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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC. and GENENTECH, INC.,	:	
Plaintiffs,	:	Civil Action No. 07-4539 (SRC)(MAS) Civil Action No. 07-4540 (SRC)(MAS)
v.	:	Civil Action No. 08-4054 (SRC)(MAS) Civil Action No. 10-6206 (SRC)(MAS)
WATSON LABORATORIES, INC., WATSON PHARMACEUTICALS, INC. WATSON PHARMA, INC., COBALT PHARMACEUTICALS INC., and COBALT LABORATORIES, INC.	:	(consolidated with 07-4539 for all purposes) **FIRST AMENDED COMPLAINT** *Document Filed Electronically*
Defendants.	:	

Plaintiffs Hoffmann-La Roche Inc. and Genentech, Inc. (collectively "Plaintiff") for its First Amended Complaint against Defendants Watson Laboratories, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc., 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 Watson Pharmaceuticals, Inc. is a Nevada Corporation with places of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07962 and 311 Bonnie Circle, Corona, California 92880.

5. On information and belief, Defendant Watson Laboratories, Inc. is a Nevada Corporation with places of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07962 and 311 Bonnie Circle, Corona, California 92880.

6. On information and belief, Defendant Watson Pharma, Inc. is a Delaware Corporation with places of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07962 and 311 Bonnie Circle, Corona, California 92880.

7. On information and belief, Defendant Cobalt Pharmaceuticals Inc. is a Canadian corporation with a principal place of business at 6500 Kitimat Road, Mississauga, Ontario, Canada L5N 2B8.

8. On information and belief, Defendant Cobalt Laboratories, Inc. is a Delaware corporation with its principal place of business located at 360 Mount Kemble Avenue, Morristown, New Jersey 07962, and having a registered agent located at 100 Canal Pointe Boulevard, Suite 212, Princeton, New Jersey 08540.

9. On information and belief, Watson Laboratories, Inc. the holder of various Abbreviated New Drug Applications on file with the U.S. Food and Drug Administration ("FDA"), pursuant to which Watson Laboratories, Inc., Watson Pharmaceuticals, Inc. and Watson Pharma, Inc. manufacture, sell and distribute generic copies of innovative pharmaceutical products.

10. On information and belief, Watson Laboratories, Inc. and Watson Pharma, Inc. are wholly owned subsidiaries of Watson Pharmaceuticals, Inc.

11. On information and belief, Cobalt Pharmaceuticals Inc. is a wholly owned subsidiary of Arrow Pharmaceuticals, Inc., which is a wholly owned subsidiary of Watson Pharmaceuticals, Inc.

12. On information and belief, Cobalt Laboratories, Inc. is a wholly owned subsidiary of Watson Cobalt Holdings LLC, which is a wholly owned subsidiary of Watson Pharmaceuticals, Inc. On further information and belief, the directors and officers of Cobalt Laboratories, Inc. are the same as Watson Laboratories, Inc.

13. Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc. are collectively referred to hereafter as "Cobalt", and are collectively referred with Watson Laboratories, Inc., Watson Pharmaceuticals, Inc., and Watson Pharma, Inc. as "Watson".

JURISDICTION AND VENUE

14. 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.

15. On information and belief, Watson Laboratories, Inc. is in the business of manufacturing generic prescription pharmaceuticals that it distributes directly and/or through an agent in New Jersey and throughout the United States.

16. On information and belief, this Court has personal jurisdiction over Watson Laboratories, Inc. by virtue of among other things, (1) its systematic and continuous contacts with the State of New Jersey including maintaining a place of business in New Jersey wherein its President and Director, Paul M. Bisaro, is located as well as deriving substantial revenue from the development, manufacture and/or sale of pharmaceutical products that are sold in New Jersey; and (2) the fact that Watson Laboratories, Inc. has availed itself of the jurisdiction of this Court by the assertion of counterclaims in Teva Women's Health, Inc v. Lupin, Ltd et al., Civ.

No. 10-0080 (FSH)(PS) and Endo Pharmaceuticals Inc. et al. v. Watson Laboratories, Inc., Civ. No. 10-1242 (KSH)(PS).

