

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. (“Cobalt Pharmaceuticals”) 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. (“Cobalt Laboratories”) 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, Defendant Cobalt Pharmaceuticals is in the business of manufacturing generic prescription pharmaceuticals that it distributes through its agent, Cobalt Laboratories, in New Jersey and throughout the United States.

8. On information and belief, this Court has personal jurisdiction over Cobalt Pharmaceuticals by virtue of, among other things, (1) its systematic and continuous

contacts with New Jersey, including those through its agent, Cobalt Laboratories, (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.*, Civil Action 07-1690 (WHW)(DNJ), and (3) the fact that Cobalt Pharmaceuticals 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.*, Civil Action No. 07-1690 (WHW)(DNJ) and *Ortho-McNeil Pharmaceutical, Inc. v. Cobalt Pharmaceutical Inc.*, Civil Action No. 05-4961 (SRC)(DNJ).

9. On information and belief, this Court has personal jurisdiction over Cobalt Laboratories by virtue of, among other things, (1) the fact that Cobalt Laboratories directly markets and sells generic drugs throughout the United States and within this District, (2) Cobalt Laboratories is registered to engage in business in New Jersey, with a registered agent designated for service in New Jersey, and (3) Cobalt Laboratories is registered as a Drug or Medical Device Manufacturer or Wholesaler with the New Jersey Department of Health and Senior Services.

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

STATEMENT OF FACTS COMMON TO ALL COUNTS

11. 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).

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, Cobalt Pharmaceuticals, 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.

17. On or about August 10, 2007, Roche received a letter from Mr. William A. Rakoczy, of Rakoczy Molino Mazzochi Siwik LLP, purporting to be a notice of Cobalt 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 three of Roche’s patents that are currently listed in the Orange Book. (Cobalt’s “Paragraph IV Notice”).

18. Cobalt’s Paragraph IV Notice to Roche states Cobalt’s intention to seek approval to market a generic copy of Roche’s Boniva[®] Once-Monthly drug product prior to expiration of three Roche 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. Notwithstanding the United States Patent and Trademark Office's grant of patent protection to Roche, Cobalt asserts in its Paragraph IV Notice that these patents are invalid, unenforceable, or would not be infringed.

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

COUNT ONE

20. Plaintiff Roche alleges paragraphs 1 through 19 above as if set forth again.

21. 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**.

22. 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.

23. 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.

24. 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).

25. On information and belief, Cobalt 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 Cobalt's ANDA.

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

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

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

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

30. 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.

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

COUNT TWO

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

33. 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.

34. 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.

35. 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).

36. On information and belief, Cobalt 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 Cobalt's ANDA.

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

38. Cobalt purported to include an "Offer of Confidential Access" to its ANDA along with its Paragraph IV Notice sent to Roche. The Federal Food Drug and Cosmetics Act, 21 U.S.C. § 355(j)(5)(C)(i)(III), specifies that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

39. Cobalt's Offer of Confidential Access to Roche restricted disclosure to Roche's outside counsel only.

40. Soon after receipt of Cobalt's purported Offer of Confidential Access, outside counsel for Roche requested that Cobalt amend its Offer of Confidential Access to permit in-house counsel for Roche to gain access to the relevant portions of Cobalt's ANDA defining the composition of Cobalt's proposed generic copy of Roche's Boniva[®] Once-Monthly drug product. Outside counsel for Roche also requested that Cobalt permit access of relevant portions of Cobalt's ANDA by outside scientific and/or testing consultants, one additional outside counsel and requested samples of the Cobalt 150 mg dosage form be provided.

41. After Cobalt initially refused all of Roche's requests, Roche's outside counsel asked that Cobalt reconsider and permit the requested access. Cobalt again refused all requests except it proposed a modification for access by Roche in-house counsel, but containing restrictions such that no Roche client representative would actually be able to access the ANDA. Cobalt never responded to any subsequent requests for modifications to the terms of Confidential Access, so Cobalt did not provide its ANDA, or any sample of any dosage form to any Roche outside counsel, to any Roche in-house client representative, or to any outside scientific and/or testing consultants.

42. Thus, no Roche outside counsel or Roche client representative has been permitted to review information concerning Cobalt's proposed generic copy of Roche's Boniva[®] Once-Monthly drug product beyond that which is set forth in Cobalt's Paragraph IV Notice itself. That Paragraph IV Notice does not specify the composition of Cobalt's

proposed generic copy of Roche's Boniva[®] Once-Monthly drug product. Further, no dosage form samples have been provided, nor have any scientific and/or testing consultants have been able to access any Cobalt confidential information. Consequently, through no fault of its own, Roche has not been able to analyze the basis, if any, for Cobalt's assertion that its proposed generic product would not infringe the '196 Patent.

