IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME LLC., *Plaintiff,* v. PRINSTON PHARMACEUTICAL 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 Abbreviated New Drug Application ("ANDA") No. 216886 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 tablets) prior to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent").

2. Prinston Pharmaceutical Inc. notified Merck by letter dated July 1, 2022 ("Prinston's Notice Letter") that Prinston Pharmaceutical Inc. had submitted to the FDA ANDA No. 216886 ("Prinston'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 ("Prinston's ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, Prinston'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 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 Prinston Pharmaceutical Inc. ("Prinston") is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 700 Atrium Drive Somerset, New Jersey 08873. Upon information and belief, Prinston is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market.

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

8. On information and belief, following any FDA approval of Prinston's ANDA, Prinston will distribute and sell Prinston's ANDA 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 Prinston.

11. Prinston Pharmaceutical 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. Prinston Pharmaceutical 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, Prinston Pharmaceutical 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 Prinston because Prinston 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.*, *Astellas Pharma Inc. et al v. Sandoz Inc. et al.*, 20-1589-JFB-CJB (D. Del. 2020); *Otsuka Pharmaceutical Co. Ltd. et al v. Prinston Pharmaceutical Inc.*. 20-1502-LPS (D. Del. 2020).

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

14. On information and belief, Prinston derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Prinston and/or for which Prinston is the named applicant on approved ANDAs. On information and belief, various products for which Prinston is the named applicant on approved ANDAs 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 Prinston Pharmaceutical Inc. under 28 U.S.C. § 1400(b) because Prinston 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 Prinston's Notice Letter, Prinston notified Merck of the submission of Prinston's ANDA to the FDA. The purpose of this submission was to obtain approval under the

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