IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INGENUS PHARMACEUTICALS, LLC, Plaintiffs, v. HETERO USA, INC., HETERO LABS LTD., and HETERO LABS LTD. UNIT-VI, Defendant.	C.A. No. 24-_____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Ingenus Pharmaceuticals, LLC ("Plaintiff"), by its undersigned attorneys, for their Complaint against Defendants Hetero USA, Inc. ("Hetero USA"), Hetero Labs Ltd. ("Hetero Labs"), and Hetero Labs Ltd. Unit-VI ("Hetero Labs Unit-VI") (collectively "Hetero" or "Defendants") herein, allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, arising from Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 219271 to the United States Food and Drug Administration ("FDA). Defendants' ANDA seeks FDA approval to market and sell Cyclophosphamide Solution; 500mg/2.5ml (200mg/ml), lgm/5ml (200mg/ml), and 2gm/10ml (200mg/ml) ("Defendants' ANDA Products") prior to the expiration of U.S. Patent No. 10,993,952 ("the '952 Patent" or "the patent in suit"). A true and correct copy of the '952 Patent is attached hereto as Exhibit A.

THE PARTIES

2. Ingenus Pharmaceuticals, LLC ("Ingenus") is a corporation organized and existing under the laws of the state of Florida having its principal place of business at 4190 Millenia Blvd., Orlando, Florida 32839.

3. On information and belief, Defendant Hetero USA Inc. 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.

4. On information and belief, Hetero Labs 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. On information and belief, Defendant Hetero Labs Ltd. Unit-VI is a division of Hetero Labs Ltd. and its principal place of business is located at Polepally, Jadcherla, Mahabubnagar, 509301, Andhra Pradesh, India.

6. On information and belief, Hetero Labs Ltd. is a parent company of Hetero USA Inc.

7. On information and belief, Hetero Labs Ltd., Hetero Labs Ltd. Unit-VI, and Hetero USA Inc. are related entities and each entity undertakes certain activities related to the development, manufacture, marketing, and/or sale of drug products in the United States and in this Judicial District.

8. Upon information and belief, Defendants derive substantial revenue from the sale of generic pharmaceutical products in the United States and Delaware.

JURISDICTION AND VENUE

9. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 1 *et seq*., and alleges infringement of the '952 Patent.

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. This Court has personal jurisdiction over Hetero USA Inc. On information and belief, Hetero USA Inc. is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Hetero USA Inc. maintains an agent for service of process at 3500 S Dupont Highway, Dover DE 19901.

12. This Court has personal jurisdiction over Hetero USA Inc. at least because, upon information and belief, Hetero USA Inc. has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Hetero USA Inc. directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Products. Hetero USA Inc. regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, thereby demonstrating that Hetero USA Inc. has continuous and systematic contacts with Delaware.

13. Hetero USA Inc. regularly engages in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g*, , *Novartis Pharmaceuticals Corp. v.*

Dr. Reddy's Laboratories, Inc. et al., C.A. No. 19-2053-LPS (D. Del. Jan. 27, 2020), D.I. 30; *Genentech, Inc. et al. v. Hetero Labs Ltd. et al.*, C.A. No. 19-178-RGA (D. Del. Apr. 1, 2019), D.I. 11; *Biogen Int'l GmbH et al. v. Hetero USA Inc. et al.*, C.A. No. 17- 825-MN (D. Del. Oct. 16, 2017), D.I. 13; *Sanofi-Aventis U.S. LLC, et al. v. Actavis LLC, et al*., C.A. No. 20-804-RGA (D. Del. July 20, 2020), D.I. 36; *Bristol-Myers Squibb Co. et al. v. Hetero USA Inc. et al.*, C.A. No. 17-376-LPS (D. Del. Jun. 16, 2017), D.I. 9; and *Amgen Inc. v. Hetero USA Inc. et al.*, C.A. No. 16-928-GMS (D. Del. Dec. 2, 2016), D.I. 12.

14. This Court has personal jurisdiction over Hetero Labs Ltd. at least because, upon information and belief, Hetero Labs Ltd. has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Hetero Labs Ltd. directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Products. Hetero Labs Ltd. regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, thereby demonstrating that Hetero Labs Ltd. has continuous and systematic contacts with Delaware.

