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Filed On Behalf Of:

Novartis AG and LTS Lohmann Therapie-Systeme AG

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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

Inter Partes Review No. 2015-00268

U.S. Patent 6,335,031

PATENT OWNERS' OPPOSITION TO PETITIONER'S MOTION FOR JOINDER

Patent Owners Novartis AG and LTS Lohmann Therapie-Systeme AG (collectively "Novartis") respectfully oppose the Motion For Joinder ("Motion") by Mylan Pharmaceuticals Inc. ("Mylan") to join this *inter partes* review proceeding, IPR 2015-00268, with that brought by Noven Pharmaceuticals Inc. ("Noven"), *Noven Pharmaceuticals Inc. v. Novartis AG and LTS Lohmann Therapie-Systeme AG*, IPR2014-00550 ("the Noven IPR") on the terms proposed by Mylan. However, Novartis would not oppose joinder if the Board were to order that (a) ***all*** filings by Mylan in the joined proceeding be consolidated with Noven's, unless a filing solely concerns issues that do not involve Noven; (b) Mylan shall not be permitted to raise any new grounds not already instituted by the Board in the Noven IPR, or introduce any argument or discovery not already introduced by Noven; (c) Mylan shall be bound by any agreement between Novartis and Noven concerning discovery and/or depositions; and (d) Mylan at deposition shall not receive any direct, cross-examination or redirect time beyond that permitted for Noven alone under either 37 C.F.R. § 42.53 or any agreement between Novartis and Noven. As set forth below, Novartis's requests in this regard are consistent with the Board's prior orders on motions for joinder.

I. THE NOVEN IPR

On April 2, 2014, Noven filed a petition to institute *inter partes* review of U.S. Patent No. 6,335,031 ("the '031 Patent"). *Noven Pharmaceuticals Inc. v.*

Novartis AG and LTS Lohmann Therapie-Systeme AG, IPR2014-00550 (Apr. 2, 2014) (Paper 1). The Board instituted review of the '031 Patent on October 14, 2014. *Noven Pharmaceuticals*, IPR2014-00550 (Oct. 14, 2014) (Paper 10). Novartis's response to Noven's petition is due on January 20, 2015. *Noven Pharmaceuticals*, IPR2014-00550 (Nov. 4, 2014) (Paper 16). Novartis and Noven have stipulated that the cross-examination of Noven's declarants will occur no earlier than January 2, 2015. *Id.*

II. ARGUMENT

The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) permits joinder of like review proceedings. The Board, acting on behalf of the Director, has the discretion to join an *inter partes* review with another *inter partes* review when warranted. *See* 35 U.S.C. § 315(c); 37 C.F.R. § 42.122. The Board has indicated that it will determine whether to grant joinder on a case-by-case basis, taking into account the particular facts of each case, substantive and procedural issues, and other considerations. *See* 157 CONG. REC. S1376 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl). In the exercise of this discretion, the Board should consider that patent trial regulations, including the rules for joinder, must be construed to secure the just, speedy, and inexpensive resolution of every proceeding. *See* 35 U.S.C. § 316(b); 37 C.F.R. § 42.1(b).

As the moving party, Mylan has the burden of proving that it is entitled to join its IPR to the Noven IPR. 37 C.F.R. §§ 42.20(c), 42.122(b). Mylan's Motion for joinder should have: (1) set forth the reasons why joinder is appropriate; (2) identified any new ground of unpatentability asserted in Mylan's petition; (3) explained what impact (if any) joinder would have on the trial schedule for the Noven IPR; and (4) addressed specifically how briefing and discovery may be simplified. *See Kyocera Corp. v. SoftView LLC*, IPR2013-00004 (Apr. 24, 2013) (Paper 15 at 4). Mylan has failed to meet this burden.

First, Mylan has failed to explain clearly how joinder would simplify briefing. Although Mylan in its Motion "agree[s] to consolidated filings on the existing briefing schedule, for which Noven will maintain responsibility" (Motion at 7), Mylan has provided no assurance that it will refrain from introducing additional, unconsolidated filings that are ***not*** on the existing briefing schedule. If Mylan is not required to consolidate all of its filings with Noven's upon joinder, Mylan potentially may force Novartis and the Board to respond to numerous additional papers. However, Novartis would not oppose joinder if the Board were to order that ***all*** filings by Mylan in the joined proceeding be consolidated with Noven's, unless a filing solely concerns issues that do not involve Noven. Novartis's request in this regard is consistent with the Board's order in *SAP*

America Inc. v. Clouding IP, LLP, IPR2014-00306 (May 19, 2014) (Paper 13 at 5), cited by Mylan in support of its motion. (Motion at 8.)

Second, Mylan has failed to explain clearly how joinder would simplify discovery. For example, although Mylan states that it "does not anticipate the need for new expert depositions following joinder" (Motion at 6) and does not "anticipate" that it will introduce new argument or discovery (*id.*), Mylan has provided no assurance that it will not, in fact, introduce new experts, argument or discovery in any joined proceeding. However, Novartis would not oppose joinder if the Board were to order that (1) Mylan shall not be permitted to introduce any experts, argument or discovery not already introduced by Noven; (2) Mylan shall be bound by any agreement between Novartis and Noven concerning discovery and/or depositions; and (3) Mylan at deposition shall not receive any direct, cross-examination or redirect time beyond that permitted for Noven alone under either 37 C.F.R. § 42.53 or any agreement between Novartis and Noven. Novartis's requested limitation on Mylan's deposition time is consistent with the Board's order in *SAP America Inc.*, IPR2014-00306 (Paper 13 at 6).

Third, Mylan has proposed that in a joined proceeding, Mylan should be permitted "separate filings" of no more than seven pages directed to points of disagreement with Noven's asserted positions in any consolidated filing. (Motion at 7.) Mylan's proposal, however, does not give Novartis an opportunity to

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