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

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,	:	Civil Action No. 07-4661 (SRC)(MAS)
	:	Civil Action No. 08-4052 (SRC)(MAS)
v.	:	Civil Action No. 11-0579 (SRC)(MAS)
	:	(consolidated with 07-4661 for all purposes)
MYLAN INC., MYLAN PHARMACEUTICALS INC., GENPHARM ULC (f/k/a GENPHARM INC.) and GENPHARM, L.P.,	:	**FIRST AMENDED COMPLAINT**
	:	*Document Electronically Filed*
Defendants.	:	

Plaintiffs Hoffmann-La Roche Inc. and Genentech, Inc. (collectively "Plaintiffs") for its First Amended Complaint against Mylan Inc., Mylan Pharmaceuticals Inc., Genpharm ULC, formerly known as Genpharm Inc. and Genpharm, L.P., alleges 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 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 Mylan Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

5. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharmaceuticals Inc., is a wholly owned subsidiary of Mylan Inc.

6. On information and belief, Defendant Genpharm Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 85 Advance Road,

Etobicoke, ON M8Z 2S6, Canada. On further information and belief, Genpharm Inc. changed its corporate name to Genpharm ULC.

7. On information and belief, Defendant Genpharm, L.P. is a corporation organized and existing under the laws of the State of New York, having a place of business at 150 Motor Parkway, Suite 309, Hauppauge, New York 11788. On further information and belief, Genpharm, L.P. distributes Genpharm ULC's (f/k/a Genpharm Inc.'s) products in the United States.

8. On information and belief Genpharm ULC (f/k/a Genpharm Inc.) and Genpharm, L.P. are wholly owned subsidiaries of Mylan Inc.

9. On information and belief, Genpharm ULC (f/k/a Genpharm Inc.) and Genpharm, L.P. are affiliates and are collectively referred to hereafter as "Genpharm," and are collectively referred to with Mylan Inc. and Mylan Pharmaceuticals Inc., as "Mylan".

JURISDICTION AND VENUE

10. 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.

11. On information and belief, Genpharm directly, or through its subsidiaries and affiliates, manufactures, markets and sells generic drugs throughout the United States and in this Judicial District. On further information and belief, HD Smith Wholesale Drug Co., based in Kearny, New Jersey, is an authorized distributor for Genpharm.

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

13. On information and belief, Genpharm has been a party to other litigation in this Judicial District and has not objected to personal jurisdiction.

14. On information and belief, both Genpharm ULC (f/k/a Genpharm Inc.) and Genpharm, L.P. have previously consented to personal jurisdiction in this District in several cases as plaintiffs and defendants, including related actions filed in this District, Hoffmann-La Roche Inc. v. Genpharm Inc. *et al*., Civ. No. 07-4661 (SRC)(MAS) and Hoffmann-La Roche Inc. v. Genpharm Inc. *et al*., Civ. No. 08-4052 (SRC)(MAS).

15. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals Inc. are in the business of making and selling generic drug products.

16. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals Inc. conduct business in New Jersey and sell various drug products in the United States, including in the State of New Jersey.

17. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals Inc. are registered to do business in New Jersey and have appointed Corporation Service Company, located at 830 Bear Tavern Road, West Trenton, New Jersey 08628, as their registered agent for service in New Jersey.

18. Mylan Inc. and Mylan Pharmaceuticals Inc. have sued and been sued in this District.

19. Mylan Inc. and Mylan Pharmaceuticals Inc. have previously submitted to the jurisdiction of this Court.

20. On information and belief, this Court has personal jurisdiction over Mylan by virtue of, *inter alia*, the facts alleged in paragraphs 10-19 above.

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

STATEMENT OF FACTS

22. This action arises because of Mylan'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 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).

23. 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.

24. In compliance with the 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.

25. 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).

26. 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).

27. On information and belief, Genpharm ULC (f/k/a Genpharm Inc.) filed ANDA No. 78-995 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.

28. On or about August 15, 2007, Roche received a letter signed by Ian Hilley, Vice President, North American Generic Partnerships, of Genpharm Inc. purporting to be a notice of Genpharm'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. (Genpharm's "First Paragraph IV Notice").

