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

MERCK SHARP & DOHME LLC,

Plaintiff,

v. **CIVIL ACTION NO. 1:19CV101**
(Judge Keeley)

MYLAN PHARMACEUTICALS INC.,

Defendant.

****SEALED****

MEMORANDUM OPINION AND ORDER FOLLOWING BENCH TRIAL

I. INTRODUCTION

In this patent infringement action, the plaintiff, Merck Sharp & Dohme LLC ("Merck"), and the defendant, Mylan Pharmaceuticals Inc. ("Mylan"),[1] dispute whether Mylan has infringed claim 3 of Merck's U.S. Patent No. 7,326,708 ("the '708 patent") and claim 1 of Merck's U.S. Patent No. 8,414,921 ("the '921 patent"). They also dispute whether claims 1, 2, 3, and 19 of '708 patent are valid and enforceable.

The '708 patent and the '921 patent ("the patents-in-suit") are associated with Januvia® and Janumet®, Merck's New Drug Application ("NDA") products approved by the Food and Drug Administration ("FDA") and directed to the dihydrogenphosphate

[1] Although Merck originally included Mylan Inc. as a defendant in this action, the parties previously stipulated to its dismissal from this civil action (Dkt. No. 43).

salt of the compound known as sitagliptin for the treatment of type 2 diabetes. Mylan seeks to market two Abbreviated New Drug Applications products ("the ANDA products") that are the bioequivalent to Januvia® and Janumet® prior to the expiration of the patents-in-suit.

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (otherwise known as the "Hatch-Waxman Act"), seeks to encourage "pioneering research and development of new drugs," as well as the "production of low-cost, generic copies of those drugs." Eli Lilly & Co. v. Teva Pharm. USA, Inc., 557 F.3d 1346, 1348 (Fed. Cir. 2009). To that end, a manufacturer may obtain FDA approval to market a generic drug by making a certification regarding patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") as covering the NDA drug, and certifying that those patents are "invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted" ("paragraph IV certification"). Id. (citing 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). Following an applicant's paragraph IV certification, a patentee may sue the applicant for patent infringement within 45 days, thus delaying FDA approval of the ANDA. Id. (citing 21 U.S.C. § 355(j)(5)(B)(iii)).

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In this case, where Merck has sued Mylan under the Hatch-Waxman Act for infringement of the patents-in-suit, the Court is tasked with deciding the following: (1) do Mylan's ANDA products infringe claim 3 of the '708 patent or claim 1 of the '921 patent; (2) are claims 1, 2, 3, and 19 of the '708 patent invalid under the judicially created obviousness-type double patenting doctrine; and (3) are claims 1, 2, 3, and 19 of the '708 patent invalid under 35 U.S.C. § 112 for lack of written description or enablement. Following a five-day bench trial, the parties submitted their memoranda of law, and the case is ripe for the Court's decision.

II. BACKGROUND

A. The Parties, Jurisdiction, and Venue

Merck Sharp & Dohme Corporation, a corporation organized under the laws of the State of New Jersey, with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889, commenced this action on May 2, 2019 (Dkt. No. 123 at 1). Due to a later transfer of ownership, however, the Court granted Merck's unopposed motion to substitute Merck Sharp & Dohme, LLC as the plaintiff in this civil action (Dkt. No. 190).[2] Merck Sharp & Dohme LLC is organized under the laws of the State of New Jersey,

[2] Effective May 1, 2022, Merck Sharp & Dohme Corporation merged into Merck Sharp & Dohme, LLC, with the latter emerging as the surviving entity (Dkt. No. 189).

with its principal place of business at 126 East Lincoln Avenue, P.O. Box 20000, Rahway, New Jersey 07065. Id. at 6. Mylan is a company organized under the laws of the State of West Virginia with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Id. The Court has subject matter and personal jurisdiction, and venue in this District is proper.

B. Factual and Procedural Background

The Court begins its analysis with a review of the chemical compound known as sitagliptin, how and why pharmaceutical salts are formed, Merck's synthesis and development of the dihydrogenphosphate salt of sitagliptin, the asserted claims of the patents-in-suit, other relevant patents and patent applications, and the parties' prior art references.

1. Sitagliptin

The patents-in-suit relate to the basic compound known as "sitagliptin," 4-oxo-4-[3-trifluorom-ethyl)-5,6-dihyrdo[1,2,4] triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine, belonging to a class of compounds that act as dipeptidyl peptidase-IV ("DPP-IV") inhibitors (Dkt. No. 123 at 2; JTX 001.0001; JTX 002.0002; Trial Trans. 55:5-11, 309:7-9 (Buckton)). DPP-IV is an enzyme produced by the human body to raise glucose, or blood sugar (Trial Trans. 55:5-11). Sitagliptin inhibits production of the DPP-IV enzyme to improve glycemic control in

adults with type 2 diabetes (Dkt. No. 123 at 2; Trial Trans. 268:9-13). Sitagliptin has one chiral center, or one carbon atom around which the molecule can orient itself (Trial Trans. 281:7-16 (Buckton); 535:21-23 (Shupe); 689:2-5 (Cockcroft)). Because it has one chiral center, sitagliptin has two isomers, or configurations, the (R)-configuration and the (S)-configuration. Id.

2. Salt Formation

The patents-in-suit relate to a particular salt form of sitagliptin synthesized by Merck. Pharmaceutical salts are formed by reacting an active compound with a counterpart acid or base. When a basic compound is combined with a counterpart acid, a salt forms when the acid donates a hydrogen ion to the base. Id. at 9:22-10:5. If the acid used in this reaction is polyprotic, or capable of donating multiple hydrogen ions, salts in different ratios or stoichiometries may form. Id. at 820:7-24 (Myerson).

But whether a salt will form is highly unpredictable (Trial Trans. 837:22-838:17, 840:4-841:3, 883:17-884:9 (Myerson); Dkt. No. 104-1 at 55, 58). Also unpredictable are what pharmaceutical properties any resulting salt might display (Trial Trans. 110:13-15 (Hansen); 344:18-22 (Buckton); 927:16-22 (Myerson); 740:3-6 (Wenslow)).

After selecting a chemical compound for development, pharmaceutical manufacturers may create one or more salt forms of

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