IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIIV HEALTHCARE COMPANY and VERTEX PHARMACEUTICALS INC., Plaintiffs, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC. Defendants.	C.A. No. _____

COMPLAINT

Plaintiffs ViiV Healthcare Company ("ViiV"), and Vertex Pharmaceuticals Inc. ("Vertex") (collectively, "Plaintiffs"), for their Complaint against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively "Lupin"), hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent No. 6,436,989 ("the '989 patent," attached as Exhibit A) arising under the patent laws of the United States, Title 35 United States Code §§ 271 and 281. This action relates to the filing by Lupin of Abbreviated New Drug Application ("ANDA") No. 204130 with the U.S. Food and Drug Administration ("FDA") seeking approval to market 700 mg fosamprenavir calcium tablets, a generic version of the 700 mg form of ViiV's LEXIVA® drug product.

PARTIES

2. ViiV is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at Five Moore Drive, Research Triangle Park, North Carolina 27709-3398.

3. Vertex is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, with its principal place of business at 50 Northern Avenue, Boston, Massachusetts 02210.

4. Upon information and belief, Defendant Lupin Limited is a corporation organized and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400051, Maharashtra, India. Upon information and belief, Lupin Limited, by itself and/or through its affiliates and agents, is in the business, *inter alia*, of developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products for distribution and sale throughout the United States, including within this judicial district.

5. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation in good standing organized and existing under the laws of the State of Delaware, having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21292. Upon information and belief, Lupin Pharmaceuticals, Inc., by itself and/or through its affiliates and agents, is in the business, *inter alia*, of developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products for distribution and sale throughout the United States, including within this judicial district.

6. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. is an indirect wholly-owned United States subsidiary of Lupin Limited.

7. Upon information and belief, Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. work in concert to develop, manufacture, and market pharmaceutical products throughout the United States, including in this judicial district.

8. Upon information and belief, Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. have cooperated in the preparation and filing of ANDA No. 204130.

9. Upon information and belief, following any FDA approval of ANDA No. 204130, Defendants Lupin Limited and Lupin Pharmaceuticals, Inc., either alone or together, will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 204130 throughout the United States, including this judicial district, and import such generic products into the United States, including into this judicial district.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq*., and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a) and 2201(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

11. This Court has personal jurisdiction over Lupin Limited and Lupin Pharmaceuticals, Inc. because, *inter alia*, they have each committed, or aided, abetted, actively induced, contributed to, or participated, in the commission of a tortious act of patent infringement by filing ANDA No. 204130 that has led and will lead to foreseeable harm and injury to ViiV, a Delaware corporation, and Vertex, a corporation actively engaged in business in Delaware.

12. This Court also has personal jurisdiction over Lupin Limited and Lupin Pharmaceuticals, Inc. because, *inter alia*, they have purposely availed themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being haled into court here. Upon information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. have had persistent, systematic and continuous contacts with Delaware, pursuant to Del. Code Ann. tit. 10, § 3104(c)(4), as set forth below.

13. Upon information and belief, Lupin Pharmaceuticals, Inc. is registered with the State of Delaware to conduct business, and maintains Corporation Trust Company, Corporation Trust Center, Wilmington, Delaware 19801 as its registered agent for service of process in Delaware.

14. Upon information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc., either alone or in concert with each other or with each other's authorization, participation, or assistance, regularly do business in Delaware and have engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including in Delaware, and/or by directly selling pharmaceutical products in Delaware..

15. Upon information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. derive substantial revenue from generic pharmaceutical products that are sold, used, and consumed within Delaware.

16. Upon information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. have previously availed themselves of this forum for litigating patent disputes. Lupin Limited has admitted to or did not contest personal jurisdiction for the purposes of multiple litigations in this district, and has submitted to this Court's jurisdiction by asserting counterclaims in civil actions in this jurisdiction, including in *Alcon Research Ltd. v. Lupin Ltd.*, C.A. No. 16-cv-00195-SLR (D. Del.); *Astellas Pharma Inc. et al. v. Lupin Ltd. et al*., 16-cv-00908-SLR (D. Del.); and *Arena Pharmaceuticals Inc. et al. v. Lupin Ltd. et al*., 16-cv-00887-RGA. In other matters, Lupin Limited and Lupin Pharmaceuticals, Inc. have submitted to this Court's jurisdiction by not contesting personal jurisdiction in this district and by asserting counterclaims in civil actions in this district, including in *Teijin Ltd., et al. v. Lupin Ltd. and*

Lupin Pharma., Inc., C.A. No. 14-cv-00184-SLR (D. Del.); *Pfizer Inc., et al. v. Lupin Ltd.*, 13-cv-01153-GMS (D. Del.).