15. Hetero Labs Ltd. regularly engages in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g*, *See, e.g.*, *Novartis Pharmaceuticals Corp. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 19-2053-LPS (D. Del. Jan. 27, 2020), D.I. 30; *Genentech, Inc. et al. v. Hetero Labs Ltd. et al.*, C.A. No. 19-178-RGA (D. Del. Apr. 1, 2019),

D.I. 11; *Biogen Int'l GmbH et al. v. Hetero USA Inc. et al.*, C.A. No. 17- 825-MN (D. Del. Oct. 16, 2017), D.I. 13; *Sanofi-Aventis U.S. LLC, et al. v. Actavis LLC, et al*., C.A. No. 20-804-RGA (D. Del. July 20, 2020), D.I. 36; *Bristol-Myers Squibb Co. et al. v. Hetero USA Inc. et al.*, C.A. No. 17-376-LPS (D. Del. Jun. 16, 2017), D.I. 9; and *Amgen Inc. v. Hetero USA Inc. et al.*, C.A. No. 16-928-GMS (D. Del. Dec. 2, 2016), D.I. 12.

16. Hetero Labs Ltd. is also subject to personal jurisdiction in the State of Delaware because Hetero Labs Ltd. has committed, aided, abetted, contributed to, and/or participated in the commission of tortious acts of patent infringement under 35 U.S.C. § 271(e)(2) that have led and/or will lead to foreseeable harm and injury to Plaintiff Ingenus Pharmaceuticals LLC.

17. This Court has personal jurisdiction over Hetero Labs Ltd. Unit-VI, at least because, upon information and belief, Hetero Labs Ltd. Unit-VI has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Hetero Labs Ltd. Unit-VI directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Products. Hetero Labs Ltd. Unit-VI regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, thereby demonstrating that Hetero Labs Ltd. Unit-VI has continuous and systematic contacts with Delaware.

18. Hetero Labs Ltd. Unit-VI regularly engages in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g., Novartis*

Pharmaceuticals Corp. v. Dr. Reddy's Laboratories, Inc. et al., C.A. No. 19-2053-LPS (D. Del. Jan. 27, 2020), D.I. 30; *Genentech, Inc. et al. v. Hetero Labs Ltd. et al.*, C.A. No. 19-178-RGA (D. Del. Apr. 1, 2019), D.I. 11; *Biogen Int'l GmbH et al. v. Hetero USA Inc. et al.*, C.A. No. 17- 825-MN (D. Del. Oct. 16, 2017), D.I. 13; *Sanofi-Aventis U.S. LLC, et al. v. Actavis LLC, et al*., C.A. No. 20-804-RGA (D. Del. July 20, 2020), D.I. 36; *Bristol-Myers Squibb Co. et al. v. Hetero USA Inc. et al.*, C.A. No. 17-376-LPS (D. Del. Jun. 16, 2017), D.I. 9; and *Amgen Inc. v. Hetero USA Inc. et al.*, C.A. No. 16-928-GMS (D. Del. Dec. 2, 2016), D.I. 12.

19. Hetero Labs Ltd. Unit-VI is also subject to personal jurisdiction in the State of Delaware because Hetero Labs Ltd. Unit-VI has committed, aided, abetted, contributed to, and/or participated in the commission of tortious acts of patent infringement under 35 U.S.C. § 271(e)(2) that have led and/or will lead to foreseeable harm and injury to Plaintiff Ingenus Pharmaceuticals LLC.

20. This Court has personal jurisdiction over Hetero at least because, upon information and belief, Hetero is the current owner of Abbreviated New Drug Application (ANDA) No. 219271 ("Hetero's ANDA") and is seeking final approval of that ANDA to engage in the commercial use, sale, and/or distribution of cyclophosphamide solution for intravenous injection, 500 mg/2.5 mL (200 mg/mL), 1 gm/5 mL (200 mg/mL), and 2 gm/10 mL (200 mg/mL) ("Hetero's ANDA Product" or "ANDA Product"), throughout the United States, including in Delaware, before the expiration of the '952 Patent.

21. This Court has personal jurisdiction over Hetero at least because, upon information and belief, if Hetero's ANDA receives final approval, Hetero's ANDA Product will be manufactured, sold, distributed, and/or used by Hetero in Delaware; prescribed by physicians practicing in Delaware; and/or administered to patients in Delaware.

22. Hetero committed an act of infringement of the '952 Patent by submitting and maintaining ANDA No. 219271 with the intent to make, use, offer to sell, and/or sell the drug products that are the subject of ANDA No. 219271 in this Judicial District, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Plaintiff, which manufactures Cyclophosphamide Injection for sale and use throughout the United States, including within this judicial district. On information and belief and as indicated by a letter dated July 31, 2024, sent by Hetero USA, Inc. and addressed to Ingenus Pharmaceuticals LLC, Leiutis Pharmaceuticals LLP and Dr. Reddy's laboratories, Inc. pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (hereinafter, the "Notice Letter"), ANDA No. 219271 was prepared and filed with the intention of seeking to market the ANDA Product nationwide, including within this judicial district.