17. On information and belief, Watson Pharmaceuticals, Inc. is in the business of manufacturing generic prescription pharmaceuticals that it distributes directly and/or through an agent in New Jersey and throughout the United States.

18. On information and belief, this Court has personal jurisdiction over Watson Pharmaceuticals, Inc. by virtue of among other things, (1) its systematic and continuous contacts with the State of New Jersey including maintaining a place of business in New Jersey wherein its President and Director, Paul M. Bisaro, is located as well as deriving substantial revenue from the development, manufacture and/or sale of pharmaceutical products that are sold in New Jersey; and (2) the fact that Watson Pharmaceuticals, Inc. has availed itself of the jurisdiction of this Court by the Rule 7.1 Disclosure Statement filed in this District, Hoffmann-La Roche Inc. v. Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc., Civ. No. 07-4539 (SRC)(MAS), Document 165.

19. On information and belief, Watson Pharma, Inc. is in the business of manufacturing generic prescription pharmaceuticals that it distributes directly and/or through an agent in New Jersey and throughout the United States.

20. On information and belief, this Court has personal jurisdiction over Watson Pharma, Inc. by virtue of among other things, its systematic and continuous contacts with the State of New Jersey including maintaining a place of business in New Jersey wherein its President and Director, Paul M. Bisaro, is located as well as deriving substantial revenue from

the development, manufacture and/or sale of pharmaceutical products that are sold in New Jersey.

21. On information and belief, Cobalt Pharmaceuticals Inc. is in the business of manufacturing generic prescription pharmaceuticals that it distributes through its agent, Cobalt Laboratories, Inc. in New Jersey and throughout the United States.

22. On information and belief this Court has personal jurisdiction over Cobalt Pharmaceuticals Inc. by virtue of among other things, (1) its systematic and continuous contacts with New Jersey, including those through its agent, Cobalt Laboratories, Inc., (2) its admission that this Court has personal jurisdiction over it in the action Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. v. Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc., Civ. No. 07-1690 (WHW), and (3) the fact that Cobalt Pharmaceuticals Inc. has availed itself of the jurisdiction of this Court by the assertion of counterclaims in Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. v. Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc., Civ. No. 07-1690 (WHW) and Ortho-McNeil Pharmaceutical, Inc. v. Cobalt Pharmaceutical Inc., Civ. No. 05-4961 (SRC).

23. On information and belief, this Court has personal jurisdiction over Cobalt Laboratories, Inc. by virtue of, among other things, (1) the fact that Cobalt Laboratories, Inc. directly markets and sells generic drugs throughout the United States and within this District, and (2) Cobalt Laboratories, Inc. having a principal place of business in Morristown, New Jersey and a registered agent designated for service in Princeton, New Jersey.

24. On information and belief, both Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc. have previously consented to personal jurisdiction in this District in several

cases as plaintiffs and defendants, including three pending related actions filed in this District, Hoffmann-La Roche Inc. v. Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc., Civ. No. 07-4539 (SRC)(MAS); Hoffmann-La Roche Inc. v. Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc., Civ. No. 07-4540 (SRC)(MAS); and Hoffmann-La Roche Inc. v. Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc., Civ. No. 08-4054 (SRC)(MAS), where all these litigations are associated with Cobalt's effort to gain approval to market a generic copy of the Boniva® Once-Monthly drug product prior to the expiration of the patent rights covering it.

25. On information and belief, this Court has personal jurisdiction over Watson by virtue of, among other things, the facts alleged in paragraphs 14-24 above.

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

STATEMENT OF FACTS

27. This action arises because of Watson's efforts to gain approval from 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).

28. 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.

29. 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.

30. 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).

31. 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).

32. On information and belief, Cobalt Pharmaceuticals Inc., has filed ANDA No. 79-002 with the FDA seeking approval to market a 2.5 mg generic copy of the Boniva® 2.5 mg drug product prior to expiration of the patent rights.

33. On information and belief, Cobalt Pharmaceuticals Inc., has filed ANDA No. 79-003 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.

