UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. and NEW YORK UNIVERSITY Plaintiffs, vs. CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC. Defendants.	Civil Action No. 1:15-cv-10698

STIPULATION

WHEREAS, Defendant Celltrion, Inc. submitted an abbreviated Biologic License Application ("aBLA") No. 125544 seeking permission to market a proposed biosimilar version of Plaintiff Janssen Biotech, Inc.'s ("Janssen") biological medicine Remicade (infliximab);

WHEREAS, Janssen has sued Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc. (collectively, "Defendants") for infringement of several patents based on the submission of aBLA No. 125544 and to enforce the patent dispute resolution provisions of the Biologic Price Competition and Innovation Act, 42 U.S.C. § 262(*l*);

WHEREAS, Defendants have answered the complaint and have asserted defenses;

WHEREAS, on April 8, 2015, Janssen filed a motion for partial summary judgment and for a preliminary and permanent injunction ("PI Motion") based on the contention that 42 U.S.C. § 262(*l*)(8)(A) prohibits Defendants from commercially marketing their biosimilar product in the United States for 180 days after it is licensed;

WHEREAS, Defendants opposed Janssen's PI Motion;

WHEREAS, on February 10, 2016, the Court denied Janssen's PI Motion without prejudice, in light of the parties' agreement that the pending appeal in *Amgen Inc. et al v. Apotex, Inc. et al*, Docket No. 16-1308 (Fed. Cir.) ("*Amgen v. Apotex*"), was likely to affect the legal disputes at issue in the PI Motion;

WHEREAS, on March 22, 2016, the parties entered into a stipulation whereby Defendants agreed not to sell their biosimilar product in the United States for use by doctors or patients before June 30, 2016;

WHEREAS, on April 5, 2016, Defendants' biosimilar product was licensed for sale in the United States by the U.S. Food & Drug Administration; and

WHEREAS, Janssen intends to file a Renewed 180-day PI Motion after the Federal Circuit's decision in *Amgen v. Apotex*.

NOW THEREFORE, IT IS HEREBY STIPULATED AND AGREED that:

1. Defendants agree not to sell in the United States their proposed biosimilar version of Janssen's Remicade for use by doctors or patients before September 15, 2016 absent:

   a. Agreement by the parties that the Federal Circuit's decision in *Amgen v. Apotex* moots Janssen's Renewed 180-day PI Motion;

   b. A Court order denying Janssen's Renewed 180-day PI Motion; or

   c. Defendants' obtaining a Court order authorizing an earlier launch date.

Dated: June 6, 2016

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was filed through the electronic filing system and served electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/ Heather B. Repicky

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