43. Roche was limited to the information contained in the Cobalt Paragraph IV Notice to determine whether or not to bring an action for infringement of the '196 Patent. Roche disputes the restrictions imposed by Cobalt and will seek entry of a protective order permitting access to Cobalt's proposed product composition whereby Roche may evaluate the basis, if any, for Cobalt's Paragraph IV Notice concerning Roche's '196 Patent.

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

45. If this Court determines that Cobalt's generic copy of Roche's Boniva[®] Once-Monthly drug product would infringe the '196 Patent, then 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 Cobalt's ANDA be a date which is not earlier than the October 7, 2019 expiration date of the '196 Patent.

46. Moreover, on information and belief, Roche is entitled to a declaration whether, if Cobalt commercially manufactures, uses, offers for sale or sells Cobalt's proposed generic copy of Boniva[®] Once-Monthly within the United States, imports Cobalt's proposed generic copy of Boniva[®] Once-Monthly into the United States, or induces or contributes to such conduct, Cobalt would further infringe the '196 Patent under 35 U.S.C. § 271(a), (b) and/or (c).

47. 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.

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

COUNT THREE

49. Plaintiff Roche alleges paragraphs 1 through 48 above as if set forth again.

50. On May 22, 1990, the United States Patent and Trademark Office duly and legally issued Gall *et al.*, U.S. Patent No. 4,927,814 ("the '814 Patent") to Plaintiff Roche. A true and correct copy of the '814 Patent is attached hereto as **Exhibit C**.

51. 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 compound and method of use is protected by Roche's '814 Patent.

52. Plaintiff Roche is the assignee of the '814 Patent and owns all rights, title and interest in the '814 Patent, including all rights needed to bring this action in Plaintiff Roche's own name.

53. The '814 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).

54. On information and belief, Cobalt included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with its ANDA alleging that the '814 Patent is invalid or will not be infringed by the manufacture, use, or sale of the generic copy of Boniva[®] Once-Monthly covered by Cobalt's ANDA.

55. Healthcare providers administering and/or patients using Cobalt's proposed generic copy of Boniva[®] Once-Monthly within the United States in the manner and for the indications described in Cobalt'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 Cobalt's proposed generic copy of Boniva[®] Once-Monthly in the methods claimed in Roche's '814 Patent will occur at Cobalt's behest and with Cobalt's intent, knowledge, and encouragement.

56. Cobalt has committed an act of infringement of the '814 Patent that creates a justiciable case or controversy between Roche and Cobalt. Pursuant to 35 U.S.C. § 271(e)(2)(A), Cobalt committed an act of infringement by filing an ANDA with a Paragraph IV certification that seeks FDA marketing approval for Cobalt's generic

copy of Roche's Boniva[®] Once-Monthly drug product prior to expiration of Roche's '814 Patent. This Court has subject matter jurisdiction with respect to this action to declare Roche's rights under the '814 Patent.

57. If this Court determines that Cobalt's generic copy of Roche Boniva[®] Once-Monthly drug product would infringe the '814 Patent, then 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 Cobalt's ANDA be a date which is not earlier than the March 17, 2012 expiration date of the '814 Patent.

58. Moreover, on information and belief, Roche is entitled to a declaration whether, if Cobalt commercially manufactures, uses, offers for sale or sells Cobalt's proposed generic copy of Boniva[®] Once-Monthly within the United States, imports Cobalt's proposed generic copy of Boniva[®] Once-Monthly into the United States, or induces or contributes to such conduct, Cobalt would further infringe the '814 Patent under 35 U.S.C. § 271(a), (b) and/or (c).

59. 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.

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

RELIEF SOUGHT

WHEREFORE, Plaintiff requests:

A) A judgment and decree that the '938, '196 and '814 Patents are valid and enforceable;

B) A judgment that Cobalt infringed Roche's '938, '196 and '814 Patents under 35 U.S.C. § 271(e)(2)(A) by submitting the aforesaid ANDA with a Paragraph IV Certification seeking to market Cobalt's generic copy of Boniva[®] Once-Monthly prior to the expiration of those patents;

C) A judgment that Cobalt would infringe and induce infringement of Roche's '938, '196 and '814 Patents upon marketing of Cobalt's generic copy of Boniva[®] Once-Monthly after grant of FDA approval and during the unexpired terms of Roche's '938, '196 and '814 Patents;

D) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) 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 last to expire of the '938, '196 and '814 Patents.

E) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) 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 Boniva[®] Once-Monthly identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '938, '196 and '814 Patents, prior to patent expiration;

- F) An award of attorneys fees from Cobalt under 35 U.S.C. § 285;
- G) Such other and further relief as the Court may deem just and proper.

Dated: September 21, 2007

Respectfully submitted,

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