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Cc: Fisher, Stanley; Genderson, Bruce; Berniker, Jessamyn; Mahaffy, Shaun; Pacchioli, Alissa M.; Sheh, Anthony; West, Christopher W.; Radeke, Heike Simone
Subject: IPR2020-00040

Follow Up Flag: Follow up
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Your Honors,

I am lead counsel for Petitioner Mylan Pharmaceuticals Inc. (“Mylan” or “Petitioner”) in IPR2020-00040. Mylan would like to request a conference call with the Panel respectfully seeking its permission to submit a 15 page Reply to the issues raised in Patent Owner’s Preliminary Response (“POPR”). Patent Owner Merck Sharp & Dohme Corp. (“Merck” or “Patent Owner”) objects to the breadth of Mylan’s request and is amenable to the Board’s granting Mylan a 5-page Reply and Merck a 5-page Surreply, both limited to the issue of whether WO ‘498 is available as prior art as asserted in Mylan’s obviousness Grounds 3 and 4. The parties have met and conferred regarding Petitioner’s request, but have been unable to reach an agreement.

Petitioner requests two weeks to file its Reply after the Board grants permission (should the Board be inclined to do so). Patent Owner requests two weeks thereafter to file its Surreply.

Patent Owner’s and Petitioner’s counsel are generally available any time next week for a conference with the Panel except Monday (March 2nd) and Friday (March 6th). Counsel for both parties are generally available any time the week of March 9th.

The parties’ respective positions are set forth below:

Petitioner (Mylan):

The issues in the 54 page POPR include alleged antedating evidence (with four separate declarations), 325(d) arguments, 314(a) arguments, and anticipation-related arguments. Petitioner’s requested 15 pages represent a near 75% decrease in page count when compared to the 54 page POPR.

In the cases cited in Merck’s POPR dealing with antedating evidence (*Associated British Foods plc v. Cornell Research Foundation, Inc.*; *FreeBit AS v. Bose Corp.*; *LG Elecs. Inc. v. Wi-LAN Inc* (POPR at 45)), those petitioners were granted 4-5 pages to respond to that issue only. Furthermore, when a patent owner raises only 325(d) and 314(a) arguments in a POPR, the PTAB has previously granted 10 pages to address those issues (even if the petitioner was able to devote some space in its original petition to 325(d) and 314(a) issues). IPR2019-00400, Order (Paper 12), Petition at 64-66 (Paper 3); IPR2019-00207, Decision at 1 (Paper 13), Petitioner’s Reply (Paper 10), Petition at 63-64 (Paper 3).

Patent Owner (Merck):

Mylan has no reply as a matter of right and “[a]ny such request must make a showing of good cause.” 37 C.F.R. § 42.108. Merck objects to Mylan’s request insofar as no good cause supports Mylan’s request for a reply concerning the Board’s discretion under 35 U.S.C. §§ 325(d) and 314(a)—or any other merits issues aside from the availability of WO ‘498 as prior art for obviousness. Many of the issues raised in Merck’s POPR were reasonably foreseeable, and the arguments that Mylan seeks to raise in reply should have been set forth in the Petition.

Relevant to § 325(d), and as Mylan has acknowledged, *see* Pet. at 2–3, WO '498 is discussed at the very beginning of the challenged patent, and Mylan is party to the parallel litigation underlying the POPR's discussion of the Board's § 314(a) discretion. *See Instrumentation Lab. Co. v. Hemosonics LLC*, IPR2018-00264, Paper 7 at 3–4 (P.T.A.B. Mar. 9, 2017). Moreover, Mylan has already addressed the Board's discretion under both statutory provisions, *see* Pet. at 66–69, without exhausting the Petition's 14,000 word limit. *See Mylan Pharms. Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2017-01526, Paper 8 at 4 (P.T.A.B. Oct. 6, 2017). In short, Mylan is not entitled to a reply to address arguments with respect to both the Board's discretion and the merits that could and should have been raised in the Petition itself.

Petitioner (Mylan) Position's on Patent Owner's Requested Sur-Reply:

Mylan appreciates that Merck is “amenable to the Board's granting Mylan a 5-page Reply,” however, Mylan objects to Patent Owner's 5 page Surreply. Put simply, Patent Owner has already addressed the alleged antedating evidence (including submitting no less than four declarations), *see* POPR. at 32–44, without exhausting the POPR's 14,000 word limit, and all of its alleged arguments should have been raised in its POPR. For that matter, no automatic right (or good cause) exists to a Surreply to a Reply that has not even been submitted, including whether 5 pages for such a Surreply without any corresponding page reduction is excessive.

Counsel for Patent Owner has been copied on this email.

Respectfully,

Jitendra Malik

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