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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,	)	Civil Action No.
v.	)	
LUPIN LIMITED and LUPIN PHARMACEUTICALS INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Janssen Products, L.P. and Janssen R&D Ireland (collectively, "Janssen" or "Plaintiffs") for their Complaint against defendants 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 of U.S. Patent No. 7,700,645 (the "'645 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 U.S. Patent No. 7,126,015 (the "'015 Patent"), and U.S. Patent No. 7,595,408 (the "'408 Patent") under 35 U.S.C. §§ 1 et seq., 28 U.S.C. §§ 2201 and 2202. This action arises out of Lupin's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell generic copies of Janssen's highly successful PREZISTA® (darunavir) 800 mg tablets prior to the expiration of patents owned by Janssen.

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 copies 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 copies 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, 1338(a), 2201, and 2202.

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 has appointed National Registered Agents, Inc. of Princeton, New Jersey as its registered agent for the receipt of service of process.

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) (SCM).

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

BACKGROUND

14. On April 20, 2010, the United States Patent and Trademark Office issued the '645 Patent, entitled "Pseudopolymorphic Forms of a HIV Protease Inhibitor." A true and correct copy of the '645 Patent is attached hereto as Exhibit A.

15. Janssen R&D Ireland holds title to the '645 Patent.

16. The '645 Patent expires on December 26, 2026.

17. The United States Food and Drug Administration ("FDA") has awarded 6 months of pediatric exclusivity for PREZISTA® (darunavir). The period of pediatric exclusivity applicable to the '645 Patent does not expire until June 26, 2027.

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

19. 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).

20. The FDA's "Orange Book" also lists patents associated with approved drugs. The '645 Patent is listed in the "Orange Book" in association with PREZISTA®. The claims of the '645 Patent cover PREZISTA®.

21. On October 24, 2006, the PTO issued the '015 Patent, entitled "Method for the Preparation of Hexahydro-furo-[2,3-b]furan-3-ol." A true and correct copy of the '015 Patent is attached hereto as Exhibit B.

22. Janssen R&D Ireland holds title to the '015 Patent.

23. The '015 Patent expires on June 21, 2023.

24. On September 29, 2009, the PTO issued the '408 Patent, entitled "Methods for the Preparation of (3R,3aS,6aR)hexahydro-furo[2,3-b]furan-3-ol." A true and correct copy of the '408 Patent is attached hereto as Exhibit C.

25. Janssen R&D Ireland holds title to the '408 Patent.

26. The '408 Patent expires on May 6, 2025.

27. The '015 and '408 Patents claim processes useful for the preparation of (3R,3aS,6aR)hexahydro-furo[2,3-b]furan-3-ol ("bis-THF") as present in PREZISTA®.

28. On information and belief, Lupin has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States products which are made by a process patented by the '015 and '408 Patents prior to their expiration.

29. On information and belief, Lupin's preparations include, but are not limited to, the development of a generic copy of PREZISTA® 800 mg tablets ("Lupin's Generic 800 mg Tablets") and the filing of an ANDA with a Paragraph IV certification.

30. On information and belief, Lupin intends to use processes claimed in the '015 and '408 Patents to prepare the bis-THF in Lupin's Generic 800 mg Tablets.

31. The bis-THF is incorporated into and present in the drug substance in Lupin's Generic 800 mg Tablets.

32. The bis-THF in Lupin's Generic 800 mg Tablets is intact and without material change from the bis-THF resulting from Janssen's patented processes.

33. The bis-THF resulting from Janssen's patented processes is an essential part of Lupin's Generic 800 mg Tablets.

34. 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 a generic copy of PREZISTA® 800 mg tablets.

35. 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 800 mg Tablets.

36. On information and belief, Lupin Pharmaceuticals will market and/or distribute Lupin's Generic 800 mg Tablets if ANDA No. 202-073 is approved by the FDA.

37. 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.

38. On or about May 14, 2013, Plaintiffs received a letter dated May 13, 2013 (the "Lupin Paragraph IV letter") stating that Lupin submitted ANDA No. 202-073 seeking approval to manufacture, use, and sell Lupin's Generic 800 mg Tablets prior to the expiration of the '645 Patent.

39. The 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 the claims of the '645 Patent are invalid.

40. In the Lupin Paragraph IV letter, Lupin did not dispute that the commercial manufacture, use or sale of Lupin's Generic 800 mg Tablets would infringe the claims of the '645 Patent.

41. Janssen is asserting the '645, '015, and '408 Patents against Lupin's generic copies of PREZISTA® 75 mg, 150 mg, 300 mg, 400 mg, and 600 mg tablets in a related consolidated action, *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, 10-cv-5954 (WHW) (SCM). Lupin has asserted counterclaims in this action.

42. On information and belief, Lupin had actual and constructive notice of the '645, '015, and '408 Patents prior to the filing of ANDA No. 202-073 seeking approval of Lupin's Generic 800 mg Tablets.

43. On information and belief, Lupin has made, and continues to make substantial preparation in the United States to manufacture, offer to sell, sell, and/or import Lupin's Generic 800 mg Tablets prior to the expiration of the '645, '015, and '408 Patents.

44. On information and belief, Lupin's actions include, but are not limited to, the development of Lupin's Generic 800 mg Tablets and the filing of an ANDA with a Paragraph IV certification.

45. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals continue to seek approval of ANDA No. 202-073 from the FDA and intend to collaborate in the commercial manufacture, marketing, and sale of Lupin's Generic 800 mg 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.

46. Plaintiffs commenced this lawsuit within 45 days of the date they received Lupin's Paragraph IV Notice of ANDA No. 202-073 seeking approval to market Lupin's Generic 800 mg Tablets.

