IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., *Plaintiff,* ANNORA PHARMA PRIVATE LIMITED and HETERO USA INC., *Defendants,*	C.A. No. _____

COMPLAINT

Plaintiff Merck Sharp & Dohme Corp. ("Merck"), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 215894 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import versions of JANUVIA® (sitagliptin phosphate) prior to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent").

2. Annora Pharma Private Limited notified Merck by letter dated May 25, 2021 ("Annora's Notice Letter") that it had submitted to the FDA ANDA No. 215894 ("Annora's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic sitagliptin phosphate oral tablets ("Annora's ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, Annora's ANDA Product is a generic version of Merck's JANUVIA® product.

PARTIES

4. Plaintiff Merck is a corporation organized and existing under the laws of New Jersey, having its corporate offices and principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

5. Merck is the holder of New Drug Application ("NDA") No. 21995 for JANUVIA® (sitagliptin phosphate), which has been approved by the FDA.

6. On information and belief, Annora Pharma Private Limited is a corporation organized and existing under the laws of India, having a principal place of business at Sy. No. 261, Annaram Village, Gummadidal Mandal, Sangareddy District, Telangana State, 502313, India. On information and belief, Annora Pharma Private Limited is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs throughout the United States, including Delaware.

7. On information and belief, 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. On information and belief, Hetero USA Inc is in the business of, among other things, manufacturing and selling generic versions of pharmaceutical drug products throughout the United States, including Delaware.

8. On information and belief, Annora Pharma Private Limited and Hetero USA Inc. acted in concert to prepare and submit ANDA No. 215894 to the FDA.

9. On information and belief, Annora Pharma Private Limited and Hetero USA Inc. know and intend that upon approval of Annora's ANDA, Annora Pharma Private

Limited and/or Hetero USA Inc. will manufacture, market, sell, and distribute Annora's ANDA Product throughout the United States, including in Delaware. On information and belief, Annora Pharma Private Limited and Hetero USA Inc. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On information and belief, Annora Pharma Private Limited and Hetero USA Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Annora's ANDA Product, and enter into agreements that are nearer than arm's length. On information and belief, Annora Pharma Private Limited and Hetero USA Inc. participated, assisted, and cooperated in carrying out the acts complained of herein.

10. On information and belief, Somaraju Indukuri, Ph.D., is the agent for service of process in the United States for Annora Pharma Private Limited. On information and belief, Somaraju Indukuri acts at the direction of, under the control of, and/or for the benefit of Annora Pharma Private Limited and is controlled by Annora Pharma Private Limited. On information and belief, Somaraju Indukuri holds title as Vice President, Regulatory Affairs, U.S. Agent, at Hetero USA Inc.

11. On information and belief, Hetero USA Inc. acts as the U.S. agent for Annora Pharma Private Limited for purposes of regulatory submissions to FDA in seeking approval for generic drugs. These two entities are hereafter collectively referred to as "Annora."

12. On information and belief, following any FDA approval of ANDA No. 215894, Annora will distribute and sell Annora's ANDA Product throughout the United States, including within Delaware.

JURISDICTION

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

14. This Court has personal jurisdiction over Annora.

15. Annora Pharma Private Limited is subject to personal jurisdiction in Delaware because, among other things, Annora has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Annora develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

16. Hetero USA Inc. is subject to personal jurisdiction in Delaware because, among other things, 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. Hetero USA Inc. is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Hetero USA Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware

17. On information and belief, if Annora's ANDA is approved, Annora will manufacture, market, sell, and/or distribute Annora's ANDA Product within the United States,

including in Delaware, consistent with Annora's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Annora regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. On information and belief, Annora's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Annora's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Merck's patent in the event that Annora's ANDA Product is approved before the '708 patent expires.

18. On information and belief, Annora derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and that are manufactured by Annora and/or for which Annora is the named applicant on approved ANDAs. On information and belief, various products for which Annora is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

19. On information and belief, Annora Pharma Private Limited and Hetero USA Inc. have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and have filed counterclaims in such cases. *See, e.g., Azurity Pharmaceuticals, Inc. v. Annora Pharma Private Limited*, C.A. No. 21-196-LPS (D. Del. June 14, 2021); *UCB, Inc. et al v. Annora Pharma Private Limited et al.*, C.A. 20-987-CFC (D. Del. Oct. 9, 2020); *Boehringer Ingelheim Pharms. Inc. v. Annora Pharma Private Ltd.*, C.A. No. 20-277-CFC (D. Del. Apr. 27, 2020); *Amgen Inc. v. Annora Pharma Private Ltd.*, C.A. No. 20-122-CFC

(D. Del. Mar. 26, 2020); *Vifor Fresenius Med. Care Renal Pharma Ltd. v. Annora Pharma Private Ltd.*, C.A. No. 18-1996-MN (D. Del. Mar. 1, 2019); *Boehringer Ingelheim Pharms. Inc. v. Annora Pharma Private Ltd.*, C.A. No. 18-1786-CFC-SRF, D.I. 19 (D. Del. Jan. 18, 2019).

