IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., *Plaintiff,* v. SUN PHARMA GLOBAL FZE, and SUN PHARMACEUTICAL INDUSTRIES 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. 202423, 205078, and 207823 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), JANUMET XR® (metformin hydrochloride; sitagliptin phosphate extended release tablets), and JANUMET® (metformin hydrochloride; sitagliptin phosphate) prior to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent") and U.S. Patent No. 8,414,921 ("the '921 patent").

2. Sun Pharma Global FZE notified Merck by letter dated December 31, 2010 ("Sun's '423 Notice Letter") that it had submitted to the FDA ANDA No. 202423 ("Sun's '423 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 ("Sun's '423 ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, Sun's '423 ANDA Product is a generic version of Merck's JANUVIA®.

4. Sun Pharma Global FZE notified Merck by letters dated June 24, 2013, and August 30, 2013 ("Sun's '078 Notice Letters") that it had submitted to the FDA ANDA No. 205078 ("Sun's '078 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 ("Sun's '078 ANDA Product") prior to the expiration of the '708 patent.

5. On information and belief, Sun's '078 ANDA Product is a generic version of Merck's JANUMET XR®.

6. Sun Pharma Global FZE notified Merck by letter dated February 10, 2015 ("Sun's '823 Notice Letter") that it had submitted to the FDA ANDA No. 207823 ("Sun's '823 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 extended release oral tablets ("Sun's '823 ANDA Product") prior to the expiration of the '708 patent and the '921 patent.

7. On information and belief, Sun's '823 ANDA Product is a generic version of Merck's JANUMET®.

8. Sun's '423 Notice Letter, Sun's '078 Notice Letters, and Sun's '823 Notice Letter are collectively referred to herein as "Sun's Notice Letters." Sun's '423 ANDA, Sun's '078 ANDA, and Sun's '823 ANDA are collectively referred to herein as "Sun's ANDAs." Sun's

'423 ANDA Product, Sun's '078 ANDA Product, and Sun's '823 ANDA Product are collectively referred to herein as "Sun's ANDA Products."

PARTIES

9. Plaintiff Merck is a corporation organized and existing under the laws of the State of New Jersey, having its corporate offices and principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

10. Merck is the holder of New Drug Application ("NDA") No. 21995 for JANUVIA® (sitagliptin phosphate), which has been approved by the FDA.

11. Merck is the holder of NDA No. 202270 for JANUMET XR® (metformin hydrochloride; sitagliptin phosphate extended release tablets), which has been approved by the FDA.

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

13. On information and belief, defendant Sun Pharma Global FZE ("Sun FZE") is a corporation organized and existing under the laws of the United Arab Emirates, having its corporate offices and principal places of business at Office #43, Block Y, SAIF Zone, P.O. Box. No. 122304, Sharjah, United Arab Emirates, and DMCC Branch, 704 Jumeirah Business Center 1, Cluster G, JLT, P.O. Box No. 643561, Dubai, United Arab Emirates. On information and belief, Sun FZE is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market, including through various operating affiliates and subsidiaries.

14. On information and belief, defendant Sun Pharmaceutical Industries Ltd. ("Sun Ltd.") is a corporation organized and existing under the laws of India with its principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai,

Maharashtra 400063, India. On information and belief, Sun Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products through various operating affiliates and subsidiaries, including Sun FZE.

15. On information and belief, Sun FZE is a wholly owned subsidiary of Sun Ltd. Sun FZE and Sun Ltd. are collectively referred to herein as "Sun."

16. On information and belief, Sun FZE and Sun Ltd. acted in concert to prepare and submit Sun's ANDAs to the FDA.

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

18. On information and belief, following any FDA approval of Sun's ANDAs, Sun FZE and Sun Ltd. will act in concert to distribute and sell Sun's ANDA Products throughout the United States, including within Delaware.

JURISDICTION

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

20. This Court has personal jurisdiction over Sun.

21. Sun FZE is subject to personal jurisdiction in Delaware because, among other things Sun 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, Sun

FZE 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.

22. Sun Ltd. is subject to personal jurisdiction in Delaware because, among other things, Sun Ltd., itself and through its wholly owned subsidiary Sun FZE, has purposely 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, Sun Ltd., itself and through its wholly owned subsidiary Sun FZE, 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. In addition, Sun Ltd. is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Sun FZE and therefore the activities of Sun FZE in this jurisdiction are attributed to Sun Ltd.

23. In addition, this Court has personal jurisdiction over Sun because Sun FZE and Sun 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 Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Sun Pharma Global FZE v. Teva Pharm. Indus. Ltd.*, No. 18- 1552-RGA, D.I. 1 (D. Del. Oct. 9, 2018) (Sun FZE); *Pharmacylics LLC v. Sun Pharma Global FZE*, No. 18-1543-CFC, D.I. 9 (D. Del. Oct. 31, 2018) (Sun FZE and Sun Ltd.); *Bristol-Myers Squibb Co. v. Sun Pharma Indus., Inc.*, No. 17- 409-LPS, D.I. 10 (D. Del. May 12, 2017) (Sun FZE); *Amgen v.*

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