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Filed on behalf of:

**Mylan Pharmaceuticals Inc.**

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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**MYLAN PHARMACEUTICALS INC.,**  
Petitioner

v.

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

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Case No. TBD  
Patent 6,335,031

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**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. 6,335,031 (“the ’031 Patent”) based on identical grounds that form the basis for pending IPR proceeding, Case No. IPR2014-00550 (“the Noven IPR”). Pursuant to 35 U.S.C. § 315(c), Mylan respectfully moves that (1) this Petition be instituted based on the same grounds, and (2) the present IPR be joined with the Noven IPR. Mylan’s petition asserts identical grounds as asserted in the Noven IPR petition, but Mylan seeks institution only on the three grounds of invalidity instituted by the Board in the Noven IPR. *See* IPR2014-00550, Paper No. 10 at 28.

## II. BACKGROUND AND RELATED PROCEEDINGS

Novartis AG and LTS Lohmann Therapie-Systeme AG (“Patent Owners”) are the owners of the ’031 Patent. On June 19, 2014, Patent Owners filed suit against Mylan Inc. and Mylan Pharmaceuticals, Inc. for infringement of the ’031 Patent in Delaware, 1:14-cv-00777 (D. Del.); and on June 20, 2014, Patent Owners also filed suit against Mylan Inc. and Mylan Pharmaceuticals, Inc. for infringement of the ’031 Patent in West Virginia, 1:14-cv-00106 (N.D. W.Va.) (collectively, “the Mylan Litigation”).

Mylan v. Novartis  
Motion for Joinder - U.S. Pat. 6,335,031

Patent Owners have filed two suits against Noven for infringement of the '031 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 Litigation”).

The '031 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 '031 Patent in the Noven IPR on April 2, 2014. On October 14, 2014, the Board instituted trial on three of the five proposed grounds of invalidity. *See* IPR2014-00550, Paper No. 10 at 28. 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 '031 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 '031 Patent will minimize issues in the Mylan Litigation, the Noven Litigation, and potentially resolve the litigation of the '031 Patent altogether thereby promoting the efficient determination of validity. If the Board permits Mylan to join the Noven IPR, and the '031 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.

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