EXHIBIT 8
March 28, 2018

Via Email (elizabeth.cutri@kirkland.com)

Elizabeth Cutri
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300 North LaSalle, Chicago, IL 60654


Dear Liz:

Defendants’ damages expert reports rely on information that has not been provided to Janssen, and on selective information on subject matters as to which Defendants expressly refused to provide discovery to Janssen. For Janssen’s experts to fairly respond to Dr. Frohlich’s and Dr. Nagaich’s opinions, Defendants must produce at least the following information:

1. All documentation underlying the laboratory testing described in Dr. Frohlich’s report (see, e.g., Frohlich Report ¶¶ 116-136, 152-159, 204-212), including lab notebooks, experimental protocols,1 and raw data, as well as information sufficient to show the costs of the testing, who performed it, and when and where it was performed.

2. Documents sufficient to describe the development of the media used in the production process for Pfizer’s IFIXI, including in particular documents sufficient to show the time and effort required to select, develop, and optimize the IFIXI media. (See Frohlich Report ¶ 224.) Defendants refused to provide this information in discovery in response to specific requests from Janssen, yet now purport to rely on Pfizer’s IXIFI media in support of their case. (See Janssen’s RFP Nos. 8-10 and Defendants’ Responses thereto; Letter from A. Cohen to E. Cutri dated October 6, 2017, at 3-4; Letter from E. Cutri to A. Cohen dated October 20, 2017, at 4.) That is unacceptable.

3. Documents sufficient to show the date of first infringement. In particular, in his “Alternative Media Regulatory Strategy,” Dr. Nagaich for the first time invokes the safe harbor of 35 U.S.C. § 271(e)(1) and states that Defendants’ use of drug product made from the accused media at certain times after October 6, 2009 was “solely for regulatory purposes.” (See Nagaich Report ¶ 183.) He also contends that Defendants

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1 Dr. Frohlich states that the protocol for his experiment is in Appendix D (Frohlich Report ¶ 120), but Appendix D only includes the ELISA testing protocol.
at times used media that was made before October 6, 2009 and therefore was not infringing. (_See id. ¶ 183 n.328_). In light of these contentions, we do not understand what date Defendants claim is the date of first infringement. It must be the first date after October 6, 2009 on which cell culture media was made that was eventually used for a non-regulatory purpose. Defendants’ reports do not identify that date and Defendants have refused our efforts to obtain discovery that would reveal that date. Please identify by batch number (and provide documents sufficient to show) the first batch of drug substance that was both made from cell culture media manufactured after October 6, 2009 and was turned into drug product that was used for any non-regulatory purpose (e.g., sold anywhere in the world). Please also identify by lot number (and provide documents sufficient to show) each lot of cell culture media (both CGM and CPM, however named) used to manufacture that batch of drug substance.

In my letter to Ryan Kane dated February 13, 2018, we specifically requested this documentation (and noted that Celltrion’s 30(b)(6) witness (Ms. Yang) was unprepared to give related testimony as to Topic 18). Following further correspondence and meet-and-confers, Defendants refused to continue the 30(b)(6) of Ms. Yang (Letter from L. Cutri dated February 22, 2018; Email from G. Sanford dated March 8, 2018); refused to answer written questions on the subject in lieu of continuing the deposition (Letter from G. Sanford dated March 2, 2018); and refused to provide business records that would permit this information to be ascertained (Email from G. Sanford dated March 8, 2018).

Given that Janssen’s reply expert reports on non-infringing alternatives are due on April 10, 2018, Janssen requests that this information be produced immediately, and in no event later than the close of business on Friday, March 30, 2018. We reserve the right to request additional information based on Defendants’ expert reports.

Best regards,

_/s/ Andrew D. Cohen_

Andrew D. Cohen