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Subject: IPR2017-00854 - Request for a Teleconference

To the Members of the Patent Trial and Appeal Board in IPR2017-00854:

We represent Patent Owner Novartis in this proceeding. We write to request an urgent conference with the Board to seek permission to move to strike Petitioners' Reply, or to file a sur-reply with supporting evidence. Our request stems from Petitioners' submission of a 60-page declaration from an entirely new expert witness with their Reply. This testimony is essential to Petitioners' *prima facie* case, and thus is improper reply evidence under the Board's rules and the Administrative Procedure Act. *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1081–82 (Fed. Cir. 2015).

The Board found in the Institution Decision that a person of skill in the art includes a pharmacologist. But Petitioners had relied solely on a declaration from a physician, Dr. Barbara Giesser, to support their Petition. The Board gave Petitioners the benefit of the doubt that Dr. Giesser knew enough pharmacology from her medical school training to institute the IPR. However, cross-examination testimony from Dr. Giesser and other evidence has shown otherwise — a point Petitioners do not dispute in their reply. Petitioners instead are attempting to back-fill Dr. Giesser's deficiency with a 60-page declaration from a new expert — a pharmacologist, Dr. Leslie Benet.

In waiting to submit this evidence on reply, Petitioners are depriving Novartis of the opportunity to submit responsive evidence, a result the Board's rules, *Belden v. Berk-Tek*, and related cases prohibit. Striking Petitioners' Reply papers would be a fair and efficient resolution. However, *Berk-Tek* suggests that other remedies may be considered, such as the submission of a sur-reply and supporting evidence. 805 F.3d at 1082. If the Board would prefer that route, then Novartis respectfully requests the opportunity to submit a single brief of 25 pages combining the reply supporting the motion to amend and a sur-reply. This accommodation would not alter the current schedule.

Novartis will be available at the Board's convenience if a conference call is scheduled.

Respectfully submitted,
Jane M. Love, Ph.D.
Lead Counsel for Patent Owner Novartis

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