

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 Owner.

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Case IPR2015-00265  
Patent 6,316,023 B1

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Before FRANCISCO C. PRATS, ERICA A. FRANKLIN, and  
SCOTT E. KAMHOLZ, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION

Institution of *Inter Partes* Review and Grant of Motion for Joinder  
*37 C.F.R. § 42.108*  
*37 C.F.R. § 42.122(b)*

## I. INTRODUCTION

Mylan Pharmaceuticals Inc., (“Petitioner” or “Mylan”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 1, 2, 4, 5, 7, and 8 of U.S. Patent No. 6,316,023 B1 (Ex. 1001, “the ’023 patent”). On February 18, 2015, Novartis AG and LTS Lohmann Therapie-Systeme AG (collectively, “Patent Owner”) waived their opportunity to file a preliminary response. Paper 13.

At the same time it filed its Petition, Petitioner also filed a Motion for Joinder to join this proceeding with *Noven Pharmaceuticals, Inc. v. Novartis AG*, IPR2014-00549. Paper 3 (“Joinder Motion”). IPR2014-00549 concerns the same patent at issue here. We instituted trial in IPR2014-00549 on October 14, 2014. We have not yet instituted trial in IPR2015-00265. Patent Owner filed an Opposition to Petitioner’s Joinder Motion. Paper 10 (“Opposition Motion”). Petitioner filed a Reply in Support of Motion for Joinder. Paper 12.

For the reasons set forth below, we (1) institute an *inter partes* review in IPR2015-00265, and (2) grant Petitioner’s Motion for Joinder, subject to the conditions detailed herein.

## II. INSTITUTION OF *INTER PARTES* REVIEW

The Petition in IPR2015-00265 challenges the same claims, and is based on the same grounds and declaration testimony as those asserted in IPR2014-00549. *Compare* Pet. 22–48, *with* IPR2014-00549, Paper 1, 21–45. In IPR2014-00549, we instituted trial on the following grounds:

1. Claims 1 and 7 under 35 U.S.C. § 103(a) as obvious over Enz,<sup>1</sup> the Handbook,<sup>2</sup> Rosin,<sup>3</sup> Elmalem,<sup>4</sup> and Ebert;<sup>5</sup>
2. Claim 2 under 35 U.S.C. § 103(a) as obvious over Enz, the Handbook, Rosin, and Ebert;
3. Claims 4 and 5 under 35 U.S.C. § 103(a) as obvious over Enz, the Handbook, and Ebert;
4. Claim 8 under 35 U.S.C. § 103(a) as obvious over Enz, the Handbook, and Ebert or Kissel;<sup>6</sup>
5. Claims 1, 2, 4, 5, and 7 under 35 U.S.C. § 103(a) as obvious over Enz and Sasaki;<sup>7</sup> and
6. Claim 8 under 35 U.S.C. § 103(a) as obvious over Enz, Sasaki, and Ebert or Kissel.

IPR2014-00549, Paper 10, 26. As Patent Owner waived filing a preliminary response in IPR2015-00265, Patent Owner has not raised additional arguments or evidence other than what we considered in the course of instituting trial in IPR2014-00549. Therefore, our consideration of the Petition in IPR2015-00265 is based upon consideration of the same issues, arguments, and oppositions raised with respect to IPR2014-00549.

In view of the similarity of the challenges in the two Petitions, we institute an *inter partes* review in this proceeding on the same grounds as those on which we instituted trial in IPR2014-00549.

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<sup>1</sup> UK Patent Application GB 2,203,040 A, published Oct. 12, 1988 (Ex. 1002).

<sup>2</sup> HANDBOOK OF PHARMACEUTICAL EXCIPIENTS (A. Wade & P.J. Weller eds., 2d ed. 1994) (Ex. 1003).

<sup>3</sup> US 4,948,807, issued Aug. 14, 1990 (Ex. 1008).

<sup>4</sup> Esther Elmalem et al., *Antagonism of Morphine-Induced Respiratory Depression by Novel Anticholinesterase Agents*, 30 NEUROPHARMACOLOGY 1059–1064 (1991) (Ex. 1009).

<sup>5</sup> WO 95/24172, published Sept. 14, 1995 (Ex. 1006).

<sup>6</sup> EP Patent Application 0155229A2, published Sept. 18, 1985 (Ex. 1007).

<sup>7</sup> JP Patent Application 59-184121, published Oct. 19, 1984 (Ex. 1005).

### III. JOINDER OF *INTER PARTES* REVIEWS

An *inter partes* review may be joined with another *inter partes* review, subject to the provisions 35 U.S.C. § 315(c), which governs joinder of *inter partes* review proceedings:

(c) JOINDER. — If the Director institutes an *inter partes* review, the Director, in his or her discretion, may join as a party to that *inter partes* review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an *inter partes* review under section 314.

As the moving party, Petitioner bears the burden of proving that it is entitled to the requested relief. 37 C.F.R. § 42.20(c). A motion for joinder should: (1) set forth the reasons joinder is appropriate; (2) identify any new grounds of unpatentability asserted in the petition; and (3) explain what impact (if any) joinder would have on the trial schedule for the existing review. *See Kyocera Corp. v. Softview, LLC*, Case IPR2013-00004, slip op. at 4 (PTAB Apr. 24, 2013) (Paper 15) (Order Authorizing Motion for Joinder); Frequently Asked Questions H5, <http://www.uspto.gov/ip/boards/bpai/prps.jsp>.

Petitioner filed its Joinder Motion within one month of the IPR2014-00549 trial institution, as required by 37 C.F.R. § 42.122(b).

As noted above, in IPR2015-00265, Petitioner limited the grounds of unpatentability asserted in the Petition to those previously raised in IPR2014-00549. Additionally, Petitioner relies on the same experts as Noven Pharmaceuticals, Inc. (“Noven”) relies on in IPR2014-00549. Paper 3, 6.

Petitioner asserts that joinder will not affect the pending schedule in IPR2014-00549, nor will it increase the complexity of that proceeding. *Id.* Specifically, Petitioner agrees to consolidated filings with Noven, for which Noven will maintain responsibility. *Id.* at 6–7. Petitioner does not anticipate introducing “any additional arguments, briefing, or need for discovery.” *Id.* at 7. Petitioner explains that “[a]s long as Noven remains an active participant in the IPR, Mylan agrees to assume a limited ‘understudy’ role.” *Id.* Petitioner will assume the primary role only if Noven ceases to participate in the IPR. *Id.*

Patent Owner does not oppose the Joinder Motion if, in the joined proceedings,

(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.

Paper 10, 1.

We agree with Petitioner that joinder is appropriate under the circumstances. We also find that the limitations on joinder requested by Patent Owner, and quoted above, are appropriate under the circumstances. Those limitations are consistent with the “understudy” role that Petitioner agrees to assume, as well as Petitioner’s assertion that its presence would not

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