IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOFFMANN-LA ROCHE INC. and GENENTECH, INC.,	:	
Plaintiffs,	:	
v.	:	Civl Action No. _____
AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA U.S.A., INC.,	:	
Defendants.	:	

COMPLAINT

Plaintiffs Hoffmann-La Roche Inc. and Genentech, Inc. (collectively "Plaintiffs"), by their attorneys, for their Complaint against Aurobindo Pharma Limited ("Aurobindo Pharma") and Aurobindo Pharma U.S.A., Inc. ("Aurobindo USA"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.* Plaintiffs bring this action to enforce their 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 Aurobindo Pharma is a corporation operating and existing under the laws of India with a Registered Office at Plot # 2, Maitri Vihar, Ameerpet, Hyderabad-500 038, Andhra Pradesh, India and having a Factor/plant at Survey No, 71 & 72, Indrakaran (V), Sangareddy (M), Medak Dist – 5020329 A.P., India.

5. On information and belief, Defendant Aurobindo USA is a corporation operating and existing under the laws of Delaware having a place of business at 2400 Route 130 North, Dayton, New Jersey 08810 USA and is listed with the Delaware Department of State Division of Professional Regulation as being a manufacturer of a controlled substance and a pharmacy wholesaler at 6 Wheeling Road, Dayton, NJ 08810 USA.

6. On information and belief, Defendant Aurobindo USA is a wholly-owned subsidiary of Aurobindo Pharma, and is controlled by Aurobindo Pharma.

7. Aurobindo USA and Aurobindo Pharma are collectively referred to hereafter as "Aurobindo."

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, Aurobindo Pharma is in the business of developing and manufacturing generic pharmaceutical products. On information and belief, Aurobindo Pharma sells and delivers pharmaceutical products to Aurobindo USA in New Jersey. On information and belief Aurobindo USA is the agent, affiliate, representative, and/or alter ego of, and/or acts in concert with, Aurobindo Pharma for the purposes of marketing, distributing, and selling generic pharmaceutical products within the United States, including the State of Delaware.

10. This Court has personal jurisdiction over Aurobindo USA because it is incorporated and registered to do business in Delaware, and because it has purposely availed itself of the privilege of doing business in this State. Further, Aurobindo USA maintains continuous and systematic contacts with the State of Delaware, including the sale of generic pharmaceutical drugs to Delaware residents, so as to reasonably allow jurisdiction to be exercised over it.

11. On information and belief, both Aurobindo USA and Aurobindo Pharma have previously consented to personal jurisdiction in this District in several cases, and taken advantage of the rights and protections provided by this Court.

12. Aurobindo Pharma does substantial business in Delaware, derives substantial revenue and engages in persistent conduct with Delaware, with and through its agent Aurobindo USA, a

Delaware corporation, including, on information and belief, the preparation and submission of the ANDA No. 20-4502.

13. Aurobindo Pharma has such substantial control over Aurobindo USA to justify treating Aurobindo USA as an alter ego of Aurobindo Pharma, and imputing Aurobindo USA's Delaware contacts to Aurobindo Pharma. *See In re Rosuvastatin Calcium Patent Litigation,* MDL No. 08-1949-BF (D. Del. Feb. 19, 2010) (Farnan, J.) (adopting Magistrate Judge Stark's recommendation to deny Aurobindo Pharma's motion to dismiss for lack of personal jurisdiction).

14. On information and belief, Aurobindo Pharma and/or Aurobindo USA participated in the preparation and/or filing of ANDA No. 20-4502.

15. On information and belief, this Court has personal jurisdiction over Aurobindo by virtue of, *inter alia,* the facts alleged in paragraphs 8-14.

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

STATEMENT OF FACTS

17. This action arises because of Aurobindo's efforts to gain approval from the United States Food and Drug Administration ("FDA") to market a generic copy of the Boniva® Once-Monthly drug product prior to the expiration of Plaintiffs' 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).

18. With the passage of the Hatch-Waxman Act in 1984, the FFDCA provisions regarding 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.

19. In compliance with the statutory obligation, Roche has submitted patent information to the FDA in connection with its NDA No. 21-455 for its Boniva® Once-Monthly drug product, and the FDA has published the same in the Orange Book.

20. 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).

21. 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).

22. On information and belief, Aurobindo has filed ANDA No. 20-4502 with the FDA seeking approval to market a 150 mg generic copy of the Boniva® Once-Monthly drug product prior to expiration of Plaintiffs' patent rights.