17. For these reasons, and for other reasons that will be presented to the Court should jurisdiction be challenged, the Court has personal jurisdiction over Lupin Limited and Lupin Pharmaceuticals, Inc. in this action.

PATENT-IN-SUIT

18. Vertex is the owner by assignment of the '989 patent, entitled "Prodrugs of Aspartyl Protease Inhibitors," which the U.S. Patent and Trademark Office duly and legally issued on August 20, 2002. A true and correct copy of the '989 patent is attached hereto as Exhibit A. The claims of the '989 patent, in particular claims 2, 3 and 10-12, are valid and enforceable. ViiV is the exclusive licensee of the '989 patent with respect to LEXIVA®, with the right to sue for and obtain equitable relief and damages for infringement of the '989 patent.

19. Fosamprenavir calcium is the active pharmaceutical ingredient in LEXIVA® and is the commercial embodiment of claims 2-3 and 10-12 of the '989 patent.

INFRINGEMENT BY LUPIN

20. By letter dated February 9, 2017 ("the Notice Letter"), Lupin notified ViiV Healthcare Company and Vertex that it had submitted ANDA No. 204130 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of generic fosamprenavir calcium tablets before the expiration of the '989 patent. Upon information and belief, Lupin intends to engage in commercial manufacture, use, and sale of generic fosamprenavir calcium tablets promptly upon receiving FDA approval to do so.

21. By filing ANDA No. 204130, Lupin has necessarily represented to the FDA that its generic fosamprenavir calcium tablets have the same active ingredients as

LEXIVA®, have the same route of administration, dosage form, and strength as LEXIVA®, and are bioequivalent to LEXIVA®.

22. Upon information and belief, upon FDA approval of ANDA No. 204130, Lupin Limited, by itself or in concert with Lupin Pharmaceuticals, Inc., will import, make, use, offer to sell, and/or sell in the United States generic 700 mg fosamprenavir calcium tablets that fall within the scope of claims 2-3 of the '989 patent, and will instruct physicians and patients to administer generic 700 mg fosamprenavir calcium tablets for treating HIV infection in a patient in a way that falls within the scope of claims 10-12 of the '989 patent.

23. If Lupin's infringement of the '989 patent is not enjoined, ViiV and Vertex will suffer substantial harm for which there is no adequate remedy at law.

COUNT I (DIRECT INFRINGEMENT OF THE '989 patent)

24. Each of the preceding paragraphs 1 to 23 is incorporated as if fully set forth herein.

25. Lupin's submission of ANDA No. 204130 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic fosamprenavir calcium tablets prior to the expiration of the '989 patent constitutes infringement of claims 2-3 and 10-12 of the '989 patent under 35 U.S.C. § 271(e)(2)(A).

26. Upon FDA approval of Lupin's ANDA No. 204130, Lupin will infringe claims 2-3 of the '989 patent by making, using, offering to sell, and selling generic fosamprenavir calcium tablets in the United States and/or importing such tablets into the United States, in violation of 35 U.S.C. § 271, unless enjoined from so doing by this Court.

27. If Lupin's infringement of the '989 patent is not enjoined, ViiV and Vertex will suffer substantial harm for which there is no adequate remedy at law.

COUNT II (INDIRECT INFRINGEMENT OF THE ’989 patent)

28. Each of the preceding paragraphs 1 through 27 is incorporated as if fully set forth herein.

29. Upon information and belief, Lupin had actual and constructive knowledge of the ’989 patent prior to filing ANDA No. 204130.

30. Upon information and belief, upon FDA approval of ANDA No. 204130, Lupin will instruct physicians to prescribe and patients to administer Lupin’s fosamprenavir calcium tablets for the treatment of HIV infection.

