph IV certification that seeks FDA marketing approval for Orchid's generic copy of the Boniva® Once-Monthly drug product prior to expiration of the '634 Patent. This Court has subject matter jurisdiction with respect to this action to declare Plaintiffs' rights under the '634 Patent.

37. Plaintiffs are 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 Orchid's ANDA be a date which is not earlier than the May 6, 2023 expiration date of the '634 Patent.

38. Plaintiffs are entitled to a declaration that, if Orchid commercially manufactures, uses, offers for sale or sells Orchid's proposed generic copy of the Boniva® Once-Monthly drug product within the United States, imports Orchid's proposed generic copy of the Boniva® Once-Monthly drug product into the United States, or induces or contributes to such conduct, Orchid would infringe the '634 Patent under 35 U.S.C. § 271.

39. Plaintiffs will be irreparably harmed by Orchid's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

40. This is an exceptional case and Plaintiffs are entitled to an award of reasonable attorneys fees from Orchid.

RELIEF SOUGHT

WHEREFORE, Plaintiffs request:

A) A judgment and decree that the '634 Patent is valid and enforceable;

B) A judgment that Orchid infringed the '634 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the aforesaid ANDA with a Paragraph IV Certification seeking to market Orchid's generic version of the Boniva® Once-Monthly prior to the expiration of the '634 patent;

C) An Order pursuant to 35 U.S.C. § 271(e)(4) that the effective date of any FDA approval of Orchid's ANDA No. 78-998 be a date that is not earlier than the expiration date for the '634 Patent;

D) A judgment that Orchid would infringe and induce infringement of the '634 Patent upon marketing of Orchid's generic copy of the Boniva® Once-Monthly drug product after grant of FDA approval and during the unexpired term of the '634 Patent;

E) A permanent injunction pursuant to 35 U.S.C. § 271 restraining and enjoining Orchid 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 the 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 '634 Patent, prior to the expiration date of the '634 Patent;

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

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

Dated: July 1, 2011

Respectfully submitted,

Michael R. Griffinger, Esq.
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/ Sheila F. McShane
Attorneys for Plaintiffs

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