**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| MERCK SHARP & DOHME CORP.,<br><br>*Plaintiff,*<br><br>v.<br><br>TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD.,<br><br>*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. 202487, 202488, 204524, and 204591 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® (metformin hydrochloride; sitagliptin phosphate), JUVISYNC® (simvastatin; sitagliptin phosphate), and JANUMET XR® (metformin hydrochloride; sitagliptin phosphate extended release tablets) prior to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent").

2. Teva Pharmaceuticals USA, Inc. notified Merck by letter dated December 14, 2010 ("Teva's '487 Notice Letter") that it had submitted to the FDA ANDA No. 202487

("Teva's '487 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 ("Teva's '487 ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, Teva's '487 ANDA Product is a generic version of Merck's JANUVIA® product.

4. Teva Pharmaceuticals USA, Inc. notified Merck by letter dated December 14, 2010 ("Teva's '488 Notice Letter") that it had submitted to the FDA ANDA No. 202488 ("Teva's '488 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 ("Teva's '488 ANDA Product") prior to the expiration of the '708 patent.

5. On information and belief, Teva's '488 ANDA Product is a generic version of Merck's JANUMET® product.

6. Teva Pharmaceuticals USA, Inc. notified Merck by letter dated December 3, 2012 ("Teva's '524 Notice Letter"), that it had submitted to the FDA ANDA No. 204524 ("Teva's '524 ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic simvastatin and sitagliptin phosphate oral tablets ("Teva's '524 ANDA Product") prior to the expiration of the '708 patent.

7. On information and belief, Teva's '524 ANDA Product is a generic version of Merck's JUVISYNC® product.

8. Teva Pharmaceuticals USA, Inc. notified Merck by letter dated March 1, 2013 ("Teva's '591 Notice Letter") that it had submitted to the FDA ANDA No. 204591 ("Teva's '591 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 ("Teva's '591 ANDA Product") prior to the expiration of the '708 patent.

9. On information and belief, Teva's '591 ANDA Product is a generic version of Merck's JANUMET XR® product.

10. Teva's '487 Notice Letter, Teva's '488 Notice Letter, Teva's '524 Notice Letter, and Teva's '591 Notice Letter are collectively referred to herein as "Teva's Notice Letters." Teva's '487 ANDA, Teva's '488 ANDA, Teva's '524 ANDA, and Teva's '591 ANDA are collectively referred to herein as "Teva's ANDAs." Teva's '487 ANDA Product, Teva's '488 ANDA Product, Teva's '524 ANDA Product, and Teva's '591 ANDA Product are collectively referred to herein as "Teva's ANDA Products."

**PARTIES**

11. 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.

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

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

14. Merck is the holder of NDA No. 202343 for JUVISYNC® (simvastatin; sitagliptin phosphate), which has been approved by the FDA.

15. 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.

16. On information and belief, defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of State of Delaware, having places of business at 425 Privet Road, Horsham, Pennsylvania 19044, and 1090 Horsham Road, North Wales, Pennsylvania 19454. On information and belief, Teva USA is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market.

17. On information and belief, defendant Teva Pharmaceutical Industries Ltd. ("Teva Israel") is a corporation organized and existing under the laws of the Israel, having its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva, 49131, Israel. On information and belief, Teva Israel is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Teva USA.

18. On information and belief, Teva USA is a wholly owned subsidiary of Teva Israel. Teva USA and Teva Israel are collectively referred to herein as "Teva."

19. On information and belief, Teva USA and Teva Israel acted in concert to prepare and submit Teva's ANDAs to the FDA.

20. On information and belief Teva USA and Teva Israel know and intend that upon approval of Teva's ANDAs, Teva USA and Teva Israel will act in concert to manufacture, market, sell, and distribute Teva's ANDA Products throughout the United States, including in Delaware. On information and belief, Teva USA and Teva Israel are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Teva's ANDA Products, and enter into agreements that are nearer than arm's length. On

information and belief, Teva USA and Teva Israel participated, assisted, and cooperated in carrying out in the acts complained of herein.

21. On information and belief, following any FDA approval of Teva's ANDAs, Teva USA and Teva Israel will act in concert to distribute and sell Teva's ANDA Products throughout the United States, including within Delaware.

**JURISDICTION**

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

23. This Court has personal jurisdiction over Teva.

24. Teva USA 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. Teva USA 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, Teva USA 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

25. Teva Israel is subject to personal jurisdiction in Delaware because, among other things, Teva Israel, itself and through its wholly owned subsidiary Teva USA, 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, Teva Israel, itself and through its wholly owned subsidiary Teva USA, develops, manufactures, imports, markets, offers to sell,

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