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Via Email

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Re: *Mylan Pharmaceuticals Inc. v. Merck Sharp & Dohme Corp*., IPR2020-00040; *Teva Pharmaceuticals USA, Inc. et al. v. Merck Sharp & Dohme Corp.*, IPR2020-01045; *Dr. Reddy's Laboratories, Inc. et al. v. Merck Sharp & Dohme Corp*., IPR2020-01060; *Sun Pharmaceuticals Industries Ltd. v. Merck Sharp & Dohme Corp.*, IPR2020-01072

Dear Counsel,

I write in connection with the motions filed by (1) Teva Pharmaceuticals USA, Inc. and Watson Laboratories, Inc. ("Teva"), (2) Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. ("DRL"), and (3) Sun Pharmaceutical Industries, Ltd. ("Sun") (collectively, "Joinder Petitioners") requesting joinder with Mylan Pharmaceuticals Inc. ("Mylan") in *Mylan Pharmaceuticals Inc. v. Merck Sharp & Dohme Corp*., IPR2020-00040 ("Mylan IPR") (collectively, "Petitioners"). Merck has considered the Joinder Petitioners' briefs as well as Petitioners' positions on joinder submitted to the Board on June 23, 2020. In the interest of advancing the conferral process, this letter outlines several issues on which Merck seeks clarity as it evaluates its position.

As I previewed on our June 23 call, Merck believes that it is entitled to party discovery from one or more of the Joinder Petitioners. While we continue to evaluate the record and reserve all rights, at this time, Merck believes that it is entitled to discovery as a matter of right under 37 C.F.R. § 42.51(b)(1)(iii) because Joinder Petitioners' arguments and/or evidence in its newly filed Petition papers (which would become "adoptive positions" if joined to the Mylan IPR) are inconsistent with documents, data, or testimony in their possession. Merck also may seek discretionary discovery related to one or more of these issues under *Garmin v. Cuozzo*, Case IPR2012-00001, Paper No. 26 (Mar. 5, 2013).

By way of example, Teva performed testing and generated non-privileged data and analysis relating to the feasibility of sitagliptin accepting a second proton and creating non-1:1 dihydrogenphosphate salts of sitagliptin in prior patent office proceedings. Merck believes that the data and testimony provided by Teva in that prior proceeding and within Teva's possession is inconsistent with Teva's and the other Petitioners' position and expert declaration that sitagliptin can only be mono-protonated and form 1:1 dihydrogenphosphate salts. Merck believes it is entitled to discovery relevant to these inconsistencies as a matter of right, and alternatively, to request discovery from the Board related to these issues "in the interests of justice" if the Board orders joinder.

Petitioners may disagree that Merck is entitled to such discovery under the governing standards. However, Merck seeks clarification from Petitioners as to how trial would proceed, in the case of joinder, when Merck seeks such discovery. Specifically:

1. Will the Petitioners confirm that, if the Board grants the joinder motions, Merck would be legally entitled to party discovery from Joinder Petitioners, just like Mylan, in the event the discovery standards are satisfied? If Petitioners dispute this, please explain why.

2. Will the Joinder Petitioners confirm that their position with respect to experts is that they will withdraw their respective experts once Dr. Chorghade is deposed and, even if they do not retain Dr. Chorghade, they intend to rely solely on Dr. Chorghade's opinions and testimony for purposes of trial?

3. Merck intends to seek party discovery from Joinder Petitioners in advance of Dr. Chorghade's deposition, so Merck has the opportunity to use that material in his deposition. As I mentioned on our June 23, 2020 call, to allow time for such discovery (and/or to resolve any disputes) before Dr. Chorghade's deposition, Merck may need an extension of the current schedule, and the current August 14, 2020 due date for its Patent Owner Response and supporting evidence, and any Motion to Amend. As I further mentioned on that call, in the case of joinder, the Board has discretion to adjust the trial schedule. *See* 35 U.S.C. §§ 316(a)(11). Mylan suggested on that call that it would likely oppose an extension request and elicited the Joinder Petitioners agreement not to seek an extension. Merck is willing to work with Mylan and the Joinder Petitioners to propose a revised schedule to the Board that accounts for these issues and works for the parties and counsel. Will Petitioners

reconsider their position and negotiate a revised schedule with Merck to propose to the Board?

4. Merck understands that Petitioners agree that Joinder Petitioners will assume a "silent understudy" role in the Mylan IPR. Could Petitioners please explain how the process will work with respect to party discovery?

5. Merck understands that Joinder Petitioners will otherwise proceed as follows:

    a. Joinder Petitioners have not raised and will not raise any new grounds not already instituted by the Board in the Mylan IPR.

    b. Joinder Petitioners will withdraw the "me too" expert declarations filed in support of their Petitions once Mylan's expert is deposed, and Joinder Petitioners will rely solely on the declaration and testimony of Mylan's expert.

    c. Joinder Petitioners will not present any additional argument, briefing, or evidence.

    d. As long as Mylan is a party, Mylan will be Lead Petitioner, file all substantive written submissions, and conduct all argument and examination of witnesses. Mylan alone is responsible for all petitioner filings in the Mylan IPR unless and until Mylan is terminated as a party. Additionally and/or specifically, other than with respect to party discovery on the Joinder Petitioners:

        i. Joinder Petitioners will not file additional pages to Mylan's papers. Mylan will be subject to the word count limits for a single party.

        ii. Joinder Petitioners will not file any papers or exhibits in the Mylan IPR, except for *pro hac vice* motions, updated mandatory notices, and similar administrative filings that do not constitute argument or evidence relating to the merits.

        iii. Joinder Petitioners must obtain prior Board authorization to file any paper or to take any action on its own in the Mylan IPR.

        iv. Joinder Petitioners will be bound by any agreement between Mylan and Merck concerning discovery and depositions.

        v. Joinder Petitioners will not serve objections to discovery requests served on Mylan in the Mylan IPR. Joinder Petitioners will not serve discovery requests in connection with the Mylan IPR.

        vi. Counsel for Joinder Petitioners will not conduct the cross-examination or redirect of any witness, and will not defend any witness deposition in the

Mylan IPR. Cross-examination and redirect will occur within the timeframe that the rules allow for one party.

vii. Counsel for Joinder Petitioners will not participate in any speaking role in any telephonic conference before the Board in the Mylan IPR.

viii. Counsel for Joinder Petitioners will not participate in oral argument in the Mylan IPR.

6. Will the Joinder Petitioners please also confirm that, in the event Mylan is no longer a party, Joinder Petitioners shall meet and confer with the remaining joined parties, if any, to select a new Lead Petitioner, and thereafter any such new Lead Petitioner will effectively take Mylan's place in this proceeding and Joinder Petitioners will continue to be bound to the present agreement.

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Please let me know your availability to discuss the issues raised in this letter. I look forward to conferring with you further in an attempt to narrow the issues in advance of the due date for Merck's opposition to joinder.

If you have any questions, please feel free to contact me.

Best Regards,

/Stanley E. Fisher/
Stanley E. Fisher