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April 18, 2016

BY ECF

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

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

Dear Judge Wolf:

I write on behalf of defendants Celltrion and Hospira in response to the letter dated April 12, 2016, submitted on behalf of plaintiffs (together, "Janssen"). *See* ECF No. 140. In that letter, Janssen notified the Court that it has decided *not* to seek a preliminary injunction.

Janssen's letter goes on, however, to (1) inappropriately argue the merits of Janssen's claim of infringement on the '083 patent based on the doctrine of equivalents, and (2) request a substantially expedited case schedule based, in part, on inaccurate statements about defendants' commitments regarding its launch date.

First, the Court should not countenance Janssen's improper attempt to proffer expert "evidence" through a letter. Defendants will not respond in kind to Janssen's detailed arguments, other than to briefly state that an injunction would never be appropriate in this case for multiple reasons, including the fact that Janseen is not even asserting literal infringement. It is asserting infringement only through the doctrine of equivalents based on an unprecedented theory, where it admits that the accused cell culture media avoids literal infringement ***twelve different ways.*** We are not aware of any court finding infringement under the doctrine of equivalents where there was more than just one missing limitation—much less a dozen, as Janssen admits here.

If Janssen's theory were correct—where all of its claims' limitations could be ignored based on "months" of "sophisticated scientific experiments" allegedly proving them unimportant—nobody would have any idea what the '083 patent covered. The patent could cover an infinite variety of cell culture media turning on the outcome of "months" of experimentation. Such disregard for the requirement of definiteness and the public notice function of patent claims would defy the settled rule that "a potential competitor is entitled to fair notice of what will infringe a patent under the doctrine of equivalents, as well as literally." *Biogen, Inc. v. Berlex Labs., Inc.*, 113 F. Supp. 2d 77, 106 (D. Mass. 2000) (Wolf, J.).

Ultimately, if Janssen wishes to present admissible evidence regarding the '083 patent, it will have ample opportunity in due course under the current schedule—not the schedule Janssen now proposes. The only element of Janssen's letter that advances the case is its disavowal of any attempt to seek a preliminary injunction on the '083 patent.

Second, Janssen ask the Court to "hold an expedited trial on the merits of the '083 patent dispute so that plaintiffs' request for a permanent injunction can be adjudicated by October 2, 2016." But this request ignores several important facts: (1) Defendants have not agreed to delay their product launch until October; (2) the Court has not yet ruled on Janssen's motion to stay the case on the '471 patent; and (3) on the '083 patent, Janssen has stated it will not seek a preliminary injunction.

In its letter, Janssen states that defendants agreed not to launch their product before October 2, 2016. That is not true. The FDA has approved their product for marketing, and defendants have repeatedly and expressly reserved their right to market as early as June 30, 2016. *See* ECF No. 138. For its contrary assertion, Janseen mischaracterized a ***conditional*** 180-day notice of commercial marketing that applies only "***if***" required by the anticipated decision in *Amgen Inc. v. Apotex Inc.*, No. 16-1308 (Fed. Cir.). In fact, in that notice, defendants expressly "***reserved their right to void this notice and to launch before October 2, 2016***" (emphases added).

Given these facts, there is no reason to alter the schedule established in this case, which was designed to address all outstanding issues, on both patents–in-suit. In January 2016, knowing FDA approval was imminent, Janssen proposed the current case schedule with a trial set for February 2017. Defendants accepted that proposed trial date, worked with Janssen to prepare a stipulated case schedule, and have been preparing for trial in accordance with that agreed-upon schedule. *See* ECF No. 124. If Janssen wanted relief before defendants' launch, its path forward was clear: seek a preliminary injunction. But Janssen has elected against that option.

Radically modifying the case schedule to set a trial in September 2016 on only one patent—five months before the currently-scheduled trial—would be highly prejudicial to defendants. Putting aside the fact that lead counsel for defendants are not available for a trial in September, Janssen's newly-proposed schedule suggests that opening expert reports would be due in only 1.5 months—an impossible burden for defendants to meet through their own testing to rebut the flawed scientific experiments commissioned by Janssen, which apparently took four months to complete.

Defendants would be open to an earlier dispositive hearing on *both* the '471 patent *and* the '083 patent, but certainly not on the '083 patent alone. Janssen's request to substantially expedite trial for only the '083 patent, based on a purported goal of enjoining defendants' product launch on the basis of a cell culture media patent it admits is not literally infringed, lacks merit. If Janssen formally proceeds with a proper motion to radically change the schedule, in particular completely ignoring the '471 patent issues, defendants will oppose.

WINSTON & STRAWN LLP

Respectfully submitted,

/s/ Charles B. Klein

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Counsel for Defendants

cc: All counsel of record