23. On information and belief, Hetero plans to sell its ANDA Product in the State of Delaware, list the ANDA Product on the State of Delaware' prescription drug formulary, and seek Medicaid reimbursements for sales of the ANDA Product in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos.

24. On information and belief, Hetero intends that its proposed ANDA Product will be distributed and sold in Delaware and will thereby displace sales of Plaintiff's Cyclophosphamide Injection, causing injury to Ingenus. Hetero intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed ANDA Product.

25. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

PLAINTIFF'S APPROVED DRUG PRODUCT AND U.S. PATENT No. 10,993,952

26. By License Agreement of June 11, 2024, Dr. Reddy's Laboratories, Inc. ("DRL") has become Ingenus' Licensee of New Drug Application (NDA) No. 212501, which was approved

by the Food and Drug Administration ("FDA") for the sale and manufacture of Cyclophosphamide solution for intravenous use ("NDA Product"). The active ingredient in the Cyclophosphamide NDA Product is cyclophosphamide. The FDA approved NDA No. 212501 on July 30, 2020.

27. Under the terms of the License Agreement, Ingenus manufactures and supplies to DRL the Products approved under NDA 212501 and DRL markets and commercializes the same, subject to the terms of the License Agreement.

28. NDA No. 212501 is directed to Cyclophosphamide 200 mg/mL (500 mg/ 2.5 mL and 1 g/ 5 mL) in a multiple-dose vial. A supplemental dosage form 200 mg/mL (2 g/ 10 ml) was approved November 19, 2021, under New Drug Application No. N212501.

29. Plaintiff's Cyclophosphamide NDA Product is an injectable solution indicated for the treatment of malignant diseases such as malignant lymphomas (Hodgkin's disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma); multiple myeloma, leukemias (chronic lymphocytic leukemia, chronic granulocytic leukemia, acute myelogenous and monocytic leukemia, acute lymphoblastic (stem-cell) leukemia); mycosis fungoides, neuroblastoma, adenocarcinoma of the ovary, retinoblastoma, and breast carcinoma.

30. Plaintiff's Cyclophosphamide NDA Product's recommended dosage is 40 mg per kg to 50 mg per kg in divided doses over 2 to 5 days.

31. The '952 Patent, entitled "Stable Ready to Use Cyclophosphamide Liquid Formulations," was duly and legally issued by the U.S. Patent and Trademark Office on May 4, 2021.

32. Ingenus is the sole owner and assignee of the '952 Patent, based on an Assignment of all right, title and interest by Assignor Leiutis Pharmaceuticals LLP of July 4, 2024, recorded

at the U.S. Patent and Trademark Office on July 10, 2024 at Reel/Frame No. 067935/0049. Prior to the Assignment by Leiutis, Ingenus and Leiutis were co-assignees of the '952 Patent.

33. Pursuant to 21 U.S.C. § 355(b)(1), the '952 Patent was submitted to FDA with NDA No. 212501and was subsequently listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for Cyclophosphamide Injection.

DEFENDANTS' ANDA NO. 219271

34. On information and belief, Defendants have submitted ANDA No. 219271 to FDA, or caused ANDA No. 219271 to be submitted to FDA, under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of cyclophosphamide injection as purported generic versions of Plaintiff's NDA Products prior to the expiration of the '952 Patent.

35. On information and belief, Hetero USA Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI acted collaboratively in the preparation and submission of ANDA No. 219271 and Hetero's Proposed ANDA Product, and all intend to directly benefit from and have a financial stake in the approval of the ANDA.

36. On information and belief, following any FDA approval of ANDA No. 219271, Hetero USA Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI will work in concert with one another to make, use, offer to sell, and/or sell the drug product that is the subject of ANDA No. 219271 throughout the United States, and/or import such drug product into the United States, including in this Judicial District.

37. On information and belief, FDA has not approved Defendants' ANDA.

38. By letter dated July 31, 2024, Hetero USA, Inc. notified Ingenus Pharmaceuticals LLC, Leiutis Pharmaceuticals LLP and Dr. Reddy's Laboratories, Inc. that Hetero submitted to

FDA ANDA No. 219271 containing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '952 Patent, which is listed in the Orange Book for Plaintiff's NDA Products, asserting that the'952 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Hetero's Proposed ANDA Product. Plaintiff reserves all rights to challenge the sufficiency of Defendants' ANDA and Notice Letter.

39. On information and belief, Defendants seek approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the ANDA Product before expiration of the '952 Patent. Hence, Defendants' purpose in submitting ANDA No. 219271 with a Paragraph IV certification is to market the ANDA product described therein before the expiration of the '952 Patent.

40. On information and belief, if approved, the ANDA Product will have the same indication as Plaintiff's Cyclophosphamide NDA Product. On further information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 219271 for the ANDA Product is the treatment of malignant diseases as described in Plaintiff's NDA.

