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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC., Plaintiff, 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. _____ **COMPLAINT FOR PATENT INFRINGEMENT** *Document electronically filed.*

Plaintiff Hoffmann-La Roche Inc. for its 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. 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 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.

4. 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.

5. 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.

6. 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.

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

JURISDICTION AND VENUE

8. 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.

9. 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.

10. 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); 08-4051 (SRC)(MAS) and 10-4050(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.

11. On information and belief, this Court has personal jurisdiction over Orchid by virtue of, *inter alia*, the facts alleged in paragraphs 9-10.

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 Orchid'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).

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 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.

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 Roche's Boniva® Once-Monthly drug product prior to expiration of Roche's 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 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 only two of Roche's patents that are currently listed in the Orange Book for Roche's Boniva® Once-Monthly drug product (Orchid's "First Paragraph IV Notice").

20. Orchid's First Paragraph IV Notice to Roche stated Orchid's intention to seek approval to market a generic copy 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 ("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 Roche's 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 Roche's Boniva® Once-Monthly drug product prior to expiration of Roche's 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 Roche's 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 Roche's Boniva® Once-Monthly drug product prior to expiration of Roche's 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. On August 6, 2010, Roche filed an action for patent infringement of the '634 Patent in Hoffmann-La Roche Inc. v. Orchid Chemicals & Pharmaceuticals Ltd., Orchid Healthcare, Orchid Pharmaceuticals Inc., and Orgenus Pharma Inc., Civ. No. 10-4050 (SRC)(MAS), which action is currently pending before this Court.

28. On or about July 26, 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 Roche's U.S. Patent No. 4,927,814 ("the '814 patent") that is currently listed in the Orange Book. (Orchid's "Fourth Paragraph IV Notice"). The Fourth Paragraph IV Notice states that "ANDA 78-998, as previously amended, contains Paragraph IV Certifications (pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)) with respect to U.S. Nos. 6,294,196 (listed to expire October 7, 2019), 7,192,938 (listed to expire May 6, 2023), 7,410,957 (listed to expire May 6, 2023) and 7,718,634 (listed to expire May 6, 2023).... Orchid has now amended ANDA 78-998 to include a Paragraph IV Certification with respect to the '814 Patent as well. The '814 Patent is listed to expire March 17, 2012."

29. Orchid's Fourth Paragraph IV Notice to Roche states Orchid'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 the '814 patent, expiring May 17, 2012. Notwithstanding the United States Patent and Trademark Office's grant of patent protection to Roche, Orchid asserts in its Fourth Paragraph IV Notice that the '814 patent is invalid, unenforceable or would not be infringed.

30. Orchid'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 Orchid with respect to the subject matter of Orchid's purported amended ANDA and Roche's patent identified in Orchid's Fourth Paragraph IV Notice.

31. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), a 30-month stay of FDA approval of amended ANDA 78-998 will be triggered by the filing of this complaint.

COUNT ONE

32. Plaintiff Roche alleges paragraphs 1 through 31 above as if set forth again.

33. On May 22, 1990, the United States Patent and Trademark Office duly and legally issued Gall *et al.,* U.S. Patent No. 4,927,814 ("the '814 Patent") to Plaintiff Roche. A true and correct copy of the '814 Patent is attached hereto as Exhibit A.

34. 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 compound and method of use is protected by Roche's '814 Patent.

35. Plaintiff Roche is the assignee of the '814 Patent and owns all rights, title and interest in the '814 Patent, including all rights needed to bring this action in Plaintiff Roche's own name.

36. The '814 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, Orchid amended its ANDA to include a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '814 Patent is invalid, unenforceable or will not be infringed by the manufacture, use, or sale of the generic copy of Boniva® Once-Monthly covered by Orchid's ANDA.

38. Healthcare providers administering and/or patients using Orchid's proposed generic copy of Boniva® Once-Monthly within the United States in the manner and for the indications described in Orchid's ANDA will be direct infringers of Roche's '814 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 Boniva® Once-Monthly claimed in Roche's '814 Patent will occur at Orchid's behest and with Orchid's intent, knowledge, and encouragement.

39. Orchid has committed an act of infringement of the '814 Patent that creates a justiciable case or controversy between Roche 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 Roche's Boniva® Once-Monthly drug product prior to expiration of Roche's '814 Patent. This Court has subject matter jurisdiction with respect to this action to declare Roche's rights under the '814 Patent.

40. If this Court determines that Orchid's generic copy of Roche's Boniva® Once-Monthly drug product would infringe the '814 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 Orchid's ANDA be a date which is not earlier than the March 17, 2012 expiration date of the '814 Patent.

41. Moreover, on information and belief, Roche is entitled to a declaration whether, if Orchid commercially manufactures, uses, offers for sale or sells Orchid's proposed generic copy of Boniva® Once-Monthly within the United States, imports Orchid's proposed generic copy of Boniva® Once-Monthly into the United States, or induces or contributes to such conduct, Orchid would further infringe the '814 Patent under 35 U.S.C. § 271(a), (b) and/or (c).

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

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

RELIEF SOUGHT

WHEREFORE, Plaintiff requests:

A) A judgment and decree that the '814 Patent is valid and enforceable;

B) A judgment that Orchid infringed Roche's '814 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 Boniva® Once-Monthly prior to the expiration of this patent;

C) A judgment that Orchid would infringe and induce infringement of Roche's '814 Patent upon marketing of Orchid's generic version of Boniva® Once-Monthly after grant of FDA approval and during the unexpired term of Roche's '814 Patent;

D) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Orchid's ANDA No. 78-948 be a date that is not earlier than the expiration date for the '814 Patent;

E) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) 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 version of Boniva® Once-Monthly identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '814 Patent, prior to patent expiration;

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

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

Respectfully submitted,

Dated: September 3, 2010

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