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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PRODUCTS, L.P. and JANSSEN R&D IRELAND, Plaintiffs, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS INC. Defendants.	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Products, L.P. and Janssen R&D Ireland (collectively, "Janssen" or "Plaintiffs") for their Complaint against Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals Inc. ("Lupin Pharmaceuticals") (collectively "Lupin" or "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement by Lupin of U.S. Patent No. 8,518,987 B2 ("the '987 Patent") arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq*. This action arises out of Lupin's filing of Abbreviated New Drug Application ("ANDA") seeking approval to sell generic versions of plaintiff Plaintiffs' highly successful PREZISTA® (darunavir) 75 mg, 150 mg, 300 mg, 400 mg, 600 mg, and 800 mg products prior to the expiration of the '987 Patent.

THE PARTIES

2. Plaintiff Janssen Products, L.P. is a partnership organized under the laws of the State of New Jersey, having its headquarters and principal place of business at 800/850 Ridgeview Drive, Horsham, PA 19044.

3. Plaintiff Janssen R&D Ireland is an Irish corporation having its principal place of business at Eastgate Village, Eastgate, Little Island, County Cork, Ireland.

4. On information and belief, Lupin Ltd. is an Indian corporation having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (E), Mumbai 400 051, India, and having a registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India. On information and belief, Lupin Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market through various operating subsidiaries, including Lupin Pharmaceuticals.

5. On information and belief, Lupin Pharmaceuticals is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202. On information and belief, Lupin Pharmaceuticals is in the business of, among other things,

manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market. Lupin Pharmaceuticals is a wholly owned subsidiary of Lupin Ltd.

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).

7. On information and belief, this Court has personal jurisdiction over Lupin Ltd. because Lupin Ltd. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Ltd. has had persistent and continuous contacts with this judicial district, including developing, manufacturing, and/or selling pharmaceutical products that are sold in this judicial district.

8. On information and belief, this Court has personal jurisdiction over Lupin Pharmaceuticals because Lupin Pharmaceuticals has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Pharmaceuticals has had persistent and continuous contacts with this judicial district, including developing, manufacturing, and/or selling pharmaceutical products that are sold in this judicial district.

9. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals operate and act in concert as an integrated, unitary business. For example, Lupin Ltd. includes within its Annual Report the activities of Lupin Pharmaceuticals, including revenue earned.

10. On information and belief, Lupin Pharmaceuticals is registered to do business in New Jersey.

11. On information and belief, Lupin Pharmaceuticals retains a registered agent in this judicial district.

12. Lupin Ltd. and Lupin Pharmaceuticals have stipulated and/or consented to personal jurisdiction in this district in numerous prior patent cases, including in the related consolidated action, *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, 10-cv-5954 (WHW) (CLW).

13. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

14. On August 27, 2013, the United States Patent and Trademark Office ("the PTO") issued the '987 Patent, entitled "Pseudopolymorphic forms of a HIV protease inhibitor." A true and correct copy of the '987 Patent is attached hereto as Exhibit A.

15. Plaintiff Janssen R&D Ireland holds title to the '987 Patent.

16. The '987 Patent expires on February 16, 2024.

17. The United States Food and Drug Administration ("FDA") has awarded 6 months of pediatric exclusivity for PREZISTA®. The period of pediatric exclusivity applicable to the '987 Patent does not expire until August 16, 2024.

18. Janssen Products L.P. is the holder of approved New Drug Application ("NDA") No. 21-976 for PREZISTA®.

19. PREZISTA® is included in FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations" also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's ANDA to obtain approval of the ANDA applicant's drug product under the provisions of 21 U.S.C. § 355(j).

20. The FDA's "Orange Book" also lists patents associated with approved drugs. The '987 Patent is listed in the "Orange Book" in association with PREZISTA®.

21. On information and belief, Lupin Ltd., itself and/or through its subsidiary, agent and alter ego, Lupin Pharmaceuticals, submitted ANDA No. 202-073 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of generic versions of PREZISTA® 75 mg, 150 mg, 300 mg, 400 mg, 600 mg and 800 mg tablets ("Lupin's Generic Tablets").

22. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals collaborated in the research, development, preparation and filing of ANDA No. 202-073 for Lupin's Generic Tablets.

23. On information and belief, Lupin Pharmaceuticals will market and/or distribute Lupin's Generic Tablets if ANDA No. 202-073 is approved by the FDA.

24. On information and belief, Lupin Ltd. participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 202-073.

25. On or about November 4, 2013, Plaintiffs received a letter dated November 1, 2013 ("the 2013 Lupin Paragraph IV Letter") stating that Lupin had submitted ANDA No. 202-073 seeking approval to manufacture, use and sell Lupin's Generic Tablets prior to the expiration of the '987 Patent.

26. The 2013 Lupin Paragraph IV Letter also states that the Lupin ANDA No. 202-073 included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '987 Patent are invalid and/or will not be infringed by the commercial manufacture, use and sale of Lupin's Generic Tablets.

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