IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME LLC., *Plaintiff,* AZURITY PHARMACEUTICALS, INC., *Defendant.*	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 Defendant's submission of submission of New Drug Application ("NDA") No. 219122 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of JANUVIA® (sitagliptin phosphate) prior to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent").

2. Azurity Pharmaceuticals, Inc. ("Azurity") notified Merck by letter dated March 19, 2024 ("Azurity's Notice Letter") that Azurity had submitted to the FDA NDA No. 219122 ("Azurity's NDA"), seeking approval from the FDA to engage in the commercial

manufacture, use, offering for sale, sale, and/or importation of generic sitagliptin oral solution ("Azurity's NDA Product") prior to the expiration of the '708 patent.

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

PARTIES

4. Plaintiff Merck is a company organized and existing under the laws of New Jersey, having its company offices and principal place of business at 126 East Lincoln Ave, P.O. Box 2000, Rahway, NJ 07065 USA.

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, Defendant Azurity is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 8 Cabot Road, Suite 2000, Woburn, MA 01801. Upon information and belief, Azurity is in the business of, among other things, manufacturing and selling pharmaceutical drugs for the U.S. market.

7. On information and belief, Azurity knows and intends that upon approval of Azurity's NDA, Azurity will manufacture, market, sell, and distribute Azurity's NDA Product throughout the United States, including in Delaware.

8. On information and belief, following any FDA approval of Azurity's NDA, Azurity will distribute and sell Azurity's NDA Product throughout the United States, including within Delaware.

JURISDICTION

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

10. This Court has personal jurisdiction over Azurity.

11. Azurity Pharmaceuticals, 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. Azurity Pharmaceuticals, 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, Azurity Pharmaceuticals, 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.

12. In addition, this Court has personal jurisdiction over Azurity because Azurity engages in patent litigation concerning FDA-approved branded drug products in this district, does not contest personal jurisdiction in this 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.*, *Azurity Pharmaceuticals, Inc. et al v. Hetero Labs Limited et al.*, 24-396-MN (D. Del. 2024); *Azurity Pharmaceuticals, Inc. et al v. Bionpharma Inc*., 23-mc-396-MSG (D. Del. 2023); *Cosette Pharmaceuticals, Inc. v. Azurity Pharmaceuticals, Inc*., 23-18-MSG (D. Del. 2023).

13. On information and belief, if Azurity's NDA is approved, Azurity will manufacture, market, sell, and/or distribute Azurity's NDA Product within the United States, including in Delaware, consistent with Azurity's practices for the marketing and distribution of other pharmaceutical products. On information and belief, Azurity regularly does business in Delaware, and its practices with other 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, Azurity's pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Azurity's NDA 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 Azurity's NDA Product is approved before the patent expires.

14. On information and belief, Azurity derives substantial revenue from pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Azurity and/or for which Azurity is the named applicant on approved NDAs and/ or Abbreviated New Drug Applications. On information and belief, various products for which Azurity is the named applicant on approved NDAs are available at retail pharmacies in Delaware.

VENUE

15. Merck incorporates each of the preceding paragraphs 1–14 as if fully set forth herein.

16. Venue is proper in this district as to Azurity Pharmaceutical Inc. under 28 U.S.C. § 1400(b) because Azurity Pharmaceutical Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

THE '708 PATENT

17. Merck incorporates each of the preceding paragraphs 1–16 as if fully set forth herein.

18. 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.

19. 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.

20. Merck is the owner and assignee of the '708 patent.

21. 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.

22. 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 – INFRINGEMENT OF THE '708 PATENT

23. Merck incorporates each of the preceding paragraphs 1–22 as if fully set forth herein.

24. In Azurity's Notice Letter, Azurity notified Merck of the submission of Azurity's NDA 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 Azurity's NDA Product prior to the expiration of the '708 patent.

25. In Azurity's Notice Letter, Azurity also notified Merck that, as part of its NDA, Azurity had filed certifications of the type described in Section 505(b)(3) of the FDCA, 21 U.S.C. § 355(b)(3), with respect to the '708 patent. Azurity submitted Azurity's NDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(b)(2)(A)(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 Azurity's NDA Product.

26. In Azurity's Notice Letter, Azurity stated that Azurity's NDA Product contains sitagliptin as an active ingredient.

27. Azurity's Notice Letter appends a document titled "Detailed Factual and Legal Bases For Azurity's Paragraph IV Certification" asserting that the commercial manufacture, use, or sale of Azurity's NDA Product will not infringe the '708 patent. However, Azurity's Notice Letter and accompanying document do not provide information regarding Azurity's NDA Product sufficient to evaluate Azurity's assertions of non-infringement.

28. Merck requested that Azurity provide its DMF and NDA, but the parties were unable to agree to terms yet under which Merck would gain access to Azurity's technical documents, and Merck has yet to receive Azurity's NDA, DMF, or any other similar internal documents and data relevant to infringement.

29. Merck brings forward this Complaint now on good faith belief that the commercial manufacture, use, offer for sale, sale and/or importation of Azurity's NDA Product

will infringe the ’708 patent, while still trying to negotiate access to Azurity’s NDA and DMF, in order to commence this action before the expiration of forty-five days from the date of the receipt of Azurity’s Notice Letter.

30. On information and belief, Azurity’s NDA Product, and the use of Azurity’s NDA Product, are covered by one or more claims of the ’708 patent.

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

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

33. The manufacture, use, sale, offer for sale, or importation of Azurity’s NDA Product would infringe one or more claims of the ’708 patent.

34. On information and belief, the manufacture, use, sale, offer for sale, or importation of Azurity’s NDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the ’708 patent.

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

36. On information and belief, Azurity knows that Azurity’s NDA Product and its proposed labeling are especially made or adapted for use in infringing the ’708 patent,

that Azurity's NDA Product is not a staple article or commodity of commerce, and that Azurity's NDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Azurity plans and intends to, and will, contribute to infringement of the '708 patent immediately and imminently upon approval of Azurity's NDA.

37. Notwithstanding Azurity's knowledge of the claims of the '708 patent, Azurity has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Azurity's NDA Product with its product labeling following FDA approval of Azurity's NDA prior to the expiration of the '708 patent.

38. The foregoing actions by Azurity 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, Azurity 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 Azurity 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.

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 Azurity's submission to the FDA of Azurity's NDA;

(b) A judgment ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of Azurity's NDA 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 Azurity, and all persons acting in concert with Azurity, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Azurity's NDA 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 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: May 3, 2024

Respectfully submitted,

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