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By ECF

The Honorable Mark L. Wolf
U.S. District Court, District of Massachusetts
1 Courthouse Way
Boston, MA 02210

Re: *Janssen Biotech Inc. et al. v. Celltrion, Inc. et al.*, 15-cv-10698 (MLW)

Dear Judge Wolf:

Plaintiffs Janssen Biotech, Inc. and New York University (collectively “Janssen”) respectfully request a conference with Your Honor at the Court’s earliest convenience. Although we understand that Defendants will join in this request for a conference at least in part, we are not authorized to speak on their behalf.

Since our last conference, Defendants’ biosimilar product was approved by FDA on April 5. Defendants have said they may launch as soon as June 30; Plaintiffs believe that Defendants are not lawfully permitted to launch under the Biologics Price Competition and Innovation Act (BPCIA) until after October 2. In either event, a launch is imminent, absent an injunction, and we believe there are matters that require Your Honor’s urgent attention.

First, Janssen requests that the Court hold oral argument on, and decide, Plaintiffs’ Motion to Stay proceedings on U.S. Patent No. 6,284,471 (the ‘471 patent) (Docket No.8) and Plaintiffs’ Motion to Modify Proposed Protective Order (*see* Docket Nos. 69, 73, 117, 135). The Court scheduled a hearing on the two motions for March 14 and 15, 2016 (Docket No. 103) but subsequently cancelled that hearing with a “[n]ew date to be set.” (Docket Entry of March 4, 2016). As discussed at the previous conference before Your Honor on February 9, 2016, these motions need to be resolved at the earliest possible time as their outcome directly affects the scope of pretrial proceedings, which are already well underway.

Second, Janssen has requested that the trial date on U.S. Patent No. 7,598,083 (‘083 patent) be moved up from February 2017 to September 2016 to allow trial to occur before October 2 and Defendants have objected to that request (Docket No. 140 & 141). Although we previously said that we would file a formal motion on this issue if Defendants did not agree, in light of Defendants’ written response Janssen now believes that the relevant issues are before the Court and that formal briefing is unnecessary. We therefore request that the Court hold an early

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conference to resolve this scheduling dispute, while a September trial date remains a realistic possibility.

Third, a conference is necessary to address Janssen's potential renewed motion for a preliminary injunction to prevent Defendants from launching their proposed biosimilar product within 180 days of its approval by FDA, i.e., after October 2, 2016. As was discussed at the February 9 conference before Your Honor, that motion may be resolved by an appeal currently pending before the Federal Circuit (*Amgen v. Apotex*, No. 16-1308) and as a result Janssen withdrew the motion without prejudice. However, Defendants have recently reiterated that they may launch their biosimilar product as early as June 30, 2016 – before the expiration of the 180-day period – in the absence of an order to contrary (Docket No. 141). If the *Amgen v. Apotex* appeal is not decided before then, or if the Federal Circuit's decision does not resolve the parties' dispute, Janssen will need to renew its preliminary injunction motion and have it decided by the Court before June 30, 2016. In order to avoid emergency proceedings, Janssen believes that a tentative schedule for proceedings on a potential renewed motion for a preliminary injunction should be set at the Court's earliest convenience.

We believe that a hearing on these issues could be concluded within 3 hours and, therefore, a two day hearing is not necessary. While all parties' counsel have some previously scheduled commitments in the weeks ahead, we will do our best to schedule a hearing as soon as possible consistent with Your Honor's schedule.

Respectfully submitted,

/s/ Gregory L. Diskant

Gregory L. Diskant
Counsel for Plaintiffs

cc: All counsel

CERTIFICATE OF SERVICE

I hereby certify that, on April 27, 2016, 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/ Alison C. Casey