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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC., Plaintiff, v. COBALT PHARMACEUTICALS INC., and COBALT LABORATORIES, INC. Defendants.	Civil Action No. _____ **COMPLAINT** *Document Filed Electronically*

Plaintiff Hoffmann-La Roche Inc. for its Complaint against 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.* 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 Cobalt Pharmaceuticals Inc. is a Canadian Corporation with a principal place of business at 6500 Kitimat Road, Mississauga, Ontario, Canada L5N 2B8.

4. On information and belief, Defendant Cobalt Laboratories, Inc. is a Delaware corporation with its corporate offices and principal place of business at 24840 S. Tamiami Trail, Bonita Springs, Florida 34134.

5. Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc. are collectively referred to hereafter as "Cobalt."

JURISDICTION AND VENUE

6. 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.

7. 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.

8. 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).

9. 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, (2) Cobalt Laboratories, Inc. has registered to engage in business in New Jersey, with a registered agent designated for service in New Jersey, and (3) Cobalt Laboratories, Inc. has registered as a Drug or Medical Device Manufacturer or Wholesaler with the New Jersey Department of Health and Senior Services.

10. 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 two 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) and Hoffmann-La Roche Inc. v. Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc., Civ. No. 07-4540 (SRC)(MAS).

11. On information and belief, this Court has personal jurisdiction over Cobalt by virtue of, among other things, the facts alleged in paragraphs 7-10 above.

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 Cobalt's efforts to gain approval from the United States Food and Drug Administration ("FDA") to market a generic copy 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 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.

15. 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).

16. 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).

17. 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 Roche's Boniva® 2.5 mg drug product prior to expiration of Roche's patent rights.

18. 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 Roche's Boniva® Once-Monthly drug product prior to expiration of Roche's patent rights.

19. On or about August 10, 2007, Roche received two letters from Mr. William A. Rakoczy, of Rakoczy Molina Mazzochi Siwik LLP, purporting to be notices of Cobalt Pharmaceutical Inc.'s filing of two ANDAs seeking to market a generic copy of Roche's Boniva® Once-Monthly drug product and Roche's 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 of Roche's patents that are currently listed in the Orange Book. (Cobalt's "Paragraph IV Notice").

20. Cobalt's Paragraph IV Notices to Roche state (i) Cobalt's intention to seek approval to market a generic copy of Roche's Boniva® Once-Monthly drug product prior to expiration of three of Roche's 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 Roche's Boniva® 2.5 mg drug product prior to expiration of three of Roche's 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.

21. 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.

COUNT ONE

22. Plaintiff Roche alleges paragraphs 1 through 21 above as if set forth again.

23. 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. A true and correct copy of the '957 Patent is attached hereto as **Exhibit A**. 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.

24. Roche's '957 Patent discloses and claims, *inter alia*, a method of 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.

25. Plaintiff Roche is the assignee of the '957 Patent and owns all rights, title and interest in the '957 Patent, including all rights needed to bring this action in Plaintiff Roche's own name.

26. Roche's '957 Patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by Roche engaged in the manufacture, use, or sale of Roche's Boniva® Once-Monthly drug product.

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

28. On information and belief, Cobalt's ANDA No. 79-003 seeks approval to commercially market a 150 mg generic copy of Roche's Boniva® Once-Monthly drug product for use in a method that is claimed in Roche's '957 Patent. On further information and belief, Cobalt continues its activities in pursuit of FDA final approval of its ANDA No. 79-003 with the aim of commercially marketing its proposed generic copy of Roche's Boniva® Once-Monthly drug product for use in a method that is claimed in Roche's '957 Patent.

29. On information and belief, Cobalt has previously filed patent certifications in its ANDA No. 79-003 seeking, *inter alia*, FDA final approval prior to May 6, 2023. Roche's '957 Patent has an expiration date of May 6, 2023. Therefore, on further information and belief, Cobalt is currently pursuing FDA final approval of its ANDA No. 79-003 prior to the expiration date of Roche's '957 Patent.

30. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii), Cobalt should file a patent certification in its pending ANDA No. 79-003 with respect to Roche's '957 Patent, and Cobalt must make a Paragraph IV Certification with respect to Roche's '957 Patent if Cobalt continues to seek FDA final approval of its ANDA No. 79-003 prior to May 6, 2023. On information and belief, Cobalt's above-described activities are continuing and constitute an act of infringement of Roche's '957 Patent under 35 U.S.C. § 271(e)(2).

31. Additionally, healthcare providers administering and/or patients using Cobalt's proposed generic copy of Roche's Boniva® Once-Monthly drug product within the United States in the manner and for the indications described in Cobalt's ANDA will be direct infringers of Roche's '957 Patent under 35 U.S.C. § 271(a). On information and belief, the healthcare providers' and/or patients' infringing use of Cobalt's proposed generic copy of Roche's Boniva® Once-Monthly drug product in a method claimed in Roche's '957 Patent will occur with Cobalt's inducement and with Cobalt's intent, knowledge, and encouragement.

32. Plaintiff Roche is entitled to a declaration that, if Cobalt commercially manufactures, uses, offers for sale or sells Cobalt's proposed generic copy of Roche's Boniva® Once-Monthly drug product within the United States, imports Cobalt's proposed generic copy of Roche's Boniva® Once-Monthly drug product into the United States, or induces or contributes to such conduct, Cobalt would infringe the '957 Patent under 35 U.S.C. § 271.

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

34. This is an exceptional case and Roche is entitled to an award of reasonable attorneys fees from Cobalt.

RELIEF SOUGHT

WHEREFORE, Plaintiff requests:

A) A judgment and decree that the '957 Patent is valid and enforceable;

B) A judgment that Cobalt's filing of ANDA No. 79-003 and its intention to commercially market its proposed generic copy of Roche's Boniva® Once-Monthly drug product

for use in the methods claimed in Roche's '957 Patent prior to expiration of this patent is an act of infringement of Roche's '957 Patent under 35 U.S.C. § 271(e)(2);

C) An Order pursuant to 35 U.S.C. § 271(e)(4) that the effective date of any FDA approval of Cobalt's ANDA No. 79-003 be a date that is not earlier than the expiration date for the '957 Patent;

D) A judgment that Cobalt would infringe and induce infringement of Roche's '957 Patent upon marketing of Cobalt's generic copy of Roche's Boniva® Once-Monthly drug product after grant of FDA approval and during the unexpired term of Roche's '957 Patent;

E) A permanent injunction pursuant to 35 U.S.C. § 271 restraining and enjoining Cobalt 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 Roche's Boniva® Once-Monthly drug product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '957 Patent, prior to the expiration date of the '957 Patent;

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

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

Dated: August 12, 2008

Respectfully submitted,

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