23. Roche received a letter on or about December 13, 2012 which was sent on or about December 10, 2012 and was signed by Robert C. Millonig, Esq. of Sterne, Kessler, Goldstein & Fox P.L.L.C. The letter purported to be a notice of Aurobindo'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 patents that are currently listed in the Orange Book for the Boniva® Once-Monthly drug product. (Aurobindo's "Paragraph IV Notice").

24. Aurobindo's Paragraph IV Notice to Roche stated Aurobindo's intention to seek approval to market a generic copy of the Boniva® Once-Monthly drug product prior to expiration of the following patents listed in the Orange Book, namely U.S. Patent 7,718,634, U.S. Patent 7,410,957, and U.S. Patent 6,294,196. Notwithstanding the United States Patent and Trademark

Office's grant of patent protection to Roche for these patents, Aurobindo asserted in its Paragraph IV Notice that these patents are invalid, unenforceable, or would not be infringed.

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

COUNT ONE

26. Plaintiffs incorporate each of the preceding paragraphs 1 through 25 as if fully set forth herein.

27. On May 18, 2010, the United States Patent and Trademark Office duly and legally issued Bauss *et al.,* U.S. Patent 7,718,634 ("the '634 Patent") to Plaintiff Roche. A true and correct copy of the '634 Patent is attached hereto as **Exhibit A.**

28. 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, by 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.

29. As noted above, Boniva® Once-Monthly is the first bisphosphonate drug approved in the United States for monthly dosing to treat osteoporosis. The FDA approved method of use is protected by Roche's '634 Patent.

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

31. 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.

32. 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).

33. On information and belief, Aurobindo 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 drug product covered by Aurobindo's ANDA No. 20-4502.

34. Additionally, healthcare providers administering and/or patients using Aurobindo's proposed generic copy of the Boniva® Once-Monthly drug product within the United States in the manner and for the indications described in Aurobindo's ANDA No. 20-4502 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 Aurobindo's proposed generic copy of the Boniva® Once-Monthly drug product in a method claimed in the '634 Patent will occur with Aurobindo's contribution and inducement and with Aurobindo's intent, knowledge, and encouragement.

35. Aurobindo has committed an act of infringement of the '634 Patent that creates a justiciable case or controversy between Plaintiffs and Aurobindo. Pursuant to 35 U.S.C. § 271(e)(2)(A), Aurobindo committed an act of infringement by filing an ANDA with a Paragraph IV certification that seeks FDA marketing approval for Aurobindo'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.

36. 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 Aurobindo's ANDA be a date which is not earlier than the current May 6, 2023 expiration date of the '634 Patent, and any extension thereof or exclusivity applicable thereto.

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

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

COUNT TWO

39. Plaintiffs incorporate each of the preceding paragraphs 1 through 38 as if fully set forth herein.

40. On August 12, 2008, the United States Patent and Trademark Office duly and legally issued Bauss *et al.*, U.S. Patent 7,410,957 ("the '957 Patent") to Plaintiff Roche. A true and correct copy of the '957 Patent is attached hereto as **Exhibit B**.

41. The '957 Patent discloses and claims, *inter alia*, a method for 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.

42. As noted above, Boniva® Once-Monthly is the first bisphosphonate drug approved in the United States for monthly dosing to treat osteoporosis. The FDA approved method of use is protected by Roche's '957 Patent.

43. Plaintiffs are the assignee or exclusive licensee of the '957 Patent and have all rights needed to bring this action.

44. The '957 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.

45. 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).

46. On information and belief, Aurobindo 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 the Boniva® Once-Monthly drug product covered by Aurobindo's ANDA No. 20-4502.

47. Additionally, healthcare providers administering and/or patients using Aurobindo's proposed generic copy of the Boniva® Once-Monthly drug product within the United States in the manner and for the indications described in Aurobindo's ANDA No. 20-4502 will be direct infringers of the '957 Patent under 35 U.S.C. § 271(a). On information and belief, the healthcare providers' and/or patients' infringing use of Aurobindo's proposed generic copy of the Boniva® Once-Monthly drug product in a method claimed in the '957 Patent will occur with Aurobindo's contribution and inducement and with Aurobindo's intent, knowledge, and encouragement.