34. On or about August 10, 2007, Roche received two letters from Mr. William A. Rakoczy, of Rakoczy Molino Mazzochi Siwik LLP, purporting to be notices of Cobalt Pharmaceutical Inc.'s filing of two ANDAs seeking to market a generic copy of the Boniva® Once-Monthly drug product and the Boniva® 2.5 mg drug product, and allegedly containing Paragraph IV certifications required by 21 U.S.C. § 355(j)(2)(B)(i) and (ii), with respect to four patents that are currently listed in the Orange Book. (Cobalt's "Paragraph IV Notice").

35. Cobalt's Paragraph IV Notices to Roche state (i) Cobalt's intention to seek approval to market a generic copy of the Boniva® Once-Monthly drug product prior to expiration of three of the patents listed in the Orange Book, namely U.S. Patent No. 7,192,938, expiring May 6, 2023, U.S. Patent No. 6,294,196, expiring October 7, 2019 and U.S. Patent No. 4,927,814, expiring March 17, 2012, and (ii) Cobalt's intention to seek approval to market a generic copy of the Boniva® 2.5 mg drug product prior to expiration of three of the patents listed in the Orange Book, namely U.S. Patent No. 6,143,326, expiring April 21, 2017, U.S. Patent No.

6,294,196, expiring October 7, 2019 and U.S. Patent No. 4,927,814, expiring March 17, 2012. Notwithstanding the United States Patent and Trademark Office's grant of patent protection to Roche, Cobalt asserts in its Paragraph IV Notices that these patents are invalid, unenforceable, or would not be infringed.

36. On September 21, 2007, Roche filed two actions for patent infringement of each of the '938, '196, '814, and '326 Patents in Hoffmann-La Roche Inc. v. Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc., Civ. No. 07-4539 (SRC)(MAS) and Hoffmann-La Roche Inc. v. Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc., Civ. No. 07-4540 (SRC)(MAS), which are currently pending before this Court.

37. On August 12, 2008, the United States Patent and Trademark Office duly and legally issued Bauss *et al.*, U.S. Patent No. 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.

38. 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.

39. On August 12, 2008, Roche filed an action for patent infringement of the '957 Patent in Hoffmann-La Roche Inc. v. Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc., Civ. No. 08-4054 (SRC)(MAS), which is currently pending before this Court.

40. On or about January 16, 2009, Roche received a letter from Mr. William A. Rakoczy, of Rakoczy Molino Mazzochi Siwik LLP, purporting to be a notice of Cobalt

Laboratories, Inc.'s filing of an ANDA seeking to market a generic copy of the Boniva® 150 mg 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 the '957 patent that is currently listed in the Orange Book. (Cobalt's "Second Paragraph IV Notice").

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

42. On information and belief, sometime during December of 2009, Watson Laboratories, Inc. took over ownership of Cobalt's ANDA Nos. 79-002 and 79-003 seeking approval to commercially market a 2.5 mg and 150 mg generic copy of the Boniva® Once-Monthly drug product.

43. On or about October 15, 2010, Roche received a letter from Joyce DelGaudio, Executive Director, Regulatory Affairs for Watson Laboratories, Inc., purporting to be a notice of Watson'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. (Watson's "Paragraph IV Notice").

44. Watson's Paragraph IV Notice to Roche states Watson'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, Watson asserts its Paragraph IV Notice that the '634 is invalid or would not be infringed.

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

COUNT ONE

46. Plaintiffs incorporate each of the preceding paragraphs 1 through 45 as if fully set forth.

47. 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.

48. 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.

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

50. 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.

51. 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).

52. On information and belief, Watson 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 Watson's ANDA 79-003.

53. Additionally, healthcare providers administering and/or patients using Watson's proposed generic copy of the Boniva® Once-Monthly drug product within the United States in the manner and for the indications described in Watson'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 Watson's proposed generic copy of the Boniva® Once-Monthly drug product in a method claimed in the '634 Patent will occur with Watson's inducement and with Watson's intent, knowledge, and encouragement.

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

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

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

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

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

RELIEF SOUGHT

WHEREFORE, Plaintiffs request:

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

B) A judgment that Watson 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 Watson'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 Watson's ANDA No. 79-003 be a date that is not earlier than the expiration date for the '634 Patent;

D) A judgment that Watson would infringe and induce and contribute to the infringement of the '634 Patent upon marketing of Watson'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 Watson 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 Watson 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,

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