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

MERCK SHARP & DOHME CORP., *Plaintiffs*, v. MYLAN PHARMACEUTICALS INC., and MYLAN INC., *Defendants*.	C.A. No. 1:19-cv-00101(IMK)

DEFENDANT'S ANSWER TO PLAINTIFF'S COMPLAINT AND COUNTERCLAIMS

Defendant Mylan Pharmaceuticals Inc. ("MPI"), by and through its undersigned counsel, for its Answer, Affirmative Defenses and Counterclaims to the Complaint filed by Plaintiff Merck Sharp & Dohme Corp. ("Plaintiff"), state as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), MPI denies all allegations in Plaintiff's Complaint except those specifically admitted below.

COMPLAINT NO. 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").

ANSWER NO. 1

Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI admits that MPI filed Abbreviated New Drug Application ("ANDA") Nos. 202473 and 202478 with United States Food and Drug Administration ("FDA") seeking approval for its sitagliptin phosphate and metformin hydrochloride product and sitagliptin phosphate product. To the extent there are allegations not expressly admitted above, such allegations are denied.

COMPLAINT NO. 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.

ANSWER NO. 2

MPI admits that MPI sent Merck a notice letter dated December 28, 2010, pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA") stating that MPI had submitted ANDA No. 202473 to FDA. To the extent there are allegations not expressly admitted, such allegations are denied.

COMPLAINT NO. 3

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

ANSWER NO. 3

MPI admits that the product that is the subject of ANDA No. 202473 ("MPI's '473 ANDA Product") contains the active ingredient sitagliptin phosphate. MPI lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in paragraph 3 of the Complaint and, on that basis, denies them.

COMPLAINT NO. 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.

ANSWER NO. 4

MPI admits that MPI sent Merck a notice letter dated December 28, 2010, pursuant to the FDCA stating that MPI had submitted ANDA No. 202478 to FDA. To the extent there are allegations not expressly admitted, such allegations are denied.

COMPLAINT NO. 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.

ANSWER NO. 5

MPI admits that MPI sent Merck a notice letter dated September 13, 2013, pursuant to the FDCA stating that MPI had submitted ANDA No. 202478 to FDA. To the extent there are allegations not expressly admitted, such allegations are denied.

COMPLAINT NO. 6

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

ANSWER NO. 6

MPI admits that the product that is the subject of ANDA No. 202478 ("MPI's '478 ANDA Product") contains the active ingredients sitagliptin phosphate and metformin hydrochloride. MPI lacks sufficient knowledge and information to form a belief as to the truth

of the remaining allegations contained in paragraph 6 of the Complaint and, on that basis, denies them.

COMPLAINT NO. 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."

ANSWER NO. 7

Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

PARTIES

COMPLAINT NO. 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.

ANSWER NO. 8

MPI lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 8 of the Complaint and, on that basis, denies them.

COMPLAINT NO. 9

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

ANSWER NO. 9

MPI lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 9 of the Complaint and, on that basis, denies them.

COMPLAINT NO. 10

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

ANSWER NO. 10

MPI lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 10 of the Complaint and, on that basis, denies them.

COMPLAINT NO. 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.

ANSWER NO. 11

MPI admits that it is incorporated in West Virginia and has its principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505. MPI further admits that it is in the business of, among other things, manufacturing and selling generic medicines.

COMPLAINT NO. 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.

ANSWER NO. 12

MPI admits that Mylan Inc. is incorporated in Pennsylvania and has its principal place of business at 1000 Mylan Boulevard, Robert J. Coury Global Center, Canonsburg, PA 15317. MPI denies that Mylan Inc. is a proper party to this action. To the extent there are allegations not expressly admitted above, such allegations are denied.

COMPLAINT NO. 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."

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.