48. Aurobindo has committed an act of infringement of the '957 Patent that creates a justiciable case or controversy between Plaintiffs and Aurobindo. Pursuant to 35 U.S.C. § 271(e)(2)(A), Aurobindo committed an act of infringement by filing an ANDA with a Paragraph IV certification that seeks FDA marketing approval for Aurobindo's generic copy of the Boniva® Once-Monthly drug product prior to expiration of the '957 Patent. This Court has subject matter jurisdiction with respect to this action to declare Plaintiffs' rights under the '957 Patent.

49. 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 Aurobindo's ANDA be a date which is not earlier than the current May 6, 2023 expiration date of the '957 Patent, and any extension thereof or exclusivity applicable thereto.

50. Plaintiffs are entitled to a declaration that, if Aurobindo commercially manufactures, uses, offers for sale or sells Aurobindo's proposed generic copy of the Boniva® Once-Monthly drug product within the United States, imports Aurobindo's proposed generic copy of the Boniva® Once-Monthly drug product into the United States, or induces or contributes to such conduct, Aurobindo would infringe the '957 Patent under 35 U.S.C. § 271 (a), (b) and/or (c).

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

COUNT THREE

52. Plaintiffs incorporate each of the preceding paragraphs 1 through 51 as if fully set forth herein.

53. On September 25, 2001, the United States Patent and Trademark Office duly and legally issued Gabel *et al.*, U.S. Patent 6,294,196 ("the '196 Patent") to Plaintiff Roche. A true and correct copy of the '196 Patent is attached hereto as **Exhibit C**.

54. The composition of the Boniva® Once-Monthly drug product is protected by Roche's '196 Patent.

55. Plaintiffs are the assignee or exclusive licensee of the '196 Patent and have all rights needed to bring this action.

56. The '196 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.

57. 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).

58. On information and belief, Aurobindo has provided a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '196 Patent is invalid or will not be infringed by the manufacture, use, or sale of the generic copy of the Boniva® Once-Monthly drug product covered by Aurobindo's ANDA No. 20-4502.

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

60. Additionally, healthcare providers administering and/or patients using Aurobindo's proposed generic copy of the Boniva® Once-Monthly drug product within the United States will be direct infringers of the '196 Patent under 35 U.S.C. § 271(a). On information and belief, the healthcare providers' and/or patients' infringing use of Aurobindo's proposed generic copy of the Boniva® Once-Monthly drug product in a composition claimed in

the '196 Patent will occur with Aurobindo's contribution and inducement and with Aurobindo's intent, knowledge, and encouragement.

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

62. 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 Aurobindo's ANDA be a date which is not earlier than the current October 17, 2019 expiration date of the '196 Patent, and any extension thereof or exclusivity applicable thereto.

63. Plaintiffs are entitled to a declaration that, if Aurobindo commercially manufactures, uses, offers for sale or sells Aurobindo's proposed generic copy of the Boniva® Once-Monthly drug product within the United States, imports Aurobindo's proposed generic copy of the Boniva® Once-Monthly drug product into the United States, or induces or contributes to such conduct, Aurobindo would infringe the '196 Patent under 35 U.S.C. § 271 (a), (b) and/or (c).

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

RELIEF SOUGHT

WHEREFORE, Plaintiffs request:

A) A judgment and decree that the '634, '957 and '196 Patents are valid and enforceable;

B) A judgment that Aurobindo infringed the '634, '957 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 Aurobindo's generic version of the Boniva® Once-Monthly prior to the expiration of those patents;

C) An Order pursuant to 35 U.S.C. § 271(e)(4) that the effective date of any FDA approval of Aurobindo's ANDA No. 20-4502 be a date that is not earlier than the current expiration date for the last to expire of the '634, '957 and '196 Patents, and any extension thereof or exclusivity applicable thereto;

D) A judgment that Aurobindo would infringe and induce and contribute to the infringement of the '634, '957 and '196 Patents upon marketing of Aurobindo's generic copy of the Boniva® Once-Monthly drug product after grant of FDA approval and during the unexpired term of those patents;

E) A permanent injunction pursuant to 35 U.S.C. § 271 restraining and enjoining Aurobindo 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 Complaint, and any other product that infringes or induces or contributes to the infringement of the '634, '957 and

'196 Patents, prior to the expiration date of the those patents and any extension thereof or exclusivity applicable thereto; and

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

Dated: January 22, 2013

Respectfully submitted,

GIBBONS P.C.

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