31. Upon information and belief, Lupin is aware and intends that physicians and patients acting in accordance with Lupin’s instructions in its proposed label will directly infringe claims 10-12 of the ’989 patent, which will induce infringement of these claims pursuant to 35 U.S.C. § 271(b).

32. Fosamprenavir calcium is the active pharmaceutical ingredient in Lupin’s generic 700 mg fosamprenavir calcium tablets, constitutes a material part of the invention claimed in the ’989 patent, and has no substantial noninfringing uses.

33. Upon information and belief, Lupin is aware that its generic 700 mg fosamprenavir calcium tablets are especially adapted for a use that infringes the ’989 patent, including claims 2-3 and 10-12, and has no substantial non-infringing use.

34. Lupin’s actions will constitute contributory infringement of the ’989 patent pursuant to 35 U.S.C. § 271(c).

COUNT III (DECLARATORY JUDGMENT OF INFRINGEMENT)

35. Each of the preceding paragraphs 1 through 34 is incorporated as if fully set forth herein.

36. An actual and immediate controversy exists between Plaintiffs and Lupin. Lupin sent Plaintiffs a notice, dated February 9, 2017, that Lupin seeks approval to engage in the commercial manufacture, use, or sale of generic 700 mg fosamprenavir calcium tablets prior to the expiration of the '989 patent and that the '989 patent is invalid, unenforceable and/or would not be infringed by Lupin's generic fosamprenavir calcium tablets.

37. Upon information and belief, upon receiving final FDA approval, Lupin will import, make, use, offer to sell, and/or sell generic 700 mg fosamprenavir calcium tablets in the United States, infringing one or more claims of the '989 patent in violation of 35 U.S.C. § 271, unless enjoined from so doing by this Court.

38. Upon information and belief, Lupin had actual and constructive knowledge of the '989 patent prior to filing ANDA No. 204130.

39. Upon information and belief, upon FDA approval of ANDA No. 204130, Lupin will instruct physicians to prescribe and patients to administer Lupin's fosamprenavir calcium tablets for the treatment of HIV infection.

40. Upon information and belief, Lupin is aware and intends that physicians and patients acting in accordance with Lupin's instructions in its proposed label will directly infringe claims 10-12 of the '989 patent, inducing infringement of these claims.

41. Fosamprenavir calcium is the active pharmaceutical ingredient in Lupin's generic 700 mg fosamprenavir calcium tablets, constitutes a material part of the invention claimed in the '989 patent, and has no substantial noninfringing uses.

42. Upon information and belief, Lupin is aware that its generic 700 mg fosamprenavir calcium tablets are especially adapted for a use that infringes the '989 patent, including claims 2-3 and 10-12, and has no substantial non-infringing use.

43. Lupin's actions will constitute contributory infringement of the '989 patent pursuant to 35 U.S.C. § 271(c).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

a) A judgment that one or more claims of the '989 patent is infringed by Lupin's submission of ANDA No. 204130, and that Lupin's making, using, offering to sell, or selling in the United States, or importing into the United States, of generic fosamprenavir calcium tablets will infringe one or more claims of the '989 patent;

b) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 204130 shall be a date which is not earlier than the latest expiration date of the '989 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

c) An order permanently enjoining Lupin, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States generic fosamprenavir calcium tablets until after the latest expiration date of the '989 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

d) Damages or other monetary relief to Plaintiffs if Lupin engages in the commercial manufacture, use, offer to sell, sale, or importation in or into the United States of generic fosamprenavir calcium tablets prior to the latest expiration date of the '989 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

e) A judgment declaring that one or more claims of the ’989 patent are infringed by Lupin’s submission of ANDA No. 204130, and that Lupin’s importing, making, using, offering to sell, or selling generic 700 mg fosamprenavir calcium tablets in the United States will infringe one or more claims of the ’989 patent;

f) A judgment declaring that the ’989 patent is valid and enforceable; and

g) Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285, and an award of costs and pre and post-judgment interest to the Plaintiffs.

Dated: March 23, 2017

Respectfully submitted,

FARNAN LLP

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