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

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

COMPLAINT FOR PATENT INFRINGEMENT

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

NATURE OF THE ACTION

1. This is a civil action for infringement of U.S. Patent No. RE42,889 (the "'889 Patent") arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq. This action arises out of Defendants' filing of an Abbreviated New Drug Application ("ANDA")

seeking approval to sell generic copies of Plaintiffs' highly successful PREZISTA® (darunavir) 75 mg, 150 mg, 300 mg, 400 mg, and 600 mg products prior to the expiration of the '889 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 (formerly known as Tibotec Pharmaceuticals) is an Irish corporation having its principal place of business at Eastgate Village, Eastgate, Little Island, County Cork, Ireland.

4. Plaintiff G.D. Searle, LLC is a Delaware limited liability company having a principal place of business at 235 East 42nd Street, New York, New York 10017.

5. 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 copies of branded pharmaceutical products for the U.S. market through various operating subsidiaries, including Lupin Pharmaceuticals.

6. 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 copies of branded pharmaceutical products for the U.S. market. Lupin Pharmaceuticals is a wholly owned subsidiary of Lupin Ltd.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. 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.

9. 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.

10. 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.

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

12. On information and belief, Lupin Pharmaceuticals has appointed National Registered Agents, Inc. of Princeton, New Jersey as its registered agent for the receipt of service of process.

13. 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) (MCA).

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

BACKGROUND

15. On November 1, 2011, the United States Patent and Trademark Office ("the PTO") issued the '889 Patent, entitled "α- and β-Amino Acid Hydroxyethylamino Sulfonamides Useful as Retroviral Protease Inhibitors". A true and correct copy of the '889 Patent is attached hereto as Exhibit A.

16. Plaintiff Searle holds title to the '889 Patent.

17. The '889 Patent is a reissue of U.S. Patent No. 5,968,942 ("the '942 Patent").

18. The '942 Patent was filed on August 23, 1994, and issued on October 19, 1999.

19. Plaintiff Janssen R&D Ireland has an exclusive license to the '889 Patent.

20. The '889 Patent expires on October 19, 2016.

21. 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 '889 Patent does not expire until April 19, 2017.

22. Janssen Products, L.P., is the holder of approved New Drug Application ("NDA") No. 21-976 for PREZISTA®. The NDA was formerly held by Tibotec Inc. The NDA was transferred to Janssen Products, L.P., on December 23, 2011.

23. PREZISTA® is included in the 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).

24. The FDA's "Orange Book" also lists patents associated with approved drugs. The '889 Patent is listed in the "Orange Book" in association with PREZISTA® (darunavir). The claims of the '889 Patent cover PREZISTA®.

25. 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 the PREZISTA® 75 mg, 150 mg, 300 mg, 400 mg and 600 mg tablets ("Lupin's Generic Tablets").

26. 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.

27. 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.

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

29. On or about March 30, 2012, Plaintiffs received a letter dated March 28, 2012 (the "March 2012 Lupin Paragraph IV Letter") stating that Defendants had submitted

ANDA No. 202-073 seeking approval to manufacture, use, and sell Lupin's Generic Tablets prior to the expiration of the '889 Patent.

30. The March 2012 Lupin Paragraph IV Letter also stated that Lupin ANDA No. 202-073 included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that claims of the '889 Patent are invalid and/or not infringed.

31. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals continue to collaborate in seeking approval of ANDA No. 202-073 from the FDA and intend to collaborate in the commercial manufacture, marketing, and sale of Lupin's Generic Tablets (including the commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves ANDA No. 202-073.

32. Plaintiffs commenced this action within forty-five days of the date they received the March 2012 Lupin Paragraph IV Letter, containing the Paragraph IV certification for the '889 Patent.

COUNT I

Infringement of the '889 Patent by Defendants

33. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 32 hereof, as if fully set forth herein.

34. Defendants have infringed the '889 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202-073 with a Paragraph IV certification and seeking FDA approval of ANDA No. 202-073 prior to the expiration of the '889 Patent.

35. Defendants had actual and constructive notice of the '889 Patent prior to filing the March 2012 Lupin Paragraph IV Letter for ANDA No. 202-073.

36. Plaintiffs have no adequate remedy at law to redress the infringement by Defendants.

37. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '889 Patent.

PRAYER

WHEREFORE, Plaintiffs respectfully request relief and judgment as follows:

(a) a judgment that Defendants have infringed the '889 Patent under 35 U.S.C. § 271(e)(2)(A);

(b) a judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Defendants' ANDA No. 202-073 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) is not earlier than the day after the expiration of the period of pediatric exclusivity applicable to the '889 Patent;

(c) a judgment declaring that the making, using, selling, offering to sell, or importing of the generic darunavir tablets described in ANDA No. 202-073 would constitute infringement of the '889 Patent, or inducing or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

(d) a judgment permanently enjoining Defendants and each of their officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially manufacturing, selling or offering for sale, using, or importing the generic darunavir tablets described in ANDA No. 202-073 until the day after the expiration of the period of pediatric exclusivity applicable to the '889 Patent;

(e) a declaration that this case is exceptional;

(f) an award of Plaintiffs' costs, expenses, reasonable attorneys fees, and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

(g) such other and further relief as the Court may deem just and proper.

Respectfully submitted,

s/John E. Flaherty

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Dated: May 10, 2012

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. This action involves the same Plaintiffs, two of the same defendants and one of the same ANDAs as in *Janssen Products L.P., et al. v. Lupin Limited, et al.*, D.N.J., 10-cv-5954-WHW-MCA, and relates to generic versions of Plaintiffs' PREZISTA® products. Further, this action involves the same Plaintiffs as in *Tibotec Inc., et al. v. Hetero Drugs, Ltd., Unit III, et al.*, D.N.J. 11-cv-1696-WHW-MCA, and relates to generic versions of Plaintiffs' PREZISTA® products.

Dated: May 10, 2012

Respectfully submitted,

s/John E. Flaherty

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