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Filed on behalf of:

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

NOVARTIS AG AND LTS LOHMANN THERAPIE-SYSTEME AG,
Patent Owners

Case No. IPR2015-00268
Patent 6,335,031

**PETITIONER REPLY IN SUPPORT OF MOTION FOR JOINDER UNDER
35 U.S.C §§ 315(C), 37 C.F.R. §§ 42.22 AND 42.122(B)**

I. Introduction

Novartis's Opposition (Paper No. 10, Dec. 15, 2014) to Mylan's Joinder Motion asks the Board to impose four conditions before Novartis will agree to joinder, and raises objections that are unrelated to the Board's guidelines on joinder. Obtaining Novartis's agreement is unnecessary, its proposed conditions are moot or unwarranted, and its objections are meritless.

Joinder is appropriate in this case. The Mylan IPR is substantively identical to the corresponding Noven IPR and, thus, will avoid multiplication of issues before the Board. If joinder is denied, Mylan's petition on these substantively identical issues would proceed independently from Noven's earlier-filed IPR, doubling the Board's burden. Mylan has agreed to procedural concessions, such as consolidated filings and discovery, thereby preventing prejudice to Novartis. Thus, Mylan has born its burden to show that joinder is appropriate. *See Kyocera Corp. v. SoftView LLC*, IPR2013-00004 (Apr. 24, 2013) (Paper 15 at 4).

II. Novartis's Conditions are Moot or Unwarranted

Novartis asks the Board to impose four conditions before Novartis will agree to joinder. Paper 10 at 1. First, Novartis asks that Mylan's filings be consolidated with Noven's. This is moot because Mylan has already agreed to this. Paper 3 at 7-8. Second, Novartis asks that Mylan not raise new grounds. This also is moot because Mylan has already agreed to this. Paper 3 at 6. Third,

Novartis asks that Mylan be bound by any agreement between Novartis and Noven. This is unwarranted; Novartis could agree with Noven to settle the IPR with Noven and conduct no discovery, thereby prejudicing Mylan. Fourth, Novartis requires that the timing for deposition be subject to 37 C.F.R. §42.53. Mylan agrees and has no intention of proceeding contrary to the Rules.

III. Novartis's Objections Are Meritless

Novartis raises four objections that are irrelevant, as they are not appropriate considerations for joinder motions under *Kyocera Corp. v. SoftView LLC*, IPR2013-00004 (Apr. 24, 2013) (Paper 15 at 4). None of the objections is relevant because none would help ensure a just, speedy, and inexpensive resolution to the IPRs. *See* 35 U.S.C. §316(b); 37 C.F.R. §42.1(b).

Novartis first objects that Mylan has not promised to refrain from filing papers that it has not been authorized to file. Paper 10 at 3. Novartis concedes, as it must, that Mylan has agreed to consolidated filings in order to simplify briefings. *Id.* However, Novartis would require that joinder motions must also promise to “refrain from introducing additional, unconsolidated filings that are *not* on the existing briefing schedule.” *Id.* (emphasis in original). Mylan has agreed to consolidated filings. Paper 3 at 7. Any paper not on the briefing schedule is subject to prior Board authorization. Thus, Novartis's proposed requirement (that Mylan promise not to do something not permitted under the

rules) is pointless. Mylan reserves the right to request relief from the Board in the event Noven pursues the joined IPR in a manner that is harmful to Mylan (for example, if Noven chooses not to depose any expert testifying on behalf of Novartis).

Novartis's second objection is that "Mylan has failed to explain clearly how joinder would simplify discovery." Paper 10 at 4. Novartis concedes, as it must, that Mylan has stated it "'does not anticipate the need for new expert depositions following joinder' [] and does not 'anticipate' that it will introduce new argument or discovery." *Id.* However, Novartis implies that Mylan is contemplating the exact opposite: "Mylan has provided no assurance that it will not, in fact, introduce new experts, argument or discovery in any joined proceeding." Given the possibility of settlement between Novartis and Noven, Mylan cannot agree to this requirement. Nonetheless, subject to the conditions that Novartis and Noven have not settled and Noven is actively pursuing the IPR in a manner that does not disadvantage Mylan, Mylan agrees to Novartis's provisions (1)-(3) of Paper 10, page 4.

Novartis states that its requested limitation on Mylan's deposition time is consistent with the Board's order in *SAP America Inc. v. Clouding IP, LLC*, IPR2014-00306 (Paper 13 at 6), but Novartis seeks to further restrict deposition time based on "any agreement between Novartis and Noven." Paper 10 at 4. The

joinder order in *SAP* required only that witness examination occur “within the time frame normally allotted by the rules for one party,” and did not restrict deposition time based on any agreement between the original parties, as urged by Novartis. *SAP America Inc.*, IPR-2014-00306 (Paper 13 at 6). This additional restriction is not warranted.

Novartis’s third objection is that Mylan’s proposal for separate filings “does not give Novartis an opportunity to respond to these ‘separate filings.’” Paper 10 at 4-5. Novartis again cites *SAP America Inc.*, IPR-2014-00306 (Paper 13 at 5) and in so doing concedes that Mylan’s request is consistent with standard Board practice. Allowing separate filings in joined IPRs is consistent with Board orders in other joined IPRs. *See* Paper 10 at 8. As the Board may provide Novartis the customary responsive paper (of a corresponding number of pages) in the event it grants Mylan’s request for separate filings, Mylan would not oppose Novartis’s request, provided such papers would not exceed the number of pages in the Mylan filing and would be limited to issues raised in the Mylan filing. *See SAP America Inc.*, IPR2014-00306 (Paper 13 at 5).

Novartis’s final objection is that “Mylan has not expressly confirmed that it will not create new issues for the Board and Novartis to address.” Paper 10 at 5. Again, Novartis is requiring Mylan to confirm it will not act impermissibly in the joined IPR. Mylan has already filed its petition; Mylan is now prohibited from

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