IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME LLC, *Plaintiff,* AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA USA, INC., *Defendants*.	C.A. No. _____

COMPLAINT

Plaintiff Merck Sharp & Dohme LLC ("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. 220279 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import versions of JANUMET XR® (metformin hydrochloride; sitagliptin phosphate extended release tablets) prior to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent").

2. Aurobindo Pharma Limited notified Merck by letter dated February 24, 2025 ("Aurobindo's Notice Letter") that it had submitted to the FDA ANDA No. 220279 ("Aurobindo's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic sitagliptin/metformin hydrochloride extended release

combination oral tablets, 100 mg/1000 mg, and 50 mg/1000mg strengths ("Aurobindo's ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, Aurobindo's ANDA Product is a generic version of Merck's JANUMET XR® product.

PARTIES

4. Plaintiff Merck is a limited liability company organized and existing under the laws of New Jersey, having its corporate offices and principal place of business at 126 E. Lincoln Avenue, Rahway, NJ 07065.

5. Merck is the holder of New Drug Application ("NDA") No. 202270 for JANUMET XR® (metformin hydrochloride; sitagliptin phosphate extended release tablets), which has been approved by the FDA.

6. On information and belief, Defendant Aurobindo Pharma Limited is a corporation organized and existing under the laws of India having its corporate offices and principal place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500038, Telangana, India. On information and belief, Aurobindo Pharma Limited is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Aurobindo Pharma USA, Inc.

7. On information and belief, Defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of Delaware having its corporate offices and principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520. On information and belief, Aurobindo Pharma 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, Aurobindo Pharma USA, Inc. is a wholly-owned subsidiary of Aurobindo Pharma Limited.

9. On information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. acted in concert to prepare and submit ANDA No. 220279 to the FDA.

10. On information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. know and intend that upon approval of Aurobindo's ANDA, Aurobindo Pharma Limited and/or Aurobindo Pharma USA, Inc. will manufacture, market, sell, and distribute Aurobindo's ANDA Product throughout the United States, including in Delaware. On information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Aurobindo's ANDA Product, and enter into agreements that are nearer than arm's length. On information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. participated, assisted, and cooperated in carrying out the acts complained of herein. These two entities are hereafter collectively referred to as "Aurobindo."

11. On information and belief, following any FDA approval of ANDA No. 220279, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. will act in concert to distribute and sell Aurobindo's ANDA Product throughout the United States, including within Delaware.

JURISDICTION

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

13. This Court has personal jurisdiction over Aurobindo.

14. Aurobindo Pharma Limited is subject to personal jurisdiction in Delaware because, among other things, Aurobindo Pharma Limited, itself and through its wholly owned subsidiary

Aurobindo Pharma USA, 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. On information and belief, Aurobindo Pharma Limited, itself and through its wholly owned subsidiary Aurobindo Pharma 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, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Aurobindo Pharma Limited is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Aurobindo Pharma USA, Inc. and therefore the activities of Aurobindo Pharma USA, Inc. in this jurisdiction are attributed to Aurobindo Pharma Limited.

15. Aurobindo Pharma 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. Aurobindo Pharma 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, Aurobindo Pharma 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.

16. On information and belief, if Aurobindo's ANDA is approved, Aurobindo will manufacture, market, sell, and/or distribute Aurobindo's ANDA Product within the United States, including in Delaware, consistent with Aurobindo's practices for the marketing and distribution of

other generic pharmaceutical products. On information and belief, Aurobindo 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, Aurobindo's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Aurobindo'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 Aurobindo's ANDA Product is approved before the '708 patent expires.

17. On information and belief, Aurobindo derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and that are manufactured by Aurobindo and/or for which Aurobindo Pharma Limited and/or Aurobindo Pharma USA, Inc. is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which Aurobindo Pharma Limited and/or Aurobindo Pharma USA, Inc. is/are the named applicant(s) on approved ANDAs are available at retail pharmacies in Delaware.

18. In addition, this Court has personal jurisdiction over Aurobindo because Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See Merck Sharp & Dohme Corp. v. Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc.*, No. 20-949-RGA (D. Del. July 15, 2020); *see also SK Biopharmaceuticals Co., Ltd. v. Aurobindo Pharma Ltd.*, No. 24-718-JLH-

CJB, D.I. 14 (D. Del. Aug. 16, 2024); *Amicus Therapeutics US, LLC v. Aurobindo Pharma Ltd.*, No. 24-1331 (D. Del. Dec. 6, 2024).

THE ’708 PATENT

19. Merck incorporates each of the preceding paragraphs 1–18 as if fully set forth herein.

20. 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.

21. 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.

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

23. 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.

24. JANUMET XR®, as well as methods of using JANUMET XR®, 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 JANUMET XR® in the FDA’s Orange Book.

COUNT I – INFRINGMENT OF THE ’708 PATENT

25. Merck incorporates each of the preceding paragraphs 1–24 as if fully set forth herein.

26. In Aurobindo’s Notice Letter, Aurobindo notified Merck of the submission of Aurobindo’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 Aurobindo's ANDA Product prior to the expiration of the '708 patent.

27. In Aurobindo's Notice Letter, Aurobindo also notified Merck that, as part of its ANDA, Aurobindo 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, Aurobindo 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 Aurobindo's ANDA Product.

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

29. Aurobindo's ANDA Product, and the use of Aurobindo'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 Aurobindo's ANDA Product.

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

31. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo'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).

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

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

34. On information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo'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.

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

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

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

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

38. The foregoing actions by Aurobindo 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.

39. On information and belief, Aurobindo 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.

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

41. Unless Aurobindo 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

42. Merck incorporates each of the preceding paragraphs 1–41 as if fully set forth herein.

43. 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 Aurobindo on the other regarding Aurobindo's infringement, active inducement of infringement, and contribution to the infringement by others of the '708 patent.

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

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 Aurobindo’s submission to the FDA of Aurobindo’s ANDA;

(b) A judgment ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of Aurobindo’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 Aurobindo, and all persons acting in concert with Aurobindo, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo’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 Aurobindo’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: April 11, 2025

Respectfully submitted,

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