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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC., Plaintiff, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC. Defendants.	Civil Action No. _____ **COMPLAINT** ***Document electronically filed.***

Plaintiff Hoffmann-La Roche Inc. for its Complaint against Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's 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 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, including three pending related actions filed in this District, *Hoffmann-La Roche Inc. v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.*, Civil Action No. 07-4516 (SRC)(MAS), *Hoffmann-La Roche Inc. v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.*, Civil Action No. 08-3607 (SRC)(MAS) and *Hoffmann-La Roche Inc. v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.*, Civil Action No. 08-4055 (SRC)(MAS).

10. On information and belief, this Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc by virtue of, *inter alia*, paragraphs 6-9.

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"). 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, Dr. Reddy's filed ANDA No. 78-997 with the FDA seeking approval to market a 150 mg generic version of Roche's Boniva® Once-Monthly drug product prior to expiration of Roche's patent rights.

18. 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 U.S. Patent No. 6,294,196 ("the '196 patent") (Dr. Reddy's "Original Paragraph IV Notice").

19. 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 U.S. Patent Nos. 4,927,814 and 7,192,938 ("the '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.

20. 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 in *Hoffmann-La Roche Inc. v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.,* Civil Action No. 07-4516 (SRC)(MAS).

21. 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").

22. Dr. Reddy's Second 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 '938 Patent on May 6, 2023.

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

24. On July 18, 2008, Plaintiff Roche filed a Complaint for infringement of the '938 Patent against Dr. Reddy's in *Hoffmann-La Roche Inc. v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.,* Civil Action No. 08-3607 (SRC)(MAS), which action is currently pending before this Court.

25. On or about September 30, 2008, Roche received a letter from Lee Banks, Esq. for Dr. Reddy's, purporting to be a notice of Dr. Reddy's Paragraph IV certification required by 21 U.S.C. § 355(j)(2)(B)(i) and (ii), with respect to Roche's U.S. Patent No. 7,410,957 ("the '957 patent") that is currently listed in the Orange Book. (Dr. Reddy's "Third Paragraph IV Notice").

26. Notwithstanding the United States Patent and Trademark Office's grant of patent protection to Roche, Dr. Reddy's asserted in its Third Paragraph IV Notice that the '957 Patent is invalid, or would not be infringed.

27. On August 12, 2008, Roche filed an action for patent infringement of the '957 Patent in *Hoffmann-La Roche Inc. v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.,* Civil Action No. 08-4055 (SRC)(MAS), which action is currently pending before this Court.

28. On or about September 13, 2010, Roche received a letter from Lee Banks, Esq. of Dr. Reddy's, purporting to be a notice of Dr. Reddy's Paragraph IV certification required by 21 U.S.C. § 355(j)(2)(B)(i) and (ii), with respect to Roche's U.S. Patent No. 7,718,634 ("the '634 patent") that is currently listed in the Orange Book. (Dr. Reddy's "Fourth Paragraph IV Notice").

29. Dr. Reddy's Fourth Paragraph IV Notice to Roche states Dr. Reddy's intention to seek approval to market a generic version of Roche's Boniva® Once-Monthly drug product prior to expiration of Roche's 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, Dr. Reddy's asserts in its Fourth Paragraph IV Notice that the '634 patent is invalid or would not be infringed.

30. 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 Roche's patent identified in Dr. Reddy's Fourth Paragraph IV Notice.

COUNT ONE

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

32. 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 application that matured into the '957 Patent, which issued on August 12, 2008.

33. Roche's '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.

34. Plaintiff Roche is the assignee of the '634 Patent and owns all rights, title and interest in the '634 Patent, including all rights needed to bring this action in Plaintiff Roche's own name.

35. Roche's '634 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.

36. 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).

37. On information and belief, Dr. Reddy's 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 Boniva® Once-Monthly covered by Dr. Reddy's ANDA.

38. Additionally, healthcare providers administering and/or patients using Dr. Reddy'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 Dr. Reddy's ANDA will be direct infringers of Roche's '634 Patent under 35 U.S.C. § 271(a). On information and belief, the healthcare providers' and/or patients' infringing use of Dr. Reddy's proposed generic copy of

Roche's Boniva® Once-Monthly drug product in a method claimed in Roche's '634 Patent will occur with Dr. Reddy's inducement and with Dr. Reddy's intent, knowledge, and encouragement.

39. Dr. Reddy's has committed an act of infringement of the '634 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 filing an ANDA with 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 '634 Patent. This Court has subject matter jurisdiction with respect to this action to declare Roche's rights under the '634 Patent.

40. 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 which is not earlier than the May 6, 2023 expiration date of the '634 Patent.

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

42. 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.

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

RELIEF SOUGHT

WHEREFORE, Plaintiff requests:

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

B) A judgment that Dr. Reddy's infringed Roche's '634 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the aforesaid ANDA with a Paragraph IV Certification seeking to market Dr. Reddy's generic version of 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 Dr. Reddy's ANDA No. 78-998 be a date that is not earlier than the expiration date for the '634 Patent;

D) A judgment that Dr. Reddy's would infringe and induce infringement of Roche's '634 Patent upon marketing of Dr. Reddy's generic copy of Roche's Boniva® Once-Monthly drug product after grant of FDA approval and during the unexpired term of Roche's '634 Patent;

E) A permanent injunction pursuant to 35 U.S.C. § 271 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 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 '634 Patent, prior to the expiration date of the '634 Patent;

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

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

Dated: October 28, 2010

Respectfully submitted,

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