IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC., ARBOR PHARMACEUTICALS, LLC, and TAKEDA PHARMACEUTICAL COMPANY LIMITED, Plaintiffs, v. HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, and HETERO USA INC., Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiffs Azurity Pharmaceuticals, Inc., Arbor Pharmaceuticals, LLC (together with Azurity Pharmaceuticals, Inc., "Azurity"), and Takeda Pharmaceutical Company Limited ("Takeda") (collectively, "Plaintiffs"), for their Complaint against Defendants Hetero Labs Limited ("Hetero Ltd."), Hetero Labs Limited Unit-V ("Hetero Unit-V"), and Hetero USA Inc. ("Hetero Inc.") (collectively, "Defendants" or "Hetero"), hereby allege as follows:

THE PARTIES

1. Azurity Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 8 Cabot Road, Suite 2000, Woburn, MA 01801.

2. Arbor Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 6 Concourse Parkway, Suite 1800, Atlanta, GA 30328.

3. Takeda is a corporation organized and existing under the laws of Japan, having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan.

4. Upon information and belief, Defendant Hetero Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Telangana, India.

5. Upon information and belief, Defendant Hetero Unit-V is a corporation organized and existing under the laws of India, having a principal place of business at 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepally Village, Mahabubnagar, Telangana 509301, India.

6. Upon information and belief, Defendant Hetero Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Ave., Piscataway, New Jersey 08854.

7. Upon information and belief, Defendant Hetero Ltd. is the parent company of Defendants Hetero Unit-V and Hetero Inc.

8. Upon information and belief, Defendant Hetero Inc. is the United States regulatory agent for Defendants Hetero Ltd. and Hetero Unit-V.

9. Upon information and belief, Hetero caused ANDA No. 219062 to be submitted to the U.S. Food and Drug Administration ("FDA"), and Hetero Inc. is acting as an agent for Hetero Ltd. and Hetero Unit-V with respect to Hetero's Proposed ANDA Products.

10. Upon information and belief, following any approval of Hetero's ANDA No. 219062, Hetero Ltd., Hetero Unit-V, and Hetero Inc. will act in concert to distribute and sell Hetero's Proposed ANDA Products through the United States, including within Delaware.

NATURE OF THE ACTION

11. This is a civil action for infringement of United States Patent No. 9,066,936 ("the '936 patent" or "the patent-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq.

JURISDICTION & VENUE

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

13. This Court has personal jurisdiction over Hetero Inc. because, *inter alia*, Hetero Inc. is a corporation organized and existing under the laws of the State of Delaware.

14. This Court also has personal jurisdiction over Hetero Inc. because, *inter alia*, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Hetero Inc. is involved in developing, manufacturing, marketing, selling, and/or distributing a broad range of generic pharmaceutical products in the United States, including in Delaware, and therefore transacts business within Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

15. On information and belief, Hetero Inc. has been previously sued in this Judicial District and has not challenged personal jurisdiction and availed itself of the legal protections of the State of Delaware by asserting counterclaims against plaintiffs in this Judicial District. *See, e.g., AbbVie Inc. v. Hetero USA, Inc. et al.*, C.A. No. 23-1332-MN (D. Del.) (filed Feb. 28, 2024); *AbbVie Inc. et al. v. Alkem Lab'ys Ltd. et al.*, C.A. No. 22-1423-RGA (D. Del.) (filed Feb. 27, 2023); *Duchesnay, Inc. v. Hetero Labs Ltd.*, C.A. No. 21-1130-LPS (D. Del.) (filed Oct. 18, 2021).

16. This Court has personal jurisdiction over Hetero Ltd. because, *inter alia*, it and through its subsidiaries, including Hetero Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Hetero Ltd., itself and through its subsidiary Hetero Inc., is involved in developing, manufacturing, marketing, selling, and/or distributing a broad range of generic pharmaceutical products in the United States, including in Delaware, and therefore transacts business within Delaware, and/or has engaged in systematic and continuous business contacts within Delaware. In addition, Hetero Ltd. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls Hetero Inc., and therefore the activities of Hetero Inc. in this jurisdiction are attributed to Hetero Ltd.

17. On information and belief, Hetero Ltd. has previously been sued in this Judicial District and not challenged personal jurisdiction and availed itself of the legal protections of the State of Delaware by asserting counterclaims against plaintiffs in this Judicial District. *See, e.g.*, *AbbVie Inc. v. Hetero USA, Inc. et al.*, C.A. No. 23-1332-MN (D. Del.) (filed Feb. 28, 2024); *AbbVie Inc. et al. v. Alkem Lab'ys Ltd. et al.*, C.A. No. 22-1423-RGA (D. Del.) (filed Feb. 27, 2023); *Duchesnay, Inc. v. Hetero Labs Ltd.*, C.A. No. 21-1130-LPS (D. Del.) (filed Oct. 18, 2021).

