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April 22, 2020

VIA ECF

The Honorable Freda L. Wolfson, U.S.D.J.
Chief Judge, United States District Court
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, NJ 08608

Re: *Mitsubishi Tanabe Pharma Corp., et al. v. Sandoz Inc., et al.*
Civil Action No. 17-5319 (consolidated) (FLW)(DEA)

Dear Chief Judge Wolfson:

This firm, together with Paul Hastings LLP and Quinn Emanuel Urquhart & Sullivan, LLP, represents plaintiffs Mitsubishi Tanabe Pharma Corporation, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, Janssen Research and Development, LLC, and Cilag GmbH International (collectively, "Plaintiffs") in the above-captioned consolidated matter.

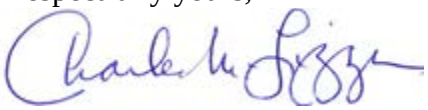
Following on the parties' discussion during the March 31, 2020 final pretrial conference regarding the potential impact of the COVID-19 pandemic on the commencement of trial, defendant Zydus Pharmaceuticals (USA) Inc. ("Zydus") has agreed to an extension of the regulatory stay for 120-days from the conclusion of the trial. Further, the parties jointly request that Your Honor set the commencement of a six-day trial in this matter for some time in July 2020, or as soon as practicable thereafter in light of the COVID-19 pandemic, subject to the Court's availability and approval.[1]

Enclosed is a Stipulation between Plaintiffs and Zydus memorializing the agreement to extend the stay and clarifying certain rights of Plaintiffs and Zydus in the context of this agreement. (Plaintiffs and Zydus had been working on this stipulation since the final pretrial conference.) If this Stipulation meets with Your Honor's approval, we have also enclosed a proposed form of Order that would formally extend the regulatory stay in accordance with the Stipulation. If this proposed Order meets with the Court's approval, we respectfully request that Your Honor sign and have it entered on the docket. If Your Honor has any questions regarding the Stipulation or the Order, we can be available for a telephone conference at the Court's convenience.

Thank you for Your Honor's kind attention to this matter.

[1] We also received word from Your Honor's Courtroom Deputy today that the trial will not commence in May, and we are mindful of the Court's need to give priority to criminal cases.

Respectfully yours,



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Enclosures

cc: The Honorable Douglas E. Arpert, U.S.M.J.
All Counsel (via e-mail)

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MITSUBISHI TANABE PHARMA CORPORATION, JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA NV, JANSSEN RESEARCH AND DEVELOPMENT, LLC, and CILAG GMBH INTERNATIONAL, Plaintiffs, v. SANDOZ INC., *et al.*, Defendants.	Civil Action No. 17-5319 (FLW)(DEA) Civil Action No. 17-6375 (FLW)(DEA) Civil Action No. 17-12082 (FLW)(DEA) Civil Action No. 18-6112 (FLW)(DEA) (consolidated) ***Document Filed Electronically***

STIPULATION TO EXTEND REGULATORY STAY

WHEREAS, Plaintiffs Mitsubishi Tanabe Pharma Corp., Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, Janssen Research and Development, LLC, and Cilag GmbH International (collectively, "Plaintiffs") have asserted that Defendant Zydus Pharmaceuticals (USA) Inc. ("Zydus"), by submitting Abbreviated New Drug Application ("ANDA") Nos. 210541 and 210542 seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of canagliflozin tablets (100 mg and 300 mg) ("Zydus's ANDA No. 210541 Products") and generic versions of canagliflozin and metformin

hydrochloride tablets (50 mg/500 mg, 50 mg/1 g, 150 mg/500 mg, and 150 mg/1 g) ("Zydus's ANDA No. 210542 Products") (collectively, "Zydus's ANDA Products"), infringes U.S. Patent No. 7,943,788 ("the '788 patent"), U.S. Patent No. 8,222,219 ("the '219 patent"), and U.S. Patent No. 8,785,403 ("the '403 patent");

WHEREAS, a trial was scheduled to commence in the above-captioned action on May 18, 2020, which Zydus and Plaintiffs anticipated would last six trial days;

WHEREAS, Zydus and Plaintiffs participated in a final pretrial conference with Judge Arpert on March 31, 2020, during which the impact of the COVID-19 pandemic on the commencement of trial was discussed;

WHEREAS, Zydus proposed (and Plaintiffs did not object to, subject to Zydus's agreement to this stipulation) an adjournment of the commencement of trial for as short a time as reasonable and necessary given the COVID-19 pandemic, with a target date for the re-scheduled commencement of trial in July 2020 or the earliest date thereafter, subject to the Court's approval and availability;

WHEREAS, the statutory stay of the Food and Drug Administration's ("FDA") approval of Zydus's ANDA Nos. 210541 and 210542 will expire on September 29, 2020 (the "Statutory Stay");

WHEREAS, as originally scheduled, there were approximately one-hundred and twenty (120) days between the anticipated conclusion of the trial and the expiration of the Statutory Stay;

NOW THEREFORE, Zydus and Plaintiffs, by their undersigned counsel, STIPULATE as follows:

1. Plaintiffs and Zydus agree that this Court should enter an order extending the statutory stay of the FDA approval of Zydus's ANDA Nos. 210541 and 210542 until

one-hundred and twenty (120) days from the conclusion of the re-scheduled trial in the above-captioned action (the "120-Day Extension"). Zydus agrees to notify the FDA of this Order within five business days after being entered by the Court, and the conclusion date of the re-scheduled trial within five business days after said conclusion date.

2. Zydus agrees to refrain from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Products within the United States during the 120-Day Extension, and Plaintiffs and Zydus further agree that nothing herein shall prevent or preclude Zydus from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Products within the United States after the expiration of the 120-Day Extension. For the avoidance of the doubt, this Stipulation does not apply to the commercial manufacture, use, offer for sale, and/or sale of Zydus's ANDA Products outside of the United States.

3. Plaintiffs and Zydus further agree that nothing herein shall prevent or preclude Plaintiffs from filing a motion for an injunction (or seeking any other relief from the Court, as appropriate) to prevent Zydus from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Products within the United States after the expiration of the 120-Day Extension.

IT IS HEREBY STIPULATED:

Dated: April 22, 2020

s/ Charles M. Lizza
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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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

This matter having come before the Court by a stipulation between Plaintiffs Mitsubishi Tanabe Pharma Corp., Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, Janssen Research and Development, LLC, and Cilag GmbH International (collectively, "Plaintiffs") and Defendant Zydus Pharmaceuticals (USA) Inc. ("Zydus"); and the Court having considered the stipulation and the provisions set forth therein; and for good cause shown,

IT IS ON THIS _____ day of _____, 2020,

ORDERED that the statutory stay of U.S. Food and Drug Administration ("FDA") approval of Zydus's ANDA Nos. 210541 and 210542 is hereby extended from September 29, 2020, until one-hundred and twenty (120) days from the conclusion date of the trial in the above-captioned action. Zydus shall notify the FDA of this Order within five business days after its entry by the Court. Zydus shall further notify the FDA of the conclusion of the trial within five business days after the conclusion date.

_____

Hon. Freda L. Wolfson, U.S.D.J.