41. On information and belief, if FDA approves Defendants' ANDA, Defendants will manufacture, offer for sale, or sell the ANDA Product, within the United States, including within the State of Delaware, or will import the ANDA Product into the United States, including into the State of Delaware.

42. On information and belief, if FDA approves Defendants' ANDA, Defendants will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Product in a manner that infringes the '952 Patent.

43. This action is being brought within forty-five days of Plaintiff's receipt of the Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C). Accordingly, Plaintiff is entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and U.S.C. § 355(j)(5)(F)(ii).

FIRST COUNT
(Hetero's Infringement of the '952 Patent)

44. Plaintiff repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

45. Upon information and belief, Hetero submitted or caused the submission of ANDA No. 219271 to FDA, seeking FDA approval of Defendants' ANDA.

46. Plaintiff owns substantial rights, title, and interest in and to the '952 Patent.

47. Hetero's ANDA Product falls within one or more claims of the '952 Patent.

48. Hetero does not contest infringement of any claims of the '952 Patent in its Notice Letter. If Hetero had a factual or legal basis to contest infringement of any claims of the '952 Patent, Hetero was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

49. Under 35 U.S.C. § 271(e)(2)(A), Hetero's submission of Hetero's ANDA with a Paragraph IV certification to the '952 Patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Hetero's ANDA Product before the expiration of the '952 Patent is itself an act of infringement of the '952 Patent.

50. If approved by the FDA, the importation, manufacture, sale, offer for sale, or use of the ANDA Product within the United States will infringe, either literally or under the doctrine of equivalents, one or more claims of the '952 Patent under 35 U.S.C. § 271(a).

51. Unless enjoined by this Court, upon FDA approval, Defendants will actively induce infringement of the '952 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA

approval of Defendants' ANDA, Defendants will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby induce infringement of one or more claims of the '952 Patent. On information and belief, upon FDA approval, Defendants will intentionally encourage acts of direct infringement with knowledge of the '952 Patent and knowledge that its acts are encouraging infringement.

52. Unless enjoined by this Court, upon FDA approval, Defendants will contributorily infringe the '952 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendants' ANDA, Defendant will offer to sell or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of one or more claims of the '952 Patent. On information and belief, Defendants have had and continues to have knowledge of the '952 Patent and knowledge that its acts will lead to infringement of the patent. On information and belief, Defendants have had and continue to have knowledge that the ANDA Product is especially made or especially adapted for a use that infringes the '952 Patent and that there are no substantial noninfringing uses for the ANDA Product.

53. Defendants had actual and constructive notice of the '952 Patent prior to filing Defendants' ANDA, and was aware that the filing of Defendants' ANDA with the request for FDA approval prior to the expiration of the '952 Patent would constitute an act of infringement of the '952 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not infringe, contribute to the infringement of, and/or induce the infringement of the '952 Patent.

54. Defendants filed their ANDA without adequate justification for asserting the '952 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants' conduct in certifying invalidity,

unenforceability, and/or noninfringement with respect to the '952 Patent was willful and renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285 and entitles Plaintiff to recovery of their attorneys' fees and such other relief as this Court deems proper.

55. Plaintiff will be irreparably harmed if Defendant is not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '952 Patent. Plaintiff does not have an adequate remedy at law and considering the balance of hardships between Plaintiff and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

A. A judgment that Defendants have infringed the '952 Patent under 35 U.S.C. § 271(e)(2)(A);

B. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Defendants' ANDA shall be no earlier than the last expiration date of the '952 Patent, or any later expiration of exclusivity for the '952 Patent, including any extensions or regulatory exclusivities;

C. Entry of a permanent injunction enjoining Defendant, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Defendant or on their behalf from commercially manufacturing, using, offering for sale, or selling the ANDA Products within the United States, or importing the ANDA Products into the United States, until the expiration of the '952 Patent;

D. A judgment that making, using, selling, offering to sell, or importing the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the '952 Patent pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

E. A declaration under 28 U.S.C. § 2201 that if Defendant, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Defendant or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of the ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

F. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendant engages in the commercial manufacture, use, offer for sale, sale, and/or importation of

the ANDA Product, or any product that infringes the '952 Patent, or induces or contributes to such conduct, prior to the expiration of the '952 Patent;

G. An order staying Hetero's ANDA for a 30-month time period referred to within 21 U.S.C. § 355(j)(5)(B)(iii);

H. A finding that this is an exceptional case, and an award of attorneys' fees and costs to Plaintiff in this action pursuant to 35 U.S.C. § 285;

I. An award to Ingenus of the costs of this action; and

J. Granting such other and further relief as the Court deems just and proper.

Respectfully submitted,

Dated: September 11, 2024

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