NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MITSUBISHI TANABE PHARMA CORPORATION, JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARAMCEUTICA NV, JANSSEN RESEARCH AND DEVELOPMENT, LLC, and CILAG GMBH INTERNATIONAL, Plaintiffs, v. SANDOZ, INC., et al., Defendants.	Civil Action No. 17-5319 (FLW) (DEA) **OPINION**

WOLFSON, Chief Judge:

This consolidated action was filed by Plaintiffs, Mitsubishi Tanabe Pharma Corp. ("MTPC"), Janssen Pharmaceuticals, Inc. ("JPI"), Janssen Pharmaceutica NV ("JNV"), Janssen Research and Development, LLC ("JRD"), and Cilag GmbH International ("Cilag")[1] (collectively, "Plaintiffs") against Defendant Zydus Pharmaceuticals (U.S.A.) Inc. ("Zydus" or "Defendant") for patent infringement in violation of section 271(e)(2) of Title 35 of the United States Code. In response, Zydus has filed a counterclaim seeking a declaratory judgment against Plaintiffs that the patents-in-suit are invalid.

Defendant is alleged to infringe the following claims of the corresponding United States Patents held by Plaintiffs: (1) claims 12 and 20 of United States Patent Number 7,943,788 ("the '788 Patent"); (2) claim 22 of United States Patent Number 8,222,219 ("the '219 Patent"); and (3)

[1] The Court refers to JPI, JNV, JRD, and Cilag, collectively, as "Janssen."

claim 26 of United States Patent Number 8,785,403 ("the '403 Patent") (collectively, the "asserted claims").[2] The patents-in-suit relate to the pharmaceutical composition and method of treatment encompassed by the drugs "Invokana" and "Invokamet" (together "the Invokana Products"), which are used to treat type 2 diabetes. Plaintiffs' infringement claims are based on Zydus's filing of Abbreviated New Drug Applications ("ANDA") with the Food and Drug Administration ("FDA") seeking approval to commercially manufacture and market generic versions of the Invokana Products prior to the expiration of the patents-in-suit.[3] Zydus has stipulated that its submission of the ANDAs and any commercial manufacture, use, offer for sale, sale, or importation of the ANDA products before expiration of the patents-in-suit would infringe the asserted claims. As its defense, Zydus contends that (1) the asserted claims of patents-in-suit are invalid as obvious; and (2) claims 12 and 20 of the '788 Patent are invalid under the doctrine of obviousness-type double patenting.

The Court conducted a six-day bench trial,[4] during which numerous experts testified as to the issues of obviousness and obviousness-type double patenting. In accordance with Federal Rule of Civil Procedure 52(a), the Court sets forth herein its findings of facts and conclusions of law. After consideration of all the evidence, the Court finds that the patents-in-suit are not invalid as obvious and that claims 12 and 20 of the '788 Patent are not invalid under the doctrine of

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[2] The Court refers to the '788, '219, and '403 Patents, collectively, as the "patents-in-suit."

[3] Zydus has agreed not to launch the products within the scope of the ANDAs at issue, *i.e.*, the generic equivalents of Invokana and Invokamet, until four months after the parties submitted their Proposed Findings of Fact and Conclusions of Law. (ECF No. 206.) The parties submitted their Proposed Findings of Fact and Conclusions of Law on November 23, 2020. (*See* Zydus Proposed Findings of Fact and Conclusions of Law ("DFOF"), ECF No. 221; Plaintiffs' Proposed Findings of Fact and Conclusions of Law ("PFOF"), ECF No. 220.)

[4] In light of the ongoing COVID-19 pandemic, the bench trial was held remotely via Zoom.

obviousness-type double patenting. Based on Zydus's concession, the Court further concludes that the filed ANDAs infringe upon the patents-in-suit.

I. OVERVIEW

A. Parties

MTPC is the lawful assignee of the patents-in-suit. (Pretrial Order, Stipulation of Facts ("SOF") ¶ 1, ECF No. 144.) JPI, JRD, and Cilag are the exclusive licensees of the patents-in-suit, and JNV is an exclusive sublicensee of the patents-in-suit. (*Id.* ¶ 8.) JPI holds approved New Drug Application ("NDA") No. 204042 for canagliflozin tablets, which are prescribed and sold as Invokana, and approved NDA No. 204353 for canagliflozin and metformin hydrochloride tablets, which are prescribed and sold as Invokamet. (*Id.* ¶ 9.) Canagliflozin is in a class of compounds known as SGLT-2 inhibitors which are used in the treatment of type 2 diabetes.

