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. HETERO USA INC., HETERO LABS LIMITED UNIT-III, and HETERO LABS LIMITED, 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 Hetero USA Inc. ("Hetero USA"), Hetero Labs Limited Unit-III ("Hetero Unit-III"), and Hetero Labs Limited ("Hetero Labs") (collectively, "Defendants" or "Hetero").

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 410 Blackwell Street, Durham, North Carolina 27701.

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 79 New Oxford Street, London, WC1A 1DG, United Kingdom.

4. On information and belief, Defendant Hetero USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

5. On information and belief, Defendant Hetero Unit-III is a corporation organized and existing under the laws of India, having a place of business at 7-2-A2 Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad, Telangana 500018, India.

6. On information and belief, Defendant Hetero Labs is a corporation organized and existing under the laws of India, having a place of business at at RMZ Nexity, Tower 30, Survey No. 83/1, Knowledge City, Raidurg Village, Serilingampalle (M), Hyderabad, Telangana 500081, India.

7. On information and belief, Hetero USA is a partially owned subsidiary of Hetero Labs and Hetero Unit-III is a division of Hetero Labs.

8. 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.

9. 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. 216543, 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.

10. On information and belief, Hetero USA acts as the U.S. regulatory agent for Hetero Unit-III with respect to ANDA No. 216543, and Hetero USA will work, either directly or indirectly, to manufacture, import, market, and sell the proposed generic product.

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. 216543, filed with the FDA seeking approval to engage in the commercial manufacture, use and sale of Dolutegravir Sodium; Lamivudine Tablets; Oral, Eq. 50 mg Base; 300 mg ("Proposed ANDA Product"), which is a generic version of ViiV's DOVATO® (dolutegravir and lamivudine) tablets, for oral use, prior to the expiration of U.S. Patent Nos. 9,242,986 ("the '986 Patent") and 11,234,985 ("the '985 Patent") (collectively, "the Patents-in-Suit").

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 Hetero USA 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, Hetero USA: (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.*, *Novartis Pharms. Corp. v. Hetero USA Inc. et al*., 21-1760-RGA (D. Del.); *Novartis Pharms. Corp. v. Alkem Labs. Ltd. et al*., 21-1330-RGA (D. Del.); *Novartis Pharms. Corp. v. Dr. Reddy's Labs., Inc. et al*., 19-2053-RGA (D. Del.); *Biogen Int'l GmbH et al. v. Hetero USA Inc. et al.*, 17-825-LPS (D. Del.); *Duchesnay Inc. et al. v. Hetero Labs Ltd. et al*., 21-538-LPS & 21-113-LPS (D. Del.).

16. This Court has personal jurisdiction over Hetero Unit-III 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, Hetero Unit-III: (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, Hetero USA; 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.*, *Novartis Pharms. Corp. v. Hetero USA Inc. et al*., 21-1760-RGA (D. Del.); *Novartis Pharms. Corp. v. Alkem Labs. Ltd. et al*., 21-1330-RGA (D. Del.); *Novartis Pharms. Corp. v. Dr. Reddy's Labs.*,

Inc. et al., 19-2053-RGA (D. Del.); *Biogen Int'l GmbH et al. v. Hetero USA Inc. et al.*, 17-825-LPS (D. Del.).

17. On information and belief, Hetero Unit-III directly or through its affiliates or subsidiaries, including Hetero USA, manufactures, imports, markets, and sells generic drugs throughout the United States and in this judicial district.

18. This Court has personal jurisdiction over Hetero Labs 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, Hetero Labs: (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, Hetero USA; 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.*, *Novartis Pharms. Corp. v. Hetero USA Inc. et al*., 21-1760-RGA (D. Del.); *Novartis Pharms. Corp. v. Alkem Labs. Ltd. et al*., 21-1330-RGA (D. Del.); *Novartis Pharms. Corp. v. Dr. Reddy's Labs., Inc. et al*., 19-2053-RGA (D. Del.); *Biogen Int'l GmbH et al. v. Hetero USA Inc. et al.*, 17-825-LPS (D. Del.); *Duchesnay Inc. et al. v. Hetero Labs Ltd. et al*., 21-538-LPS & 21-113-LPS (D. Del.).

19. On information and belief, Hetero Labs directly or through its subsidiaries, including Hetero USA, manufactures, imports, markets, and sells generic drugs throughout the United States and in this judicial district.

20. On information and belief, Defendants intend to manufacture for distribution, and to distribute and sell, products that are generic equivalents of ViiV's DOVATO® (dolutegravir and lamivudine) tablets, for oral use, throughout the United States and in this judicial district.

21. For the reasons set forth above, 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.

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

THE PATENTS-IN-SUIT

23. 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. The '986 Patent has been awarded pediatric exclusivity through June 8, 2030. 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.

24. The '985 Patent, entitled "Antiviral Therapy," was duly and legally issued on February 1, 2022 and will expire on January 24, 2031. A copy of the '985 Patent is attached as Exhibit B. ViiV Healthcare Company is the assignee of the '985 Patent.

FACTUAL BACKGROUND

DOVATO® (Dolutegravir and Lamivudine) Tablets, for Oral Use

25. DOVATO® (dolutegravir and lamivudine) tablets, for oral use, are approved by the FDA as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents 12 years of age and older and weighing at least 25 kg with no antiretroviral treatment history and with no known substitutions associated with resistance to the individual components of DOVATO®.