COUNT I

Infringement of the '645 Patent by Lupin under 35 U.S.C. § 271(e)(2)(A)

47. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 46 hereof, as if fully set forth herein.

48. Lupin Ltd. and Lupin Pharmaceuticals have infringed the '645 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 to market Lupin's Generic 800 mg Tablets prior to the expiration of the '645 Patent.

49. Lupin's Paragraph IV letter does not dispute that Lupin's Generic 800 mg Tablets infringe the claims of the '645 Patent.

50. Lupin has also stipulated in the related consolidated action, *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, 10-cv-5954 (WHW) (SCM), that Lupin's Generic 800 mg Tablets infringe the claims of the '645 Patent.

51. Lupin had actual and constructive notice of the '645 Patent prior to the filing of ANDA No. 202-073 seeking approval of Lupin's Generic 800 mg Tablets.

52. Janssen has no adequate remedy at law to redress the infringement by Lupin.

53. Janssen will be irreparably harmed if Lupin is not enjoined from infringing or actively inducing or contributing to infringement of the '645 Patent.

COUNT II

Declaratory Judgment of Infringement by Lupin of the '015 Patent Under 35 U.S.C. § 271(g)

54. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 53 hereof, as if set forth fully herein.

55. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Janssen and Lupin regarding infringement of the '015 Patent.

56. Lupin had actual and constructive notice of the '015 Patents prior to the filing of ANDA No. 202-073 seeking approval of Lupin's Generic 800 mg Tablets.

57. Lupin has made and will continue to make substantial and meaningful preparations to import into the United States or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '015 Patent prior to its expiration.

58. Lupin's actions, including, but not limited to, the filing of ANDA No. 202-073, systematically attempting to meet the applicable regulatory requirements for approval of ANDA No. 202-073, and engaging in litigation to manufacture, offer to sell, sell, use, and/or import Lupin's generic products prior to the expiration of the '015 Patent, including the assertion of counterclaims, indicate a refusal to change its course of action.

59. Any importation into the United States and/or use, offer for sale, and/or sale in the United States of Lupin's Generic 800 mg Tablets will constitute infringement of the '015 Patent under 35 U.S.C. § 271(g).

60. Janssen is entitled to a judicial declaration that the importation into the United States and/or use, offer for sale, and/or sale in the United States of Lupin's Generic 800 mg Tablets will constitute infringement of the '015 Patent by Lupin under 35 U.S.C. § 271(g).

61. Janssen has no adequate remedy at law to redress the infringement by Lupin.

62. Janssen will be irreparably harmed if Lupin is not enjoined from infringing or actively inducing or contributing to infringement of the '015 Patent.

COUNT III

Declaratory Judgment of Infringement by Lupin of the '408 Patent Under 35 U.S.C. § 271(g)

63. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 62 hereof, as if set forth fully herein.

64. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Janssen and Lupin regarding infringement of the '408 Patent.

65. Lupin had actual and constructive notice of the '408 Patent prior to the filing of ANDA No. 202-073 seeking approval of Lupin's Generic 800 mg Tablets.

66. Lupin has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '408 Patent prior to its expiration.

67. Lupin's actions, including, but not limited to, the filing of ANDA No. 202-073, systematically attempting to meet the applicable regulatory requirements for approval of ANDA No. 202-073, and engaging in litigation to manufacture, offer to sell, sell, use, and/or import Lupin's generic products prior to the expiration of the '408 Patent, including the assertion of counterclaims, indicate a refusal to change its course of action.

68. Any importation into the United States and/or use, offer for sale, and/or

sale in the United States of Lupin's Generic 800 mg Tablets will constitute infringement of the '408 Patent under 35 U.S.C. § 271(g).

69. Janssen is entitled to a judicial declaration that the importation into the United States and/or use, offer for sale, and/or sale in the United States of Lupin's Generic 800 mg Tablets will constitute infringement of the '408 Patent by Lupin under 35 U.S.C. § 271(g).

70. Janssen has no adequate remedy at law to redress the infringement by Lupin.

71. Janssen will be irreparably harmed if Lupin is not enjoined from infringing or actively inducing or contributing to infringement of the '408 Patent.

PRAYER

WHEREFORE, Plaintiffs respectfully request relief and judgment as follows:

(a) a judgment that Lupin has infringed the '645 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 Lupin 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 '645 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 '645 Patent, or inducing or contributing to such conduct, by Lupin pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

(d) a judgment permanently enjoining Lupin and each of its 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 '645 Patent;

(e) a judgment declaring that importing, selling, offering to sell, or using the generic darunavir tablets described in ANDA No. 202-073 would constitute infringement of the '015 and '408 Patents, or inducing or contributing to such conduct, by Lupin pursuant to 35 U.S.C. § 271(g);

(f) a judgment permanently enjoining Lupin and each of its 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 after the expiration of the '015 and '408 Patents;

(g) a declaration that this case is exceptional;

(h) an award of Janssen's 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

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

Respectfully submitted,

s/John E. Flaherty

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Dated: June 24, 2013

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 two of the same Plaintiffs, two of the same defendants, and three of the same patents as in the *Janssen Products L.P., et al. v. Lupin Limited, et al.*, D.N.J., 10-cv-5954-WHW-SCM, action. Furthermore, this action involves two of the same patents as in the *Janssen Products L.P., et al. v. Hetero Drugs, Ltd., et al.*, D.N.J., 2:13-cv-01444-WHW-SCM, action.

Respectfully submitted,

s/John E. Flaherty

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