IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., *Plaintiff,* v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD., *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") Nos. 214700 and 214685 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a version of JANUVIA® (sitagliptin phosphate) and JANUMET® (metformin hydrochloride; sitagliptin phosphate) prior to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent").

2. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. notified Merck by letter dated May 14, 2020 ("Dr. Reddy's '700 Notice Letter") that they had submitted to the FDA ANDA No. 214700 ("Dr. Reddy's '700 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 ("Dr. Reddy's '700 ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, Dr. Reddy's '700 ANDA Product is a generic version of Merck's JANUVIA®.

4. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. notified Merck by letter dated June 16, 2020 ("Dr. Reddy's '685 Notice Letter") that they had submitted to the FDA ANDA No. 214685 ("Dr. Reddy's '685 ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic metformin hydrochloride and sitagliptin phosphate oral tablets ("Dr. Reddy's '685 ANDA Product") prior to the expiration of the '708 patent.

5. On information and belief, Dr. Reddy's '685 ANDA Product is a generic version of Merck's JANUVIA®.

6. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. are collectively referred to as "Dr. Reddy's." Dr. Reddy's '700 Notice Letter and Dr. Reddy's '685 Notice Letter are collectively referred to herein as "Dr. Reddy's Notice Letters." Dr. Reddy's '700 ANDA and Dr. Reddy's '685 ANDA are collectively referred to herein as "Dr. Reddy's ANDAs." Dr. Reddy's '700 ANDA Product and Dr. Reddy's '685 ANDA Product are collectively referred to herein as "Dr. Reddy's ANDA Products."

PARTIES

7. 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.

8. Merck is the holder of NDA No. 021995 for JANUVIA® (sitagliptin phosphate), which has been approved by the FDA.

9. Merck is the holder of NDA No. 22044 for JANUMET® (metformin hydrochloride; sitagliptin phosphate), which has been approved by the FDA.

10. On information and belief, defendant Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 107 College Road East, Princeton, New Jersey 08540. On information and belief, Dr. Reddy's Laboratories, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market.

11. On information and belief, defendant Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India, with a principal place of business of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telenangana 500034, India. Upon information and belief, Dr. Reddy's Laboratories, Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Dr. Reddy's Laboratories, Inc.

12. On information and belief, Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd.

13. On information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. acted in concert to prepare and submit Dr. Reddy's ANDAs to the FDA.

14. On information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. know and intend that upon approval of Dr. Reddy's ANDAs, Dr. Reddy's will manufacture, market, sell, and distribute Dr. Reddy's ANDA Products throughout the United States, including in Delaware. On information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Dr. Reddy's ANDA Products, and enter

into agreements that are nearer than arm's length. On information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. participated, assisted, and cooperated in carrying out the acts complained of herein.

15. On information and belief, following any FDA approval of Dr. Reddy's ANDAs, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. will act in concert to distribute and sell Dr. Reddy's ANDA Products throughout the United States, including within Delaware.

JURISDICTION

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

17. This Court has personal jurisdiction over Dr. Reddy's.

18. Dr. Reddy's Laboratories, 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. In addition, on information and belief, Dr. Reddy's Laboratories, 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.

19. Dr. Reddy's Laboratories, Ltd. is subject to personal jurisdiction in Delaware because, among other things, Dr. Reddy's Laboratories, Ltd., itself and through its wholly owned subsidiary Dr. Reddy's Laboratories, 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, Dr. Reddy's Laboratories, Ltd., itself and through its wholly owned subsidiary Dr. Reddy's Laboratories, 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, Dr. Reddy's Laboratories, Ltd. is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Dr. Reddy's Laboratories, Inc., and therefore the activities of Dr. Reddy's Laboratories, Inc. in this jurisdiction are attributed to Dr. Reddy's Laboratories, Ltd.

20. In addition, this Court has personal jurisdiction over Dr. Reddy's because Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. 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 district by asserting claims and/or counterclaims in this district. *See, e.g.*, *Genzyme Corp. et al. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd*, No. 19-2045-CFC (D. Del. Nov. 20, 2019); *Boehringer Ingelheim Pharmaceuticals Inc. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, No. 19-1495-CFC (D. Del. Sep. 4, 2019); *Genzyme Corp. et al. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, No. 18-1839-CFC (D. Del. Jan. 16, 2019); *Pfizer Inc. et al. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, No. 19-750-CFC (D. Del. Jul. 15, 2019), D.I. 12; *Onyx Therapeutics, Inc. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, No. 17-1811-LPS (D. Del. Jan. 23, 2018); *Viiv Healthcare Co., Shionogi & Co., Ltd., and Viiv Healthcare UK (No. 3) Ltd. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, No. 17-1678-MSG (D. Del. Feb. 12, 2018).

21. On information and belief, if Dr. Reddy's ANDAs are approved, Dr. Reddy's will manufacture, market, sell, and/or distribute Dr. Reddy's ANDA Products within the United

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