

**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.

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