26. ViiV Healthcare Company is the holder of approved New Drug Application No. 211994 for DOVATO® (dolutegravir and lamivudine) tablets, for oral use, containing 50 mg of dolutegravir (equivalent to 52.6 mg dolutegravir sodium) and 300 mg of lamivudine.

27. DOVATO® (dolutegravir and lamivudine) tablets, for oral use, are covered by one or more claims of the '986 and '985 Patents, and the '986 and '985 Patents have been listed for NDA No. 211994 in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book."

28. ViiV sells and distributes DOVATO® (dolutegravir and lamivudine) tablets, for oral use, in the United States pursuant to NDA No. 211994.

Defendants' ANDA No. 216543

29. By the Notice Letter dated June 20, 2024, Defendants notified Plaintiffs that Defendants, by submitting ANDA No. 216543 to the FDA seek approval to engage in the commercial manufacture, use or sale of the Proposed ANDA Product prior to the expiration of the '986 and '985 Patents, and that ANDA No. 216543 included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '986 and '985 Patents are allegedly invalid, unenforceable and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Proposed ANDA Product.

30. On information and belief, Defendants were necessarily aware of the Patents-in-Suit when ANDA No. 216543 was filed with the Paragraph IV Certification.

31. On information and belief, dolutegravir sodium as covered in one or more of the claims of the '986 and '985 Patents is and/or will be present in the Proposed ANDA Product.

32. On information and belief, ANDA No. 216543 refers to and relies upon NDA No. 211994 for DOVATO® (dolutegravir and lamivudine) tablets, for oral use, and contains data that,

according to Defendants, demonstrate the bioequivalence of the Proposed ANDA Product and DOVATO® (dolutegravir and lamivudine) tablets, for oral use.

33. On information and belief, the Proposed ANDA Product will have instructions for use that substantially copy the instructions for DOVATO® (dolutegravir and lamivudine) tablets, for oral use. 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

34. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1-33 of this Complaint.

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

36. Defendants' submission of ANDA No. 216543 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).

37. 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. 216543 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

38. On information and belief, upon FDA approval of ANDA No. 216543, 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, or selling the Proposed ANDA Product in the United States, and/or importing the Proposed ANDA Product in the United States.

39. Upon FDA approval of ANDA No. 216543, 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, or selling the Proposed ANDA Product in the United States, 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.

40. Each of Hetero USA, Hetero Unit-III and Hetero Labs is jointly and severally liable for infringement of the ’986 Patent.

41. In the Notice Letter, Defendants do not dispute that the Proposed ANDA Product will infringe Claims 1-6, 8-9, and 11 of the ’986 Patent unless Claims 1-6, 8-9, and 11 of the ’986 Patent are found invalid.

42. On information and belief, Defendants had knowledge of the ’986 Patent when they submitted ANDA No. 216543 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.

43. 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.

44. On information and belief, Defendants lacked a good faith basis for alleging noninfringement of Claims 7, 10, and 12 and invalidity of Claims 1-6, 8-9, and 11 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.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 11,234,985

45. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1-44 of this Complaint.

46. The Proposed ANDA Product infringes one or more claims of the '985 Patent, either literally or under the doctrine of equivalents.

47. Defendants' submission of ANDA No. 216543 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 '985 Patent constitutes infringement of one or more claims of the '985 Patent under 35 U.S.C. § 271(e)(2).

48. 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. 216543 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

49. On information and belief, upon FDA approval of ANDA No. 216543, Defendants will infringe the '985 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, or selling the Proposed ANDA Product in the United States, and/or importing the Proposed ANDA Product in the United States.

50. Upon FDA approval of ANDA No. 216543, Defendants will infringe the '985 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, or selling the Proposed ANDA Product in the United States, 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.

51. Each of Hetero USA, Hetero Unit-III and Hetero Labs is jointly and severally liable for infringement of the ’985 Patent.

52. In the Notice Letter, Defendants do not dispute that the Proposed ANDA Product will infringe Claims 1-7, 9, 11-14, and 16 of the ’985 Patent unless Claims 1-7, 9, 11-14, and 16 of the ’985 Patent are found invalid.

53. On information and belief, Defendants had knowledge of the ’985 Patent when they submitted ANDA No. 216543 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 ’985 Patent.

54. 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.

55. On information and belief, Defendants lacked a good faith basis for alleging invalidity of Claims 1-7, 9, 11-14, and 16 of the ’985 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 and ’985 Patents are valid and enforceable;

b) Judgment that Defendants’ submission of ANDA No. 216543 was an act of infringement under 35 U.S.C. § 271(e)(2) of one or more claims of the ’986 and ’985 Patents;

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 and ’985 Patents including any extensions or exclusivities, will infringe, will actively induce infringement, and/or will contribute to the infringement of one or more claims of the ’986 and ’985 Patents;

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. 216543 shall be a date that is not earlier than the expiration of the ’986 and ’985 Patents plus any other extensions or exclusivities 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, or distributing in the United States, or importing into the Unites States, the Proposed ANDA Product until after the expiration of the ’986 and ’985

Patents plus any other extensions or exclusivities 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 expenses, reasonable costs and attorneys' fees incurred in connection with prosecuting this action; and

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

DATED: August 2, 2024

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Plaintiffs ViiV Healthcare Company, Shionogi & Co., Ltd., and ViiV Healthcare UK (No. 3) Limited

OF COUNSEL:

Lisa B. Pensabene, Esq.
Caitlin Hogan, Esq.
O'MELVENY & MYERS LLP
7 Times Square
New York, New York 10036
(212) 326-2000