IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIIV HEALTHCARE COMPANY, SHIONOGI & CO., LTD., and VIIV HEALTHCARE UK (NO.3) LIMITED, Plaintiffs, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Defendants.	)	Case No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs ViiV Healthcare Company, Shionogi & Co., Ltd., and ViiV Healthcare UK (No. 3) Limited (collectively, "Plaintiffs" or "ViiV") bring this action for patent infringement against Lupin Limited ("LLTD") and Lupin Pharmaceuticals, Inc. ("LPI") (collectively, "Defendants" or "Lupin").

THE PARTIES

1. Plaintiff ViiV Healthcare Company, a wholly owned subsidiary of ViiV Healthcare Limited, is a corporation organized and existing under the laws of the State of Delaware, with a trading address at Five Moore Drive, Research Triangle Park, North Carolina 27709.

2. Plaintiff Shionogi & Co., Ltd., also known as Shionogi Seiyaku Kabushiki Kaisha, is a corporation organized and existing under the laws of Japan, with a principal place of business at 1-8, Doshomachi 3-chome, Chuo Ku, Osaka, 541-0045, Japan.

3. Plaintiff ViiV Healthcare UK (No. 3) Limited is a corporation organized and existing under the laws of the United Kingdom, with a registered office at 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom.

4. On information and belief, Defendant LLTD is a corporation organized and existing under the laws of India, with its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India.

5. On information and belief, Defendant LPI is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202.

6. On information and belief, Defendants are in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within this District.

7. On information and belief, LPI is a wholly owned subsidiary of LLTD.

8. On information and belief, Defendants acted in concert to develop the proposed generic product that is the subject of Abbreviated New Drug Application ("ANDA") No. 216470, and to seek regulatory approval from the U.S. Food and Drug Administration ("FDA") to market and sell that proposed generic product throughout the United States, including within this District.

9. On information and belief, LPI acts as the U.S. agent of LLTD with respect to ANDA No. 216470, and LPI will work, either directly or indirectly, to manufacture, import, market, and sell the proposed generic product.

10. On information and belief, ANDA No. 216470 references a Drug Master File for dolutegravir sodium held by LLTD.

NATURE OF THE ACTION

11. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of Defendants' ANDA No. 216470, filed with the FDA seeking approval to engage in the commercial manufacture, use and sale of Dolutegravir Tablets for Oral Suspension, 5 mg ("Proposed ANDA Product"), which is a generic version of ViiV's TIVICAY PD™ (dolutegravir) tablets for oral suspension prior to the expiration of Plaintiffs' U.S. Patent No. 9,242,986 ("the '986 Patent").

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 35 U.S.C. § 1 *et seq*.

13. This Court has personal jurisdiction over Defendants because, *inter alia*, they have maintained continuous and systematic contacts with the State of Delaware and this District.

14. On information and belief, Defendants collaborate to market and sell generic pharmaceutical products, pursuant to the Abbreviated New Drug Application process, throughout the United States, including in the State of Delaware, at least by making and shipping into this judicial district, or by offering to sell or selling, or causing others to offer to sell or sell, generic pharmaceutical products. Defendants derive substantial revenue from goods used or consumed or services rendered in this judicial district.

15. This Court has personal jurisdiction over LLTD by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of Delaware law, and its substantial, continuous, and systematic contacts with the State of Delaware. On information and belief, LLTD: (1) intentionally markets and provides its generic

pharmaceutical products to residents of this State; (2) enjoys substantial income from this State; (3) created a presence in the State through its related company, LPI; and (4) affirmatively avails itself of the jurisdiction of this Court by filing counterclaims in this District and by being sued in this District without challenging personal jurisdiction. *See, e.g.*, *Arena Pharm., Inc. et al. v. Lupin Ltd. et al.*, 16-887 (D. Del.); *Bayer Intell. Prop. GMBH et al. v. Lupin Ltd. et al.*, 17-1047 (D. Del.); *Omeros Corp. v. Lupin Ltd. et al.*, 17-803 (D. Del.); *ViiV Healthcare Co. et al. v. Lupin Ltd. et al.*, 17-315 (D. Del.); *ViiV Healthcare Co. et al. v. Lupin Ltd. et al.*, 17-1576 (D. Del.); *ViiV Healthcare Co. et al. v. Lupin Ltd. et al.*, 20-293 (D. Del.).

16. This Court has personal jurisdiction over LPI by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of Delaware law, and its substantial, continuous, and systematic contacts with the State of Delaware. On information and belief, LPI: (1) is incorporated in the state of Delaware; (2) intentionally markets and provides its generic pharmaceutical products to residents of this State; (3) enjoys substantial income from this State; and (4) affirmatively avails itself of the jurisdiction of this Court by filing counterclaims in this District and by being sued in this District without challenging personal jurisdiction. *See, e.g.*, *Arena Pharm., Inc. et al. v. Lupin Ltd. et al.*, 16-887 (D. Del.); *Bayer Intell. Prop. GMBH et al. v. Lupin Ltd. et al.*, 17-1047 (D. Del.); *Omeros Corp. v. Lupin Ltd. et al.*, 17-803 (D. Del.); *ViiV Healthcare Co. et al. v. Lupin Ltd. et al.*, 17-315 (D. Del.); *ViiV Healthcare Co. et al. v. Lupin Ltd. et al.*, 17-1576 (D. Del.); *ViiV Healthcare Co. et al. v. Lupin Ltd. et al.*, 20-293 (D. Del.).

17. On information and belief, LLTD directly or through its subsidiaries, including LPI, manufactures, imports, markets, and sells generic drugs throughout the United States and in this judicial district.

18. On information and belief, Defendants intend to manufacture for distribution, and to distribute and sell, products that are generic equivalents of ViiV's TIVICAY PD™ (dolutegravir) tablets for oral suspension throughout the United States and in this judicial district.