18. This Court has personal jurisdiction over Hetero Unit-V because, *inter alia*, directly or indirectly, it has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Hetero Unit-V, directly or indirectly, is involved in developing, manufacturing, marketing, selling, and/or distributing a broad range of generic pharmaceutical

products in the United States, including in Delaware, and therefore transacts business within Delaware, and/or has engaged in systematic and continuous business contacts within Delaware.

19. On information and belief, Hetero Unit-V has previously been sued in this Judicial District and not challenged personal jurisdiction and availed itself of the legal protections of the State of Delaware by asserting counterclaims against plaintiffs in this Judicial District. *See, e.g., AbbVie Inc. v. Hetero USA, Inc. et al.*, C.A. No. 23-1332-MN (D. Del.) (filed Feb. 28, 2024); *AbbVie Inc. et al. v. Alkem Lab'ys Ltd. et al.*, C.A. No. 22-1423-RGA (D. Del.) (filed Feb. 27, 2023); *Duchesnay, Inc. v. Hetero Labs Ltd.*, C.A. No. 21-1130-LPS (D. Del.) (filed Oct. 18, 2021).

20. Upon information and belief, Hetero has sought approval in ANDA No. 219062 to distribute Hetero's Proposed ANDA Products in the United States, including in Delaware and will do so upon approval of ANDA No. 219062. The filing of ANDA No. 219062 is therefore tied, in purpose and planned effect, to the deliberate making of sales in Delaware, and indicates that Hetero plans to engage in the marketing of Hetero's Proposed ANDA Products in Delaware.

21. Upon information and belief, if ANDA No. 219062 is approved, Hetero will directly or indirectly market and/or sell Hetero's Proposed ANDA Products within the United States, including in Delaware, consistent with Hetero's practices for the marketing and distribution of other pharmaceutical products on its own and/or through its affiliates.

22. Upon information and belief, if ANDA No. 219062 is approved, Hetero's Proposed ANDA Products, under the direction and control of physicians practicing in Delaware, will be administered to patients in Delaware. These activities, as well as Hetero's marketing, selling, and/or distributing of Hetero's Proposed ANDA Products, would have a substantial

effect within Delaware and would constitute infringement of the patent-in-suit in the event that Hetero's Proposed ANDA Products are approved before the '936 patent expires.

23. For the reasons described above, among others, the filing of ANDA No. 219062 was suit-related conduct with a substantial connection to Delaware and this District, the exercise of personal jurisdiction over Hetero does not offend traditional notions of fair play and substantial justice, and this Court may properly exercise personal jurisdiction over Hetero.

24. In the alternative, this Court has personal jurisdiction over Hetero Ltd. and Hetero Unit-V because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Plaintiffs' claims arise under federal law; (b) Hetero Ltd. and Hetero Unit-V are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) Hetero Ltd. and Hetero Unit-V have sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Hetero Ltd. and Hetero Unit-V satisfies due process.

25. Venue is proper in this judicial district as to Hetero Inc. under 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Hetero Inc. is a corporation organized and existing under the laws of Delaware, Hetero Inc. has previously consented to venue in this judicial district, and on information and belief is subject to venue in this judicial district for the purpose of this case. Hetero Inc. has also consented to venue in this judicial district in numerous patent litigations, including but not limited to the following actions: *AbbVie Inc. v. Hetero USA, Inc. et al.*, C.A. No. 23-1332-MN (D. Del.) (filed Feb. 28, 2024); *AbbVie Inc. et al. v. Alkem Lab'ys Ltd. et al.*, C.A. No. 22-1423-RGA (D. Del.) (filed Feb. 27, 2023); *Duchesnay, Inc. v. Hetero Labs Ltd.*,

C.A. No. 21-1130-LPS (D. Del.) (filed Oct. 18, 2021); *Otsuka Pharm. Co., Ltd. et al. v. Hetero Labs, Ltd. et al.*, C.A. No. 20-1531-LPS (D. Del.) (filed Nov. 25, 2020); *Pfizer Inc. et al. v. Hetero USA, Inc. et al.*, C.A. No. 19-751-CFC (D. Del.) (filed May 30, 2019).

26. Venue is proper in this judicial district as to Hetero Ltd. and Hetero Unit-V under 28 U.S.C. §§ 1391 and 1400(b) because Hetero Ltd. and Hetero Unit-V are incorporated in India and may be sued in any judicial district in the United States.