THE ’708 PATENT

20. Merck incorporates each of the preceding paragraphs 1–19 as if fully set forth herein.

21. The inventors named on the ’708 patent are Stephen Howard Cypes, Alex Minhua Chen, Russell R. Ferlita, Karl Hansen, Ivan Lee, Vicky K. Vydra, and Robert M. Wenslow, Jr.

22. The ’708 patent, entitled “Phosphoric Acid Salt of a Dipeptidyl Peptidase-IV Inhibitor” (attached as Exhibit A), was duly and legally issued on February 5, 2008.

23. Merck is the owner and assignee of the ’708 patent.

24. The ’708 patent claims, *inter alia*, a dihydrogenphosphate salt of 4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine of structural formula I, or a hydrate thereof, as recited in claim 1 of the ’708 patent.

25. JANUVIA®, as well as methods of using JANUVIA®, are covered by one or more claims of the ’708 patent, including claim 1 of the ’708 patent, and the ’708 patent has been listed in connection with JANUVIA® in the FDA’s Orange Book.

COUNT I – INFRINGMENT OF THE ’708 PATENT

26. Merck incorporates each of the preceding paragraphs 1–25 as if fully set forth herein.

27. In Annora's Notice Letter, Annora notified Merck of the submission of Annora's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Annora's ANDA Product prior to the expiration of the '708 patent.

28. In Annora's Notice Letter, Annora also notified Merck that, as part of its ANDA, Annora had filed certifications 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 '708 patent. On information and belief, Annora submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '708 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Annora's ANDA Product.

29. In Annora's Notice Letter, Annora stated that Annora's ANDA Product contains sitagliptin phosphate as an active ingredient.

30. Annora's ANDA Product, and the use of Annora's ANDA Product, is covered by one or more claims of the '708 patent, including at least claim 1 of the '708 patent, because claim 1 of the '708 patent covers the sitagliptin phosphate contained in Annora's ANDA Product.

31. In Annora's Notice Letter, Annora did not contest infringement of claim 1 of the '708 patent.

32. Annora's submission of Annora's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Annora's ANDA Product before the expiration of the '708 patent was an act of infringement of the '708 patent under 35 U.S.C. § 271(e)(2)(A).

33. On information and belief, Annora will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Annora's ANDA Product immediately and imminently upon approval of its ANDA.

34. The manufacture, use, sale, offer for sale, or importation of Annora's ANDA Product would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

35. On information and belief, the manufacture, use, sale, offer for sale, or importation of Annora's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

36. On information and belief, Annora plans and intends to, and will, actively induce infringement of the '708 patent when Annora's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Annora's activities will be done with knowledge of the '708 patent and specific intent to infringe that patent.

37. On information and belief, Annora knows that Annora's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '708 patent, that Annora's ANDA Product is not a staple article or commodity of commerce, and that Annora's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Annora plans and intends to, and will, contribute to infringement of the '708 patent immediately and imminently upon approval of Annora's ANDA.

38. Notwithstanding Annora's knowledge of the claims of the '708 patent, Annora has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or

import Annora's ANDA Product with its product labeling following FDA approval of Annora's ANDA prior to the expiration of the '708 patent.

39. The foregoing actions by Annora constitute and/or will constitute infringement of the '708 patent; active inducement of infringement of the '708 patent; and contribution to the infringement by others of the '708 patent.

40. On information and belief, Annora has acted with full knowledge of the '708 patent and without a reasonable basis for believing that it would not be liable for infringement of the '708 patent; active inducement of infringement of the '708 patent; and/or contribution to the infringement by others of the '708 patent.

41. Merck will be substantially and irreparably damaged by infringement of the '708 patent.

42. Unless Annora is enjoined from infringing the '708 patent, actively inducing infringement of the '708 patent, and contributing to the infringement by others of the '708 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '708 PATENT

43. Merck incorporates each of the preceding paragraphs 1–42 as if fully set forth herein.

44. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Annora on the other regarding Annora's infringement, active inducement of infringement, and contribution to the infringement by others of the '708 patent.

45. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Annora's ANDA Product with its proposed labeling, or any other Annora

drug product that is covered by or whose use is covered by the '708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '708 patent, and that the claims of the '708 patent are valid.

PRAYER FOR RELIEF

WHEREFORE, Merck requests the following relief:

(a) A judgment that the '708 patent has been infringed under 35 U.S.C. § 271(e)(2) by Annora's submission to the FDA of Annora's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of Annora's ANDA Product, or any other drug product that infringes or the use of which infringes the '708 patent, be not earlier than the latest of the expiration date of the '708 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Annora, and all persons acting in concert with Annora, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Annora's ANDA Product, or any other drug product covered by or whose use is covered by the '708 patent, prior to the expiration of the '708 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Annora's ANDA Product, or any other drug product that is covered by or whose use is covered by the '708 patent, prior to the expiration of the '708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of, the '708 patent;

(e) A declaration that this is an exceptional case and an award of attorney's fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Dated: July 9, 2021

Respectfully submitted,

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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