19. For the reasons set forth above, for the reasons set forth in the Court of Appeals for the Federal Circuit's decision in *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016), and for additional reasons which will be supplied if Defendants challenge personal jurisdiction in this action, Defendants are subject to personal jurisdiction in this District.

20. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b).

THE PATENT-IN-SUIT

21. The '986 Patent, entitled "Synthesis of carbamoylpyridone HIV integrase inhibitors and intermediates," was duly and legally issued on January 26, 2016 and will expire on December 8, 2029. A copy of the '986 Patent is attached as Exhibit A. Shionogi & Co., Ltd. is the assignee of the '986 Patent. ViiV Healthcare UK (No. 3) Limited is the exclusive licensee of the '986 Patent.

FACTUAL BACKGROUND

TIVICAY PD™ (Dolutegravir) Tablets for Oral Suspension

22. TIVICAY PD™ (dolutegravir) tablets for oral suspension are approved by the FDA for the treatment of HIV-1 infection.

23. ViiV Healthcare Company is the holder of approved New Drug Application No. 213983 for TIVICAY PD™ (dolutegravir) tablets for oral suspension, containing 5.26 mg of dolutegravir sodium, which is equivalent to 5 mg dolutegravir free acid.

24. TIVICAY PD™ (dolutegravir) tablets for oral suspension are covered by one or more claims of the '986 Patent, and the '986 Patent has been listed for NDA No. 213983 in the

FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book."

25. ViiV sells and distributes TIVICAY PD™ (dolutegravir) tablets for oral suspension in the United States pursuant to NDA No. 213983.

Defendants' ANDA No. 216470

26. By the Notice Letter dated September 21, 2021, Defendants notified Plaintiffs that Defendants, by submitting ANDA No. 216470 to the FDA seek approval to engage in the commercial manufacture, use and sale of the Proposed ANDA Product prior to the expiration of the '986 Patent, and that ANDA No. 216470 included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '986 Patent is allegedly invalid, unenforceable and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Proposed ANDA Product.

27. On information and belief, Defendants were necessarily aware of the Patent-in-Suit when ANDA No. 216470 was filed with the Paragraph IV Certification.

28. On information and belief, dolutegravir sodium as covered in one or more of the claims of the '986 Patent is and/or will be present in the Proposed ANDA Product.

29. On information and belief, ANDA No. 216470 refers to and relies upon NDA No. 213983 for TIVICAY PD™ (dolutegravir) tablets for oral suspension, and contains data that, according to Defendants, demonstrate the bioequivalence of the Proposed ANDA Product and TIVICAY PD™ (dolutegravir) tablets for oral suspension.

30. On information and belief, the Proposed ANDA Product will have instructions for use that substantially copy the instructions for TIVICAY PD™ (dolutegravir) tablets for oral suspension. The instructions accompanying the Proposed ANDA Product will induce others to

use and/or contribute to others' use of the Proposed ANDA Product in the manner set forth in the instructions.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 9,242,986

31. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1-30 of this Complaint.

32. The Proposed ANDA Product infringes one or more claims of the '986 Patent, either literally or under the doctrine of equivalents.

33. Defendants' submission of ANDA No. 216470 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '986 Patent constitutes infringement of one or more claims of the '986 Patent under 35 U.S.C. § 271(e)(2).

34. On information and belief, Defendants plan to, intend to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 216470 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

35. On information and belief, upon FDA approval of ANDA No. 216470, Defendants will infringe the '986 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States.

36. Upon FDA approval of ANDA No. 216470, Defendants will infringe the '986 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United

States, and will infringe under 35 U.S.C. § 271(b) and/or (c), literally and/or through the doctrine of equivalents, by actively inducing and/or contributing to infringement by others.

37. In the Notice Letter, Defendants do not dispute that the Proposed ANDA Product will infringe Claims 1-6 of the ’986 Patent unless Claims 1-6 of the ’986 Patent are found invalid.

38. On information and belief, Defendants had knowledge of the ’986 Patent when they submitted ANDA No. 216470 to the FDA, and Defendants know or should know that they will aid and abet another’s direct infringement of at least one of the claims of the ’986 Patent.

39. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

40. On information and belief, Defendants lacked a good faith basis for alleging noninfringement of Claims 7-12 and invalidity of Claims 1-12 of the ’986 Patent when they filed their Paragraph IV Certification. Accordingly, Defendants’ Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

a) Judgment that the ’986 Patent is valid and enforceable;

b) Judgment that Defendants’ submission of ANDA No. 216470 was an act of infringement under 35 U.S.C. § 271(e)(2) of one or more claims of the ’986 Patent;

c) Judgment that Defendants’ making, using, offering to sell, selling or importing into the United States of the Proposed ANDA Product

prior to the expiration of the ’986 Patent, will infringe, will actively induce infringement, and/or will contribute to the infringement of one or more claims of the ’986 Patent;

d) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 216470 shall be a date that is not earlier than the expiration of the ’986 Patent plus any other exclusivity to which Plaintiffs are or become entitled;

e) An Order permanently enjoining Defendants, their affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with Defendants, from making, using, offering to sell, selling, marketing, distributing, or importing into the Unites States the Proposed ANDA Product until after the expiration of the ’986 Patent plus any other exclusivity to which Plaintiffs are or become entitled;

f) A declaration that this case is an exceptional case within the meaning of 35 U.S.C. § 285, and an award to Plaintiffs of their reasonable costs and attorneys’ fees incurred in connection with this action; and

g) Such further and other relief as this Court deems proper and just.

Dated: November 2, 2021

MCCARTER & ENGLISH, LLP

/s/ *Daniel M. Silver*

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