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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. HETERO DRUGS, LTD., UNIT III, and INVAGEN PHARMACEUTICALS, INC., Defendants.	)	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Janssen Products, L.P. and Janssen R&D Ireland (collectively, "Janssen"), and G.D. Searle, LLC ("Searle") (Janssen and Searle, collectively, "Plaintiffs") for their Complaint against defendants Hetero Drugs, Ltd., Unit III ("Hetero Drugs") and Invagen Pharmaceuticals, Inc. ("Invagen") (collectively, "Hetero") 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. and for a declaratory judgment of infringement of the '889 Patent under 28 U.S.C. §§ 2201 and 2202. This

action arises out of Hetero's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell generic copies of plaintiff Janssen's highly successful PREZISTA® (darunavir) 400 mg and 600 mg products prior to the expiration of patents owned by and exclusively licensed to Plaintiffs.

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, Hetero Drugs Ltd., Unit III is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500 018, A.P. India. On information and belief, Hetero Drugs 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.

6. On information and belief, Invagen Pharmaceuticals, Inc. is a New York corporation having a principal place of business at 7 Oser Ave., Hauppauge, New York 11788. On information and belief, Invagen is a U.S. agent for Hetero Drugs and is in the business, of among other things, manufacturing, marketing and distributing generic versions of branded pharmaceutical products for the U.S. market.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. On information and belief, this Court has personal jurisdiction over Hetero Drugs because Hetero Drugs 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, Hetero Drugs 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 Invagen because Invagen 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, Invagen 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, Hetero Drugs maintains a marketing office in New Jersey.

11. Hetero Drugs has previously stipulated and/or consented to personal jurisdiction in this district in prior patent cases, including in the related action, *Tibotec Inc., et al v. Hetero Drugs, Ltd. Unit III et al*, 11-cv-1696 (WHW) (MCA).

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

BACKGROUND

13. 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 as Exhibit A.

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

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

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

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

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

19. 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.

20. 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.

21. 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).

22. The FDA's "Orange Book" also lists patents associated with approved drugs. The '889 Patent, U.S. Patent Nos. 5,843,946 ("'the '946 Patent") and 6,248,775 ("'the '775 Patent") are listed in the "Orange Book" in association with PREZISTA® (darunavir). The claims of the '889, '946, and '775 Patents cover PREZISTA® or its use.

23. On information and belief, Hetero Drugs, itself and/or through its U.S. agent Invagen submitted ANDA No. 202-083 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 darunavir tablets in 400 mg and 600 mg dosages ("Hetero's Generic Tablets") as generic versions of the PREZISTA® 400 mg and 600 mg tablets.

24. On information and belief, Hetero Drugs and Invagen collaborated in the research, development, preparation, and/or filing of ANDA No. 202-083 for Hetero's Generic Tablets.

25. On information and belief, Invagen participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 202-083.

26. Plaintiffs received a letter from Hetero (the "Hetero Paragraph IV letter") stating that Hetero had submitted ANDA No. 202-083 seeking approval to manufacture, use, and sell Hetero's Generic Tablets prior to the expiration of the '946 and '775 Patents.

27. The Hetero Paragraph IV letter also stated that Hetero ANDA No. 202-083 included certifications, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '946 and '775 are invalid.

28. Plaintiffs asserted the '946 and '775 Patents against Hetero in a related action, *Tibotec Inc., et al v. Hetero Drugs, Ltd. Unit III et al*, 11-cv-1696 (WHW) (MCA).

29. The '889 Patent had not issued at the time Hetero submitted its ANDA or certifications, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

30. The '889 Patent was listed in the "Orange Book" in association with PREZISTA® (darunavir) within thirty days of its issuance.

31. On information and belief, Hetero has sought or will seek approval to manufacture, use, and sell Hetero's Generic Tablets prior to the expiration of the '889 Patent.

32. On information and belief, Hetero has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import Hetero's Generic Tablets prior to the expiration of patents owned by and exclusively licensed to Plaintiffs.

33. On information and belief, Hetero's actions include, but are not limited to, the development of Hetero's Generic Tablets and the filing of an ANDA with a Paragraph IV certification.

34. On information and belief, Hetero continues to seek approval of ANDA No. 202-083 from the FDA and intends to engage in the commercial manufacture, marketing, and sale of Hetero'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. 202-083.

COUNT I

Infringement of the '889 Patent by Hetero under 35 U.S.C. § 271(e)(2)(A)

35. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 34 hereof, as if fully set forth herein.

36. Hetero has infringed the '889 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202-083 and seeking FDA approval of ANDA No. 202-083 prior to patent expiry.

37. Plaintiffs have no adequate remedy at law to redress the infringement by Hetero.

38. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing or contributing to infringement of the '889 Patent.

COUNT II

Declaratory Judgment of Infringement by Hetero of the '889 Patent Under 35 U.S.C. § 271(a), (b), or (c)

39. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 38 hereof, as if fully set forth herein.

40. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Hetero regarding infringement of the '889 Patent.

41. Hetero has made and will continue to make substantial preparation manufacture, offer to sell, sell and/or import Hetero's Generic Tablets.

42. Hetero's actions including, but not limited to, the filing of ANDA No. 202-083 and systematically attempting to meet the applicable regulatory requirements for approval of

ANDA No. 202-083, indicate a refusal to change its course of action.

43. Any commercial manufacture, use, offer for sale, sale, and/or importation of Hetero's Generic Tablets will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '889 Patent.

44. Plaintiffs are entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero's Generic Tablets will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '889 Patent.

PRAYER

WHEREFORE, Plaintiffs respectfully request relief and judgment as follows:

(a) a judgment that Hetero has 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 Hetero ANDA No. 202-083 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. 202-083 would constitute infringement of the '889 Patent, or inducing or contributing to such conduct, by Hetero pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

(d) a judgment permanently enjoining Hetero and each of its officers, agents, servants and employees, and those persons in active concert or participation with it, from commercially manufacturing, selling or offering for sale, using, or importing the generic

darunavir tablets described in ANDA No. 202-083 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,

Dated: June 13, 2012

s/John E. Flaherty

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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 and patent as *Janssen Products L.P., et al. v. Lupin Limited, et al.*, D.N.J., 12-cv-2840-WHW-MCA and *Janssen Products L.P., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, which was filed on June 13, 2012 and has not yet been assigned a civil action number. Further, this action involves the same Plaintiffs as in *Janssen Products L.P., et al. v. Lupin Limited, et al.*, D.N.J., 10-cv-5954-WHW-MCA. Lastly, this action involves the same Plaintiffs and one of the same Defendants as in *Tibotec Inc., et al. v. Hetero Drugs, Ltd., Unit III, et al.*, D.N.J. 11-cv-1696-WHW-MCA. These actions all relate to generic versions of Plaintiff Janssen's PREZISTA® products.

Respectfully submitted,

Dated: June 13, 2012

s/John E. Flaherty

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