UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

HOSPIRA, INC.,

Plaintiff,

-against-

JANSSEN BIOTECH, INC.; NEW YORK UNIVERSITY; NYU LANGONE MEDICAL CENTER; and THE KENNEDY TRUST FOR RHEUMATOLOGY RESEARCH,

Defendants.

14 Civ. 7049 (PAC)

OPINION & ORDER

HONORABLE PAUL A. CROTTY, United States District Judge:

The pursuit of FDA approval for a biosimilar version of the rheumatoid arthritis treatment Remicade has triggered a lot of litigation, but none of it is ripe for federal court jurisdiction. Defendants Janssen and NYU move to dismiss the complaint; for the reasons stated below, and in the Court's Order in the related case, *Celltrion Healthcare Co. v. Kennedy Trust for Rheumatology Research*, 14 Civ. 2256, the motion to dismiss is granted and the complaint is dismissed.

BACKGROUND

Plaintiff Hospira, "the world's leading provider of injectable drugs and infusion technologies," is preparing to offer for sale a biosimilar version of infliximab, currently sold by Janssen as Remicade. Complaint ("Compl."), ¶ 9. In 2009, Hospira entered into an agreement with Celltrion to co-exclusively market infliximab under the name Inflectra. *Id.* ¶ 20. On

August 8, 2014, Celltrion filed its abbreviated biologic license application ("aBLA") on August 8, 2014.[1] *Id.* ¶ 29. No other biosimilar has ever been approved by the FDA.

In order to enable sales of Inflectra as soon as it receives FDA approval, Hospira seeks a declaration that the following patents are invalid: the '471 patent, the '396 patent (collectively, the "Janssen patents")[2], the '442 patent, the '537 patent, and the '120 patent (collectively, the "Kennedy patents").

DISCUSSION

The motion to dismiss is granted for many of the same reasons as those discussed in the Court's dismissal order in *Celltrion*. Indeed, the instant case presents an even more compelling reason for dismissal than that presented in *Celltrion*. Hospira seeks to benefit from the BPCIA where it can, and ignore those features of the BPCIA that hinder its ambitions. For the following reasons, Hospira cannot have it both ways.

For example, Hospira asserts that it has engaged in meaningful preparation to sell Inflectra sufficient to show the existence of a justiciable case or controversy. *See* Compl. ¶¶ 20-31; Hospira's Memorandum of Law in Opposition to Defendants' Motion to Dismiss ("Pl. Mem."), at 18-21. In support of this assertion, Hospira treats Celltrion like its alter ego, and cites to Celltrion's preparations of Remsima. *Id.* Yet in response to Janssen's argument that this dispute should be resolved by means of the BPCIA's dispute resolution procedures, Hospira minimizes its coextensive relationship with Celltrion and declares that because it is not the applicant under the BPCIA, it need not engage in its procedures. This argument is a microcosm

[1] This fact was not taken into account in the Court's opinion in *Celltrion*, because Celltrion filed its complaint prior to this factual development, and subject matter jurisdiction is assessed at the time of the filing of the complaint.

[2] Because Celltrion did not name Janssen as a defendant in the *Celltrion* case, these patents are not involved in that litigation.

of the larger tension in Hospira's complaint: it seeks to utilize the BPCIA pathway for approval of its biosimilar drug, yet disavows the BPCIA's authority over patent disputes.

Despite Hospira's best attempts to twist the BPCIA to serve its interests without hindering its pursuit of litigation, this effort fails. As the Court found in *Celltrion*, even if the Court were to find that Hospira had engaged in meaningful preparation and that Janssen had sufficiently demonstrated an intent to pursue its patent rights against Hospira, which it has not, the existence of the BPCIA mechanisms for dispute resolution counsels against the exercise of jurisdiction over this complaint. The BPCIA purposefully ties the dispute resolution process to events throughout the biosimilar approval process, ensuring that full information exchange occurs at relevant and crucial periods during the approval process. As defendants argue, adjudicating this case would enable any biosimilar developer to partner with another distributor and thereby skirt the dispute resolution procedures Congress purposefully enacted for use in such situations. Indeed, Hospira's argument that it is not an applicant simply suggests that Hospira's claims are too attenuated from any crystallized dispute between the relevant parties, further demonstrating the lack of a justiciable case or controversy.

The Court notes that the parties have informed the Court that Celltrion has voluntarily dismissed its identical suit against Janssen in the District of Massachusetts and has begun engaging in the information exchange procedures of the BPCIA. *See* Def. Letter of Nov. 5, 2014 (Dkt. 58); Pl. Letter of Nov. 11, 2014 (Dkt. 59). Should this procedure lead to the resolution of Celltrion's claims against Janssen, it is unclear what claims would remain for Hospira to pursue against Janssen.

CONCLUSION

For the foregoing reasons, the motion to dismiss is granted. This order moots the pending motion to sever or transfer. In light of the Court's dismissal of Celltrion's claims against Kennedy, Hospira's claims against Kennedy are dismissed for the reasons stated above and in the *Celltrion* order. The Clerk of Court is directed to terminate the pending motions and close this case.

Dated: New York, New York
December 1, 2014

SO ORDERED

PAUL A. CROTTY
United States District Judge