IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

MERCK SHARP & DOHME CORP.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC., and MYLAN INC.,

Defendants.

C.A. No. 1:19 CV 101
Keeley

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. 202473 and 202478 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) 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. Mylan Pharmaceuticals Inc. notified Merck by letter dated December 28, 2010 ("Mylan's '473 Notice Letter") that it had submitted to the FDA ANDA No. 202473 ("Mylan's '473 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 ("Mylan's '473 ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, Mylan's '473 ANDA Product is a generic version of Merck's JANUVIA® product.

4. Mylan Pharmaceuticals Inc. notified Merck by letter dated December 28, 2010 ("Mylan's First '478 Notice Letter") that it had submitted to the FDA ANDA No. 202478 ("Mylan's '478 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 ("Mylan's '478 ANDA Product") prior to the expiration of the '708 patent.

5. Mylan Pharmaceuticals Inc. notified Merck by letter dated September 13, 2013 ("Mylan's Second '478 Notice Letter") that it had amended Mylan's '478 ANDA to additionally seek approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Mylan's '478 ANDA Product prior to the expiration of the '921 patent.

6. On information and belief, Mylan's '478 ANDA Product is a generic version of Merck's JANUMET® product

7. Mylan's '473 Notice Letter, Mylan's First '478 Notice Letter, and Mylan's Second '478 Notice Letter are collectively referred to herein as "Mylan's Notice Letters." Mylan's '473 ANDA and Mylan's '478 ANDA are collectively referred to herein as "Mylan's ANDAs." Mylan's '473 ANDA Product and Mylan's '478 ANDA Product are collectively referred to herein as "Mylan's ANDA Products."

PARTIES

8. 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.

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

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

11. On information and belief, defendant Mylan Pharmaceuticals Inc. ("MPI") is a corporation organized and existing under the laws of the State of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505. On information and belief, MPI is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market.

12. On information and belief, defendant Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having its principal place of business at 1000 Mylan Boulevard, Canonsburg, PA 15317. On information and belief, Mylan Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including MPI.

13. On information and belief, MPI is a wholly owned subsidiary of Mylan Inc. MPI and Mylan Inc. are collectively referred to herein as "Mylan."

14. On information and belief, MPI and Mylan Inc. acted in concert to prepare and submit Mylan's ANDAs to the FDA.

15. On information and belief, MPI and Mylan Inc. know and intend that upon approval of Mylan's ANDAs, MPI and Mylan Inc. will manufacture, market, sell, and distribute

Mylan's ANDA Products throughout the United States, including in West Virginia. On information and belief, MPI and Mylan Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Mylan's ANDA Products, and enter into agreements that are nearer than arm's length. On information and belief, MPI and Mylan Inc. participated, assisted, and cooperated in carrying out the acts complained of herein.

16. On information and belief, following any FDA approval of Mylan's ANDAs, MPI and Mylan will act in concert to distribute and sell Mylan's ANDA Products throughout the United States, including within West Virginia.

JURISDICTION

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

18. This Court has personal jurisdiction over Mylan.

19. MPI is subject to personal jurisdiction in West Virginia because, among other things, it has purposely availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being haled into court here. In addition, on information and belief, MPI develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of , and therefore transacts business within the State of West Virginia related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of West Virginia

20. Mylan Inc. is subject to personal jurisdiction in West Virginia because, among other things, Mylan Inc., itself and through its wholly owned subsidiary MPI, has purposefully availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being haled into court here. On information and belief, Mylan Inc., itself and through its wholly owned subsidiary MPI, develops, manufactures, imports, markets, offers

to sell, and/or sells generic drugs throughout the United States, including in the State of West Virginia, and therefore transacts business within the State of West Virginia, and/or has engaged in systematic and continuous business contacts within the State of West Virginia. In addition, Mylan Inc. is subject to personal jurisdiction in West Virginia because, on information and belief, it controls and dominates MPI, and therefore the activities of MPI in this jurisdiction are attributed to Mylan Inc.

21. On information and belief, if Mylan's ANDAs are approved, Mylan will manufacture, market, sell; and/or distribute Mylan's ANDA Products within the United States, including in West Virginia, consistent with Mylan's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Mylan regularly does business in West Virginia, 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 West Virginia. On information and belief, Mylan's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in West Virginia. On information and belief, Mylan's ANDA Products will be prescribed by physicians practicing in West Virginia, dispensed by pharmacies located within West Virginia, and used by patients in West Virginia. Each of these activities would have a substantial effect within West Virginia and would constitute infringement of Merck's patent in the event that Mylan's ANDA Products are approved before the patent expires. Each of these activities would have a substantial effect within West Virginia and would constitute infringement of Merck's patent rights in the even that Mylan's ANDA Product is approved before

22. On information and belief, Mylan derives substantial revenue from generic pharmaceutical products that are used and/or consumed within West Virginia, and that are

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