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Subject: RE: IPR2017-00854 Conference Call Request

Good Morning Your Honors. We represent Patent Owner Novartis and write in response to Mr. Parmelee's email from this morning. We can be available for a conference call Thursday, March 29, 2018. We oppose Petitioners' requests, about which we were not given a chance to confer before Petitioners' email to the Board. We lay out our position here in comparable length to Petitioners' submission.

First, Novartis's sur-reply and supporting declarations were authorized in Paper 45. They specifically respond to the new, 60-page pharmacology declaration from Dr. Leslie Benet that Petitioners submitted on reply (Ex. 1047), and Petitioners' arguments in their reply brief based on Dr. Benet's testimony (Paper 49).

The Board defined a person of skill in the Institution Decision to include an MS physician and a pharmacologist. (Paper 11 at 8-9.) Petitioners submitted no pharmacologist testimony with the Petition. Instead, they only submitted pharmacologist testimony on reply, depriving Novartis the opportunity to rebut this evidence at all. Novartis objected, moved to strike, or in the alternative for leave to respond to Dr. Benet's testimony. The Board received emails and held a teleconference on the issue on February 21, 2018. (Exs. 3004 (email requesting conference) and 2084 (transcript of proceedings).) Rather than strike Dr. Benet's declaration, the Board granted Novartis's request for a sur-reply with supporting evidence. (Paper 54.)

Novartis's sur-reply and supporting evidence are limited to responding to Dr. Benet's opinions. Dr. Benet cites many pharmacologic and other facts in support of his views as a pharmacologist. Novartis's expert testimony responds in comparable total length and level of detail, including the following:

- Dr. Jusko's declaration (Ex. 2095) responds to Dr. Benet's argument that the animal dose scaling methods would have pointed a person of skill toward the dose method claimed in the '405 Patent.

- Dr. Steinman's declaration (Ex. 2096) responds to Dr. Benet's claim construction arguments, and his argument that Webb, Kahan 2003, and Park 2005 point toward the dose claimed in the '405 Patent.

- Dr. Chun is a co-author of Webb and his declaration (Ex. 2098) responds to Dr. Benet's argument that Webb does not mean what it says.

- Dr. Lublin's declaration (Ex. 2097) responds to Dr. Benet's various arguments about the Phase III clinical trials.

Petitioners' effort to limit the Board's authorization to only "pharmacokinetic" arguments takes the Board's order out of context. In authorizing Novartis to file a sur-reply (rather than strike Dr. Benet's testimony entirely), the Board referred to a passage from the Institution Decision in which the Board explained its reasoning for including a pharmacologist in the definition of a person of skill. That passage identifies pharmacokinetic information in the prior art as relevant in this case.

The Board's Order does not require parsing Dr. Benet's opinion into "pharmacokinetic" and "non-pharmacokinetic" bits, requiring a response only to the first. Nor would such parsing be practical—all of Dr. Benet's opinions on pharmacokinetics are informed and, in his view, corroborated by the other parts of his declaration. As we explained at the conference on the sur-reply (Ex. 2094 at 23), the Board's rules and the Administrative Procedure Act required that Novartis be given a chance to respond to Dr. Benet's full evidence. Proceeding otherwise would be prejudicial to Novartis. Novartis properly limited our sur-reply and supporting declarations to those opinions.

Petitioners will of course have the opportunity to cross-examine Novartis's witnesses, who currently are scheduled for testimony per prior agreement on April 5, 6, 9, and 10. Petitioners can also file observations based on those cross-examinations. If Petitioners believe that any of Novartis's evidence is improper, Petitioners can move to exclude.

It was Petitioners' failure to properly support the Petition in the first place and the effort to back-fill on reply that prompted Novartis's sur-reply. The Board should not permit the Petitioners to file another round of papers and extend the proceedings even further.

Second, as for Petitioners' request for a sur-reply on the motion to amend, that argument has been waived.

In October 2017, Novartis raised with Petitioners the exact issue they raise in their email of today (see highlighted portions of attached email correspondence). When seeking to adjust the schedule to account for *In re Aqua*, Novartis invited Petitioners to discuss whether that decision's shifting of burdens would require a different order of briefs on the motion to amend, including by giving Petitioners the final brief.

Petitioners never took up that suggestion, and since then have agreed to an order of briefing in multiple adjusted schedules that does not provide for a sur-reply in connection with the motion to amend. (Papers 25, 46, 58) Novartis and the Board have relied on that schedule and altering it at this late stage of the proceeding would be prejudicial.

Moreover, notwithstanding the shifted burdens of *In re Aqua*, the Board has issued a guidance stating that the order of briefing on motions to amend should generally remain the same. ("Guidance on Motions to Amend in view of *Aqua Products*," at 2 (November 21, 2017).)

Respectfully submitted,

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