THE PATENT-IN-SUIT

27. On June 30, 2015, the ’936 patent, entitled “Solid pharmaceutical composition comprising a benzimidazole-7-carboxylate derivative and a pH control agent” was duly and legally issued. A copy of the ’936 patent is attached as Exhibit A.

28. Takeda owns the ’936 patent. Azurity holds an exclusive license to the ’936 patent in the United States.

ACTS GIVING RISE TO THIS ACTION

29. Azurity holds New Drug Application (“NDA”) No. 200796 for oral tablets containing 40 mg or 80 mg azilsartan medoxomil as the active ingredient. Azurity markets and sells these oral tablets in the United States under the brand name EDARBI®.

30. Pursuant to 21 U.S.C. § 355(b)(1), the ’936 patent is listed in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) as covering EDARBI® or its use. U.S. Patent Nos. 7,157,584 (“the ’584 patent”) and 7,572,920 (“the ’920 patent”) are further listed in the Orange Book as covering EDARBI® or its use.

31. Upon information and belief, Hetero caused ANDA No. 219062 to be submitted to the FDA under 21 U.S.C. § 355(j). Upon information and belief, Hetero’s ANDA No. 219062 seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of oral tablets containing 40 mg or 80

mg azilsartan medoxomil ("Hetero's Proposed ANDA Products") prior to the expiration of the patent-in-suit.

32. Upon information and belief, by filing ANDA No. 219062, Hetero has certified to the FDA that Hetero's Proposed ANDA Products have the same active ingredient as EDARBI® and the same or substantially the same proposed labeling as EDARBI®.

33. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Hetero certified in ANDA No. 219062 that the claims of the '936 patent are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, sale, or offer for sale of Hetero's Proposed ANDA Products.

34. Upon information and belief, Hetero did not certify the claims of the '584 patent and the '920 patent to be invalid, unenforceable, or not to be infringed by the commercial manufacture, use, sale, or offer for sale of Hetero's Proposed ANDA Products in ANDA No. 219062.

35. Plaintiffs received written notification of Hetero's ANDA No. 219062 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by FedEx®, dated February 16, 2024 ("Hetero's Notice Letter").

36. To date, Hetero has not provided Plaintiffs with a copy of any portions of ANDA No. 219062 or any information regarding Hetero's Proposed ANDA Products, beyond the information set forth in Hetero's Notice Letter.

37. The limited information relating to Hetero's Proposed ANDA Products that was provided in Hetero's Notice Letter does not demonstrate that Hetero's Proposed ANDA Products, which Hetero has asked the FDA to approve for sale in the U.S., will not fall within the scope of issued claims of the patent-in-suit.

38. This action was commenced within 45 days of Plaintiffs receiving Hetero's Notice Letter.

COUNT I
INFRINGEMENT BY HETERO OF U.S. PATENT NO. 9,066,936

39. Plaintiffs re-allege paragraphs 1-38 as if fully set forth herein.

40. Hetero's submission of ANDA No. 219062 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '936 patent under 35 U.S.C. § 271(e)(2)(A).

41. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of Hetero's Proposed ANDA Products—if approved by the FDA, prior to the expiration of the '936 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '936 patent.

42. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Hetero's ANDA No. 219062 be a date that is not earlier than the expiration of the '936 patent, or any later expiration of patent term extension, adjustment, or exclusivity for the '936 patent to which Plaintiffs are or become entitled.

43. Plaintiffs will be irreparably harmed by Hetero's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

44. Upon information and belief, Hetero was aware of the existence of the '936 patent and was aware that the filing of ANDA No. 219062 and the certification with respect to the '936 patent constituted an act of infringement of that patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment that:

A. Hetero has infringed one or more claims of the ’936 patent;

B. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Hetero’s ANDA No. 219062 will not be earlier than the expiration date of the ’936 patent, or any later expiration of any patent term extension, adjustment, or exclusivity for the ’936 patent to which Plaintiffs are or become entitled;

C. Hetero, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling, marketing, distributing, or importing Hetero’s Proposed ANDA Products and any other product that infringes or induces or contributes to the infringement of the ’936 patent, prior to the expiration of the ’936 patent, including any exclusivity, adjustment, or extension to which Plaintiffs are or become entitled;

D. Plaintiffs be awarded monetary relief to the extent Hetero commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, any product that infringes or induces or contributes to the infringement of the ’936 patent within the United States prior to its expiration, including any later expiration of any patent term extension, adjustment, or exclusivity for the ’936 patent to which Plaintiffs are or will become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

E. Plaintiffs be awarded the attorneys’ fees, costs, and expenses that they incur in litigating this action; and

F. Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated: March 28, 2024

MCCARTER & ENGLISH, LLP

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