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,

Civil Action No. 17-5319 (FLW) (DEA)

ORDER

Plaintiffs.

v.

SANDOZ, INC., et al.,

Defendants.

THIS MATTER comes before the Court upon the filing of a Complaint by Charles M. Lizza, Esq., counsel for Plaintiffs Mitsubishi Tanabe Pharma Corp, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, Janssen Research and Development, LLC, and Cilag GmbH International (collectively, "Plaintiffs"), against Defendant Zydus Pharmaceutical (U.S.A.) Inc. ("Defendant") for patent infringement in violation of 35 U.S.C. § 271(e)(2); it appearing that Plaintiffs allege that Defendant has infringed the following claims of 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) claim 26 of United States Patent Number 8,785,403 ("the '403 patent") (collectively, "the patents-in-suit"); it appearing that Defendant, through its counsel Sean R. Kelly, Esq., stipulates to infringement of the patents-in-suit, but, in its defense, contends that (1) the asserted claims of the patents-in-suit are invalid as obvious, and (2) the asserted claims of the '788 patent are invalid under the doctrine of obviousness-type double patenting; it appearing that the Court held a six-day bench trial on the issues of obviousness and obviousness-type double patenting; the Court having stated its findings of fact and conclusions of law, pursuant to Federal Rule of Civil Procedure 52(a), in the Opinion



IT IS on this 22nd day of March, 2021,

ORDERED that Judgment on Defendant's affirmative defense to infringement, asserting the invalidity of claims 12 and 20 of the '788 Patent, claim 22 of the '219 Patent, and claim 26 of the '403 Patent based on obviousness, is hereby entered in Plaintiffs' favor; and it is further

ORDERED that Judgment on Defendant's affirmative defense to infringement, asserting the invalidity of claims 12 and 20 of the '788 Patent based on obviousness-type double patenting, is hereby entered in Plaintiffs' favor; and it is further

ORDERED that Defendant's filing of ANDA Nos. 210541 and 210542 constitutes an act of infringement of claims 12 and 20 of the '788 Patent, claim 22 of the '219 Patent, and claim 26 of the '403 Patent, and Judgment on Plaintiffs' claims of infringement, set forth in the Complaint in Civil Action No. 17-5319, is hereby entered in Plaintiffs' favor, and it is further

ORDERED that the effective date of any approval of the drug that is the subject of ANDA Nos. 210541 and 210542 may not be earlier than the date of the expiration of the patents-in-suit; and it is further

ORDERED that the parties shall submit a joint, proposed Final Judgment within 10 days of the date of this order; and it is further

ORDERED that an unredacted version of this Court's Opinion shall be filed under temporary seal and that, in accordance with Local Civil Rule 5.3, the parties shall submit a joint submission indicating the portions of this Court's Opinion that they seek to have redacted, as well as a statement of reasons as to why each redaction is necessary, within 30 days of the date of this Order.

/s/ Freda L. Wolfson Freda L. Wolfson U.S. Chief District Judge

