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Filed on behalf of:

Mylan Pharmaceuticals Inc.

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| BEFORE TH | IE PATENT TR | IAL AND API | PEAL BOARD |

MYLAN PHARMACEUTICALS INC., Petitioner

V.

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

Case No. TBD
Patent 6,316,023

MOTION FOR JOINDER UNDER 35 U.S.C §§ 315(C), 37 C.F.R. §§ 42.22 AND 42.122(B)



I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Mylan") submits concurrently herewith a Petition for *Inter Partes* Review of U.S. Patent No. 6,316,023 ("the '023 Patent") ("Petition") based on <u>identical grounds</u> that form the basis for pending IPR proceeding, Case No. IPR2014-00549 ("the Noven IPR"). Pursuant to 35 U.S.C. § 315(c), Mylan respectfully moves that this Petition be instituted, and that the present IPR be joined with the Noven IPR.

II. BACKGROUND AND RELATED PROCEEDINGS

Novartis AG and LTS Lohmann Therapie-Systeme AG ("Patent Owners") are the owners of the '023 Patent. On June 19, 2014, Patent Owners filed suit against Mylan Inc. and Mylan Pharmaceuticals Inc. for infringement of the '023 Patent in Delaware, 1:14-cv-00777 (D. Del.); on June 20, 2014, Patent Owners also filed suit against Mylan Inc. and Mylan Pharmaceuticals Inc. for infringement of the '023 Patent in West Virginia, 1:14-cv-00106 (N.D. W.Va.) (collectively, "the Mylan Litigations").

Patent Owners have filed two suits against Noven for infringement of the '023 Patent: Novartis Pharm. Corp. et al. v. Noven Pharm. Inc., 1:13-cv-00527 (D. Del.); and Novartis Pharm. Corp. et al. v. Noven Pharm. Inc., 1:14-cv-00111 (D. Del.) (collectively, "the Noven Litigations").



The '023 Patent is also being asserted in the following patent infringement lawsuits: Novartis Pharm. Corp. et al. v. Par Pharm. Inc. et al., 1:11-cv-01077 (D. Del.); Novartis Pharm. Corp. et al. v. Watson Labs. Inc. et al., 1:11-cv-01112 (D. Del.); Novartis Pharm. Corp. et al. v. Alvogen Pine Brook Inc. et al., 1:13-cv-00052 (D. Del.); Novartis Pharm. Corp. et al. v. Alvogen Pine Brook Inc. et al., 1:13-cv-00370 (D. Del.); Novartis Pharm. Corp. et al. v. Actavis, Inc. et al., No. 1:13-cv-00371 (D. Del.); Novartis Pharm. Corp. et al. v. Par Pharm. Inc. et al., No. 1:13-cv-01467 (D. Del.); Novartis Pharm. Corp. et al. v. Zydus Noveltech Inc. et al., No. 1:14-cv-05405 (D. N.J.); Novartis Pharm. Corp. et al. v. Zydus Noveltech Inc. et al., No. 1:14-cv-01104 (D. Del.); Par Pharm. Inc. et al. v. Novartis Pharm. Corp. et al., 1:14-cv-00843 (D. Del.); Watson Labs Inc. v. Novartis Pharm. Corp et al., 14-1799 (C.A.F.C.); Novartis Pharm. Corp et al. v. Par Pharm. Inc. et al, 15-1061 (C.A.F.C.); Novartis Pharm. Corp et al. v. Par Pharm. Inc. et al, 15-1062 (C.A.F.C.); Par Pharm. Inc. v. Novartis Pharm Corp. et al., 15-1120 (C.A.F.C.); and Par Pharm. Inc. v. Novartis Pharm Corp. et al., 15-1121 (C.A.F.C.).

Noven filed its petition for *Inter Partes* Review of the '023 Patent in the Noven IPR on April 2, 2014. On October 14, 2014, the Board instituted trial on all proposed grounds of invalidity. *See* IPR2014-00549, Paper No. 10 at 25. Under



Rule 42.122, this Motion is timely as it is filed within one month of the institution of the Noven IPR.

III. THE REQUIREMENTS FOR MOTION FOR JOINDER ARE MET

In accordance with the Board's Representative Order identifying matters to be addressed in a motion for joinder (IPR2013-00004, Paper No. 15, April 24, 2013), Mylan submits that joinder is appropriate because: (1) joinder will promote efficient determination of the validity of the '023 Patent without prejudice to Patent Owners or Noven; (2) Mylan's petition raises the same grounds of unpatentability as the Noven IPR; (3) joinder will not affect the pending schedule in the Noven IPR nor increase the complexity of that proceeding in any way; and (4) Mylan will agree to consolidated filings with Noven to minimize burden and schedule impact.

a. Joinder Will Promote the Efficient Determination of Validity Without Prejudice to the Patent Owners or Noven

Granting joinder and allowing a consolidated IPR will not prejudice Patent Owners. Mylan raises no issues that are not already before the Board, such that joinder would not affect the timing of the IPR or the content of Patent Owners' responses. Indeed, Mylan's Petition challenges the same claims and is based on the same grounds and same combinations of prior art considered by the Board in instituting trial in the Noven IPR. Since Mylan's Petition does not raise any new



issues beyond those already considered by Patent Owners, Mylan does not anticipate that Patent Owners will need a substantial amount of time to complete its Preliminary Response, should it choose to file one. Likewise, as Mylan agrees to consolidated filings with Noven, Patent Owners will not need to coordinate with or respond to arguments by more parties than they already do.

Noven also will not be prejudiced by the Board's grant of this Motion and consolidation of Mylan's IPR with the Noven IPR. Mylan agrees to act in a limited "understudy" role, and will assume an active lead role only in the event that Noven settles with the Patent Owners or otherwise ceases to participate.

Moreover, a final written decision on the validity of the '023 Patent will minimize issues in the Mylan Litigation, the Noven Litigation, and potentially resolve the litigation of the '023 Patent altogether thereby promoting the efficient determination of validity. If the Board permits Mylan to join the Noven IPR, and the '023 Patent is upheld in a final decision, Mylan will be estopped from further challenging the validity of the patent on these grounds, avoiding duplication of Patent Owner's efforts at least as to Mylan and Noven. *See* 35 U.S.C. § 315(e)(1). Accordingly, to avoid duplicate efforts and promote efficiency, joinder is appropriate.



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