

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR.REDDY'S LABORATORIES INC. and
DR. REDDY'S LABORATORIES LTD.,
Petitioners,

v.

MERCK SHARP & DOHME CORP.,
Patent Owner.

Case No. IPR2020-01060
U.S. Patent No. 7,326,708

PATENT OWNER'S PRELIMINARY RESPONSE

The Petition at issue is a “Me-Too” petition brought by Dr. Reddy’s Laboratories Inc. and Dr. Reddy’s Laboratories Ltd. (collectively, “Petitioners” or “DRL”) after the Board instituted trial on the petition of Mylan Pharmaceuticals Inc. (“Mylan”) in IPR2020-00040 (“Mylan Proceeding”). Paper 2. DRL filed a motion for joinder within one month of institution of the Mylan Proceeding, seeking joinder. Paper 3. Merck has filed an opposition to the joinder motion, Paper 7, and has participated in two calls with the Board to address various conditions pertinent to joinder.

Pursuant to 37 C.F.R. § 42.107(b), Patent Owner Merck Sharp & Dohme Corp. (“Merck”) hereby files a preliminary response in the above captioned case.

I. If Joinder Is Ordered, Merck Reserves All Rights To Present Evidence and Argument In Response to the DRL Petition in Its Patent Owner Response and Other Papers.

In the Mylan Proceeding, Merck filed a Preliminary Patent Owner Response opposing institution. IPR2020-00040, Paper 10. In that filing, Merck argued that the Board should exercise its discretion pursuant to §§ 325(d) and 314(a) to deny institution, and also argued that Mylan’s grounds were deficient because they did not address the stoichiometry required by all challenged claims. *Id.* The Board granted Mylan’s petition and instituted review in IPR2020-00040 notwithstanding Merck’s Preliminary Patent Owner Response.

For efficiency and to conserve judicial resources, Merck will not restate, in this Preliminary Patent Owner Response, all the arguments it made in the Preliminary Patent Owner Response in the Mylan Proceeding, which the Board has rejected, preliminarily or otherwise. Paper 21 at 64. However, Merck does not waive any such evidence or arguments and reserves all rights in the above captioned or any consolidated proceeding. Patent Owner specifically reserves all rights to submit a Patent Owner Response and/or a Motion to Amend pursuant to 37 C.F.R. §§ 42.120 and 42.121. Patent Owner reserves the right to address grounds presented in the Petition should the Board institute *inter partes* review, to dispute in the Patent Owner's Response any fact alleged to be material by Petitioners, and to provide material facts in support of Patent Owner's position. Patent Owner reserves the right to raise any and all arguments against those grounds and in favor of patentability during the trial.

II. If Joinder Is Not Ordered, the Board Should Exercise Its Discretion and Decline to Institute Trial Under § 314(a).

In Merck's Preliminary Patent Owner Response in the Mylan proceeding, Merck argued that discretionary denial of institution was warranted pursuant to § 314(a) because trial on Mylan's petition would be an inefficient use of the Board's limited resources given that the same patent, arguments, and evidence were the subject of parallel proceedings in the district courts. IPR2020-00040, Paper 10 at 23-30.

In its institution decision, the Board rejected these arguments in part because the Board expected “to issue a final written decision at least *five months before* the MDL trial date,” *Id.*, Paper 21 at 28 (emphasis in original). The Board also declined to exercise its discretion because of the stage of the MDL proceedings at the time, noting that “a claim construction hearing is not scheduled until three months after the institution due date.” *Id.*

Neither consideration remains true here. First, trial on the DRL petition could lag as much as six months behind the Mylan proceeding and a final written opinion may not be due until *after* trial in the MDL. *See* IPR2020-00040, EX 2006 (MDL Scheduling Order). Second, claim construction briefing has already concluded in the MDL, and a claim construction hearing was held on August 18, 2020. *See* EX2040 (MDL Docket). Fact discovery is proceeding this Fall and opening expert reports are due in January 2021.

These circumstances distinguish the posture of the DRL petition from Mylan’s and warrant discretionary denial under § 314(a). *See NHK Spring Co., Ltd. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 at 20 (P.T.A.B. Sept. 12, 2018) (precedential). Even DRL concedes that absent joinder, “a separate IPR proceeding involving DRL would needlessly duplicate efforts with multiple briefs, experts and hearings on the same patent claims and grounds already being litigated.” Paper 9 at 3. This kind of duplication and waste of resources is of the

exact kind § 314(a) was designed to prevent. *See* Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 2019) at 59 (“Based on the Board’s experience, one petition should be sufficient to challenge the claims of a patent in most situations. Two or more petitions filed against the same patent at or about the same time . . . may place a substantial and unnecessary burden on the Board and the patent owner and could raise fairness, timing, and efficiency concerns.”) Apart from the ongoing Mylan IPR regarding the same patent, Petitioners and Patent Owner, too, are already involved in ongoing litigation regarding the same patent and arguments in district court. *See* EX2039 (DRL Complaint).

If the Board denies joinder, it should exercise its discretion and not institute an IPR on DRL’s Petition.

Date: August 20, 2020

Respectfully submitted,

/Stanley E. Fisher/

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