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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC., Plaintiff, v. MUTUAL PHARMACEUTICAL COMPANY, INC., UNITED RESEARCH LABORATORIES, INC., and PHARMACEUTICAL HOLDINGS CORP., Defendants.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Hoffmann-La Roche Inc. for its Complaint against Mutual Pharmaceutical Company, Inc., United Research Laboratories, Inc., and Pharmaceutical Holdings Corp., 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 Mutual Pharmaceutical Company, Inc. ("Mutual Pharmaceutical") is a Pennsylvania corporation having its corporate offices and principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania, 19124.

4. On information and belief, Defendant United Research Laboratories, Inc. ("United") is a Pennsylvania corporation having its corporate offices and principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania, 19124.

5. On information and belief, Defendant Pharmaceutical Holdings Corp. ("Pharmaceutical Holdings") is a Delaware corporation having its corporate offices and principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania, 19124.

6. On information and belief, Mutual Pharmaceutical is a wholly-owned subsidiary of Pharmaceutical Holdings and has common officers and directors with United and Pharmaceutical Holdings.

7. On information and belief, United is also a wholly-owned subsidiary of Pharmaceutical Holdings and has common officers and directors with Mutual Pharmaceutical and Pharmaceutical Holdings.

8. On information and belief, United and Mutual Pharmaceutical do business as and regularly hold themselves out to the public as "URL Mutual."

9. On information and belief, "URL Mutual" is a registered trademark owned by Pharmaceutical Holdings.

10. Mutual Pharmaceutical, United, and Pharmaceutical Holdings are collectively referred to hereafter as "URL Mutual."

STATEMENT OF FACTS COMMON TO ALL COUNTS

11. This action arises because of URL Mutual'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).

12. 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").

13. 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.

14. 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.

15. 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).

16. On information and belief, URL Mutual has filed ANDA No. 78-996 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.

17. On or about July 30, 2007, Roche received letters signed by E. Brendan Magrab, Esq., Executive Vice President of Commercial Operations, General Counsel of URL Mutual, purporting to be notice of Mutual Pharmaceutical'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 for Roche's Boniva® Once-Monthly drug product. (URL Mutual's "Paragraph IV Notice").

18. On information and belief the acts of Mutual Pharmaceutical complained of in paragraph 17 above were done at the direction of, with the authorization, cooperation, participation and assistance of, and for the benefit of United and Pharmaceutical Holdings.

19. URL Mutual's Paragraph IV Notice to Roche states URL Mutual'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, URL Mutual asserts in its Paragraph IV Notice that these patents are invalid, unenforceable, or would not be infringed.

20. URL Mutual'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 URL Mutual with respect to the subject matter of URL Mutual's purported ANDA and the Roche patents identified in URL Mutual's Paragraph IV Notice.

JURISDICTION AND VENUE

21. 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.

22. On information and belief, United is registered to do business in the State of New Jersey and has designated an agent for service of process in New Jersey, namely Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey 08628.

23. On information and belief, URL Mutual is in the business of preparing generic prescription pharmaceuticals that it distributes in the State of New Jersey and throughout the United States.

24. On information and belief, URL Mutual has maintained continuous and systematic contacts with the State of New Jersey.

25. On information and belief, URL Mutual plans to continue to maintain continuous and systematic contacts with the State of New Jersey, including, but not limited to, its aforesaid business of preparing generic prescription pharmaceuticals that it distributes in the State of New Jersey, and its attendance at pharmaceutical industry conferences held within the State of New Jersey.

26. On further information and belief, at least a portion of the development and testing work in support of URL Mutual's ANDA for its proposed generic copy of Roche's Boniva® Once-Monthly drug product was performed in New Jersey utilizing contract testing laboratories located in New Jersey.

27. On information and belief, URL Mutual plans to continue to use at least some of those same contract testing laboratories located in New Jersey in URL Mutual's future commercial manufacturing and testing of its proposed generic copy of Roche's Boniva® Once-Monthly drug product.

28. On information and belief, URL Mutual has contracted with companies located in the State of New Jersey who have supplied and will continue to supply ingredients that URL Mutual has used in the preparation and filing of its ANDA and that URL Mutual will continue to use in URL Mutual's commercial manufacturing of its proposed generic copy of Roche's Boniva® Once-Monthly drug product.

29. On information and belief, this Court has personal jurisdiction over URL Mutual by virtue of, *inter alia*, the facts alleged in paragraphs 22-28.

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

COUNT ONE

31. Plaintiff Roche alleges paragraphs 1 through 30 above as if set forth again.

32. 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**.

33. 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.

34. 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.

35. 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).

36. On information and belief, URL Mutual 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 URL Mutual's ANDA.

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

38. URL Mutual has committed an act of infringement of the '938 Patent that creates a justiciable case or controversy between Roche and URL Mutual. Pursuant to 35 U.S.C. § 271(e)(2)(A), URL Mutual committed an act of infringement by filing an ANDA with a Paragraph IV certification that seeks FDA marketing approval for URL Mutual'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.

39. 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 URL Mutual's ANDA be a date which is not earlier than the May 6, 2023 expiration date of the '938 Patent.

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

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

42. This is an exceptional case and Roche is entitled to an award of reasonable attorneys fees from URL Mutual.

COUNT TWO

43. Plaintiff Roche alleges paragraphs 1 through 42 above as if set forth again.

44. 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.

45. 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.

46. 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).

47. On information and belief, URL Mutual 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 URL Mutual's ANDA.

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

49. URL Mutual has committed an act of infringement of the '196 Patent that creates a justiciable case or controversy between Roche and URL Mutual. Pursuant to 35 U.S.C. § 271(e)(2)(A), URL Mutual committed an act of infringement by filing an ANDA with a Paragraph IV certification that seeks FDA marketing approval for URL Mutual'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.

50. 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 URL Mutual's ANDA be a date which is not earlier than the October 7, 2019 expiration date of the '196 Patent.

51. Plaintiff Roche is further entitled to a declaration that, if URL Mutual commercially manufactures, uses, offers for sale or sells URL Mutual's proposed generic version of Boniva® Once-Monthly within the United States, imports URL Mutual's proposed generic version of Boniva® Once-Monthly into the United States, or induces or contributes to such conduct, URL Mutual would further infringe the '196 Patent under 35 U.S.C. § 271(a), (b) and/or (c).

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

53. This is an exceptional case and Roche is entitled to an award of reasonable attorney fees from URL Mutual.

RELIEF SOUGHT

WHEREFORE, Plaintiff requests:

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

B) A judgment that URL Mutual 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 URL Mutual's generic version of Boniva® Once-Monthly prior to the expiration of those patents;

C) A judgment that URL Mutual would infringe and induce infringement of Roche's '938 and '196 Patents upon marketing of URL Mutual'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 URL Mutual's ANDA No. 78-996 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 URL Mutual 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 URL Mutual under 35 U.S.C. § 285;

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

Dated: September 11, 2007

Respectfully submitted,

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