29. Genpharm's First Paragraph IV Notice to Roche stated Genpharm's intention to seek approval to market a generic copy of the Boniva® Once-Monthly drug product prior to expiration of the patents listed in the Orange Book, namely U.S. Patent 7,192,938 ("the '938 Patent"), expiring May 6, 2023, and U.S. Patent 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, Genpharm asserted in its First Paragraph IV Notice that these patents are invalid, unenforceable, or would not be infringed.

30. On September 28, 2007, Roche filed an action for patent infringement of both of the '938 and '196 Patents in Hoffmann-La Roche v. Genpharm Inc. and Genpharm, L.P., Civ. No. 07-4661 (SRC)(MAS).

31. 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. 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.

32. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Roche submitted patent information for the '957 Patent to the FDA in connection with its NDA No. 21-455 for the Boniva® Once-Monthly drug product. The FDA has published the same in the Orange Book.

33. On August 12, 2008, Roche filed an action for patent infringement of the '957 Patent in Hoffmann-La Roche Inc. v. Genpharm Inc. and Genpharm, L.P., Civ. No. 08-4052 (SRC)(MAS) (consolidated with Civ. No. 07-4661), which is currently pending before this Court.

34. On or about October 30, 2008, a letter signed by Richard E. Parke, counsel for Mylan, purporting to be a notice of a Paragraph IV certification required by 21 U.S.C. § 355(j)(2)(B)(i) and (ii), with respect to the '957 Patent that is currently listed in the Orange Book. (Genpharm's "Second Paragraph IV Notice").

35. Genpharm's Second Paragraph IV Notice to Roche states Genpharm's intention to seek approval to market a generic copy of the Boniva® 150 mg drug product prior to expiration of the '957 Patent. Notwithstanding the United States Patent and Trademark Office's grant of patent protection to Roche, Genpharm asserted in its Second Paragraph IV Notice that the patent is invalid or would not be infringed.

36. On information and belief, sometime during October of 2009, Mylan Pharmaceuticals Inc. took over ownership of Genpharm's ANDA No. 78-995 seeking approval to commercially market a 150 mg generic copy of the Boniva® Once-Monthly drug product.

37. On or about January 26, 2011, Roche received a letter from Richard E. Parke, counsel for Mylan, purporting to be a notice of Mylan's Paragraph IV certification required by 21 U.S.C. § 355(j)(2)(B), with respect to U.S. Patent 7,718,634 ("the '634 Patent") that is currently listed in the Orange Book. (Mylan's "Paragraph IV Notice").

38. Mylan's Paragraph IV Notice to Roche states Mylan'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, Mylan asserts under its Paragraph IV Notice that the '634 patent is invalid or would not be infringed.

39. Mylan'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 Mylan with respect to the subject matter of Mylan's purported ANDA and the patent identified in Mylan's Paragraph IV Notice.

COUNT ONE

40. Plaintiffs allege paragraphs 1 through 39 above as if set forth again.

41. 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**. 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.

42. 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..

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

44. 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.

45. 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).

46. On information and belief, Mylan 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 Mylan's ANDA No. 78-995.

47. Additionally, healthcare providers administering and/or patients using Mylan's proposed generic copy of the Boniva® Once-Monthly drug product within the United States in the manner and for the indications described in Mylan's ANDA No. 78-995 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 Mylan's proposed generic copy of the Boniva® Once-Monthly drug product in a method claimed in the '634 Patent will occur with Mylan's inducement and with Mylan's intent, knowledge, and encouragement.

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

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

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

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

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

RELIEF SOUGHT

WHEREFORE, Plaintiffs request:

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

B) A judgment that Mylan 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 Mylan'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 Mylan's ANDA No. 78-995 be a date that is not earlier than the expiration date for the '634 Patent;

D) A judgment that Mylan would infringe and induce and contribute to the infringement of the '634 Patent upon marketing of Mylan'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 Mylan 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 Patent, prior to the expiration date of the '634 Patent;

F) An award of attorneys fees from Mylan 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