IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., *Plaintiff,* v. LAURUS LABS LIMITED and LAURUS GENERICS 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. 216057 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. Laurus Labs Limited notified Merck by letter dated July 8, 2021 ("Laurus's Notice Letter") that Laurus Labs Limited had submitted to the FDA ANDA No. 216057 ("Laurus'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 ("Laurus's ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, Laurus'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, defendant Laurus Generics Inc. ("Laurus Generics") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 400 Connell Dr., Berkeley Heights, New Jersey 07922. On information and belief, Laurus Generics. 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, defendant Laurus Labs Limited ("Laurus Labs") is a corporation organized and existing under the laws of India, with a principal place of business at Serene Chambers, Road No. 7, Banjara Hills, Hyderabad-500 034, India. Upon information and belief, Laurus Labs is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Laurus Generics.

8. On information and belief, Laurus Generics is a wholly owned subsidiary of Laurus Labs. Laurus Labs and Laurus Generics are herein collectively referred to "Laurus."

9. On information and belief, Laurus Labs and Laurus Generics acted in concert to prepare and submit Laurus's ANDA to the FDA.

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

11. On information and belief, following any FDA approval of Laurus's ANDA, Laurus Labs and Laurus Generics will act in concert to distribute and sell Laurus'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 Laurus.

14. Laurus Generics 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. Laurus Generics 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, Laurus Generics 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.

15. Laurus Labs is subject to personal jurisdiction in Delaware because, among other things, Laurus Labs, itself and through its wholly owned subsidiary Laurus Generics, 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 Laurus Labs, itself and through its wholly owned subsidiary Laurus Generics, 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, Laurus Labs is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Laurus Generics, and therefore the activities of Laurus Generics in this jurisdiction are attributed to Laurus Labs.

16. In addition, this Court has personal jurisdiction over Laurus because Laurus Labs and Laurus Generics 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, e.g.*, *Genentech, Inc. et al v. Laurus Labs Ltd. et al.*, 19-104-RGA (D. Del. 2019); *Novartis Pharmaceuticals Corporation v. Alkem Laboratories Ltd. et al.*, 19-1979-LPS (D. Del. 2019); *Boehringer Ingelheim Pharmaceuticals Inc. et al v. Laurus Labs Ltd. et al.*, 18-1758-CFC-SRF (D. Del. 2018).

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

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

VENUE

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

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

21. Venue is also proper in this district as to Laurus Labs under 28 U.S.C. § 1391 because Laurus Labs is a corporation organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

THE '708 PATENT

22. Merck incorporates each of the preceding paragraphs 1–21 as if fully set forth herein.

23. 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.

24. 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.

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

26. 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.

27. 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

28. Merck incorporates each of the preceding paragraphs 1–27 as if fully set forth herein.

29. In Laurus's Notice Letter, Laurus notified Merck of the submission of Laurus'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 Laurus's ANDA Product prior to the expiration of the '708 patent.

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

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

32. Laurus's ANDA Product, and the use of Laurus'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 Laurus's ANDA Product.

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

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

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

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

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

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

39. On information and belief, Laurus knows that Laurus's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '708 patent, that Laurus's ANDA Product is not a staple article or commodity of commerce, and that Laurus's ANDA Product and its proposed labeling are not suitable for substantial noninfringing

use. On information and belief, Laurus plans and intends to, and will, contribute to infringement of the '708 patent immediately and imminently upon approval of Laurus's ANDA.

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

41. The foregoing actions by Laurus 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.

42. On information and belief, Laurus 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.

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

44. Unless Laurus 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

45. Merck incorporates each of the preceding paragraphs 1–44 as if fully set forth herein.

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

47. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Laurus's ANDA Product with its proposed labeling, or any other Laurus 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 Laurus's submission to the FDA of Laurus's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of Laurus'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 Laurus, and all persons acting in concert with Laurus, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Laurus'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 Laurus'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: August 12, 2021

Respectfully submitted,

OF COUNSEL:

Bruce R. Genderson
Jessamyn S. Berniker
Stanley E. Fisher
Alexander S. Zolan
Elise M. Baumgarten
Shaun P. Mahaffy
Anthony H. Sheh
Jingyuan Luo
Sarahi Uribe
Vanessa Omoroghomwan
Jihad Komis*
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
T: (202) 434-5000
F: (202) 434-5029
bgenderson@wc.com
jberniker@wc.com
sfisher@wc.com
azolan@wc.com
ebaumgarten@wc.com
smahaffy@wc.com
asheh@wc.com
jluo@wc.com
suribe@wc.com
vomoroghomwan@wc.com
jkomis@wc.com

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MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver
Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
T: (302) 984-6300
mkelly@mccarter.com
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Plaintiff
Merck Sharp & Dohme Corp.