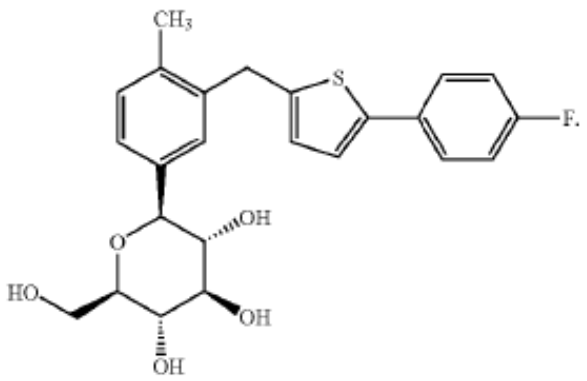
Zydus is a manufacturer and distributor of generic drugs. Zydus filed ANDA Nos. 210541 and 210542 with the FDA, seeking approval to commercially manufacture and market generic versions of the Invokana Products prior to the expiration of the patents-in-suit. (*Id.* ¶ 14.)

B. The Patents-in-Suit

1. The '788 Patent

The '788 Patent was issued by the United States Patent and Trademark Office ("USPTO") on May 17, 2011, and is entitled "Glucopyranoside Compound." (*Id.* ¶ 22; DTX-001.) The '788 Patent lists Sumihiro Nomura, Eiji Kawanishi, and Kiichiro Ueta as the named inventors. (SOF ¶ 23.) The '788 Patent was issued in connection with U.S. Patent Application No. 11/045,446 (the "'446 application"), which was filed on January 31, 2005, and was a continuation of International Application No. PCT/JP2004/011312, which was filed on July 30, 2004. (*Id.* ¶¶ 24–25.) Asserted claims 12 and 20 of the '788 Patent are directed to the compound now known as canagliflozin.

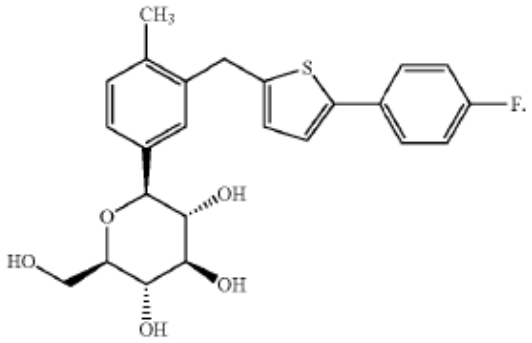
(*Id.* ¶¶ 26–27.) Specifically, claim 12 recites "1-(β-D-glucopyranosyl)-4-methyl-3-[5-(4-fluoro-phenyl)-2-thienylmethyl]benzene," which is the chemical name for canagliflozin. (*Id.* ¶ 26.) Claim 20 of the '788 Patent recites "[a] compound having the following structure," and depicts the chemical structure of canagliflozin:



(DTX-001, at 224:40-55.)

2. The '219 Patent

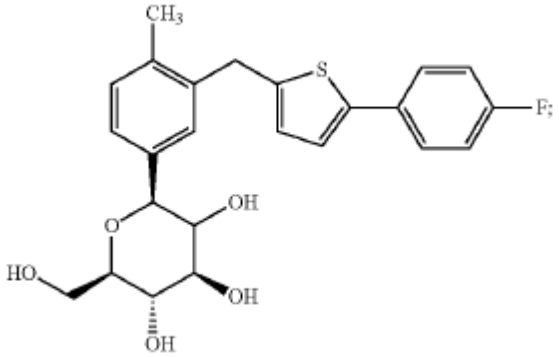
The '219 Patent was issued by the USPTO on July 17, 2012, and is titled "Glucopyranoside Compound." (SOF ¶ 28; DTX-002.) Like the '788 Patent, the listed inventors of the '219 Patent are Drs. Nomura, Kawanishi, and Ueta. (*Id.* ¶ 29.) The '219 Patent was issued in connection with U.S. Patent Application No. 13/174,814 ("the '814 application"), which was filed on July 1, 2011. (*Id.* ¶ 30.) The '814 application was filed as a division of U.S. Patent Application No. 13/005,757 ("the '757 application"), which was filed on January 13, 2011. (*Id.* ¶ 31.) The '757 application was filed as a division of the '446 application, which was issued as the '788 Patent. (*Id.*) Asserted claim 22 of the '219 Patent is directed to a method of treating or delaying the progression or onset of type 2 diabetes with the compound of the following structure, which is now known as canagliflozin:



(SOF ¶ 32; DTX-002, at 220:43-46.)

3. The '403 Patent

The '403 patent is titled "Glucopyranoside Compound" and was issued by the USPTO on July 22, 2014. (SF ¶ 33; DTX-003.) The '403 Patent lists Drs. Nomura, Kawanishi, and Ueta as the inventors. (SF ¶ 34.) The '403 Patent was issued in connection with U.S. Patent Application No. 13/494,602 (the "'602 application"), which was filed on June 12, 2012. (*Id.* ¶ 35.) The '602 application was a continuation of the '814 application. (*Id.* ¶ 36.) Asserted claim 26 of the '403 Patent is directed to a pharmaceutical composition comprising a biguanide compound and the compound of the following structure, which is now known as canagliflozin:



(SOF ¶ 37; DTX-003, at 221:25–26.)

C. The Invokana Products

Invokana, with canagliflozin as its active ingredient, was approved for use by the FDA in

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