

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 Dr. Reddy’s Laboratories, Ltd. is an Indian public limited liability company organized and existing under the laws of India, having a place of business at 7-1-27, Ameerpet, Hyderabad 500 016, India.

4. On information and belief, Defendant Dr. Reddy’s Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 200 Somerset Corporate Boulevard, 7th Floor, Bridgewater, New Jersey 08807.

JURISDICTION AND VENUE

5. 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.

6. On information and belief, Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. are in the business of developing and manufacturing generic drug products.

7. On information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. conduct business in the State of New Jersey and sell various drug products in the United States including in the State of New Jersey.

8. On information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have maintained continuous and systematic contacts with the State of New Jersey.

9. On information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have previously consented to personal jurisdiction in this District in several cases as plaintiffs and defendants.

10. On information and belief, this Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.

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

12. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. are collectively referred to hereafter as "Dr. Reddy's."

STATEMENT OF FACTS

13. This action arises because of Dr. Reddy'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 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”).

15. 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.

16. 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.

17. 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).

18. Three patents are currently listed in the Orange Book for Boniva[®] Once-Monthly: U.S. Patent No. 4,927,814, expiring March 17, 2012 (“the ‘814 Patent”); U.S. Patent No. 6,294,196, expiring October 7, 2019 (“the ‘196 Patent”); and U.S. Patent No. 7,192,938, expiring May 6, 2023 (“the ‘938 Patent”).

19. On or about August 7, 2007, Roche received a letter signed by Lee Banks, Esq. of Dr. Reddy’s Laboratories, Inc. purporting to be a notice of Dr. Reddy’s filing of ANDA No. 78-997 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 Roche’s ‘196 Patent (Dr. Reddy’s “Original Paragraph IV Notice”).

20. Dr. Reddy’s Original Paragraph IV Notice to Roche stated Dr. Reddy’s intention to seek approval to market a generic copy of Roche’s Boniva[®] Once-Monthly drug product prior to expiration of Roche’s ‘196 Patent expiring October 7, 2019. On

information and belief, Dr. Reddy's originally filed Paragraph III certifications with respect to Roche's '814 Patent and '938 Patent stating that Dr. Reddy's did not seek marketing approval prior to their respective expiration dates of March 17, 2012 and May 6, 2023.

21. On September 20, 2007, Plaintiff Roche filed a Complaint for infringement of the '196 Patent against Dr. Reddy's in the District of New Jersey. *Hoffmann-La Roche Inc. v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.*, Civil Action No. 07-4516 (SRC)(MAS). That action is pending.

22. On or about June 6, 2008, Roche received a letter signed by Lee Banks, Esq. of Dr. Reddy's Laboratories, Inc. purporting to be a notice of Dr. Reddy's amendment to its ANDA No. 78-997 seeking to market a generic copy of Roche's Boniva[®] Once-Monthly drug product and allegedly now containing a Paragraph IV certification required by 21 U.S.C. § 355(j)(2)(B)(i) and (ii), with respect to Roche's '938 Patent (Dr. Reddy's "Second Paragraph IV Notice").

23. Dr. Reddy's Second Paragraph IV Notice to Roche states Dr. Reddy's intention to seek approval to market a generic copy of Roche's Boniva[®] Once-Monthly drug product prior to expiration of Roche's '938 Patent on May 6, 2023.

24. Notwithstanding the United States Patent and Trademark Office's grant of patent protection to Roche, Dr. Reddy's asserts in its Paragraph IV Notice that the '938 Patent is invalid, or would not be infringed.

25. Dr. Reddy's efforts to seek FDA approval to market a generic copy of Roche's Boniva[®] Once-Monthly drug product prior to expiration of Roche's patent creates a justiciable controversy between Roche and Dr. Reddy's with respect to the subject matter of Dr. Reddy's purported ANDA and the Roche patent identified in Dr. Reddy's Second Paragraph IV Notice.

COUNT ONE

26. Plaintiff Roche alleges paragraphs 1 through 25 above as if set forth again.

27. 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"). A true and correct copy of the '938 Patent is attached hereto as **Exhibit A**.

28. 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.

29. 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.

30. 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).

31. On information and belief, Dr. Reddy's has amended its ANDA to include a Paragraph IV certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) 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 Dr. Reddy's ANDA.

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

33. 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 Dr. Reddy's ANDA be a date that is not earlier than the expiration date for the last to expire of the '938 Patent or any other patent listed in the Orange Book for Boniva[®] Once-Monthly.

34. Dr. Reddy's Detailed Statement attached to Dr. Reddy's Second Paragraph IV Notice does not contain an allegation of non-infringement of claims 1, 3, 5, 10-12, 16, 18, 20, and 25-27 of the '938 Patent.

35. On information and belief, if Dr. Reddy's commercially manufactures, uses, offers for sale or sells Dr. Reddy's generic copy of Boniva[®] Once-Monthly within the United States, imports Dr. Reddy's generic copy of Boniva[®] Once-Monthly into the

United States, or induces or contributes to such conduct, Dr. Reddy's would infringe at least claims 1, 3, 5, 10-12, 16, 18, 20, and/or 25-27 of the '938 Patent under 35 U.S.C. § 271(a), (b) and/or (c).

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

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

38. This is an exceptional case and Roche is entitled to an award of reasonable attorney fees from Dr. Reddy's.

RELIEF SOUGHT

WHEREFORE, Plaintiff requests:

- A) A judgment and decree that the '938 Patent is valid and enforceable;
- B) A judgment that Dr. Reddy's infringed Roche's '938 Patent under 35 U.S.C. § 271(e)(2)(A) by amending the aforesaid ANDA with a Paragraph IV Certification seeking to market Dr. Reddy's generic copy of Boniva[®] Once-Monthly prior to the expiration of the '938 Patent;

C) A judgment that Dr. Reddy's would infringe and induce infringement of Roche's '938 Patent upon marketing of Dr. Reddy's generic copy of Boniva[®] Once-Monthly after grant of FDA approval and during the unexpired term of Roche's '938 Patent;

D) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Dr. Reddy's ANDA No. 78-997 be a date that is not earlier than the expiration date for the last to expire of the '938 Patent or any other patent listed in the Orange Book for Boniva[®] Once-Monthly.

E) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Dr. Reddy's 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 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 Patent, prior to patent expiration;

F) An award of attorneys fees from Dr. Reddy's under 35 U.S.C. § 285;

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

Dated: July 18, 2008

Respectfully submitted,

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

s/ David E. De Lorenzi
Attorneys for Plaintiff

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