

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, INC.,
Petitioner

v.

HORIZON PHARMA USA, INC. and NUVO PHARMACEUTICALS
(IRELAND) DESIGNATED ACTIVITY COMPANY,
Patent Owners.

Case IPR2018-01341
Patent 9,393,208 B2

Before TONI R. SCHEINER, MICHELLE N. ANKENBRAND, and
DEBRA L. DENNETT, *Administrative Patent Judges*.

DENNETT, *Administrative Patent Judge*.

DECISION

Granting Petitioner's Motion for Joinder and
Instituting *Inter Partes* Review
35 U.S.C. § 314(a); 37 C.F.R. § 42.122

I. INTRODUCTION

Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's" or "Petitioner") filed a Petition (Paper 2, "Pet.") on July 2, 2018, requesting an *inter partes* review of claims 1–7 of U.S. Patent No. 9,393,208 B2 (Ex. 1001, "the '208 patent"). Concurrently with the Petition, Dr. Reddy's filed a Motion for Joinder (Paper 3, "Mot.") to the *inter partes* review in *Mylan Pharms. Inc. v. Horizon Pharma USA, Inc.*, Case IPR2018-00272 (the "Mylan IPR" and Petitioner "Mylan"), an ongoing *inter partes* review, which we instituted on June 14, 2018. *See* IPR2018-00272, Paper 9. On August 31, 2018 (prior to the due date for Patent Owners' Preliminary Response), we stayed the proceeding because one of the owners of the '208 patent filed a bankruptcy petition.¹ Paper 10. The bankruptcy court entered a sale order on December 27, 2018, which lifted the stay of this proceeding. Mylan IPR, Ex. 1051. Horizon Pharma USA, Inc. and Nuvo Pharmaceuticals (Ireland) Designated Activity Company ("Patent Owners") filed a Preliminary Response to the Petition on January 31, 2019. Paper 15 ("Prelim. Resp."). Patent Owners did not file an opposition to the joinder motion.

In the Motion for Joinder, Dr. Reddy's confirms that it seeks review of the same claims at issue in the Mylan IPR, based solely on the grounds of unpatentability we instituted in the Mylan IPR. Mot. 1. Dr. Reddy's commits to rely on the declarations and testimony of Mylan's experts. *Id.*

¹ Pozen Inc. and Horizon Pharma USA, Inc. were the patent owners at the time the Petition was filed. *See* Paper 5. Nuvo Pharmaceuticals (Ireland) Limited acquired Pozen Inc.'s rights in the '208 patent in September 2018. Mylan IPR, Ex. 1052.

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). A petitioner may be joined as a party to a previously instituted *inter partes* review if that petitioner “properly files a petition . . . that we determine[] warrants the institution of an *inter partes* review.” 35 U.S.C. § 315(c); 37 C.F.R. § 42.4(a).

After considering the Petition and the evidence currently of record, we conclude that Dr. Reddy’s has demonstrated that there is a reasonable likelihood that it would prevail with respect to at least one of the claims challenged in the Petition. Our conclusion is consistent with our Institution Decision in the Mylan IPR. *See* Mylan IPR, Paper 9. Thus, as we explain below, we institute an *inter partes* review of claims 1–7 of the ’208 patent on the same grounds we instituted in the Mylan IPR. We also grant the Motion for Joinder subject to the conditions discussed below.

The Scheduling Order in place in the Mylan IPR shall govern. Mylan IPR, Paper 27.

A. Additional Related Proceedings

Dr. Reddy’s identifies the following pending litigation related to the ’208 patent: *Horizon Pharma, Inc. v. Dr. Reddy’s Labs., Inc.*, No. 15-3324 (D.N.J.); *Horizon Pharma, Inc. v. Dr. Reddy’s Labs., Inc.*, No. 16-4918 (D.N.J.); *Horizon Pharma, Inc. v. Dr. Reddy’s Labs., Inc.*, No. 16-9035 (D.N.J.); *Horizon Pharma, Inc. v. Mylan Pharms. Inc.*, No. 15-3327 (D.N.J.); *Horizon Pharma, Inc. v. Mylan Pharms. Inc.*, No. 16-4921 (D.N.J.); and *Horizon Pharma, Inc. v. Lupin Ltd.*, No. 16-4920 (D.N.J.).
Pet. 2.

II. ANALYSIS

A. Instituting Review of Claims 1–7 of the ’208 Patent

We address whether joinder is appropriate only after determining that the Petition warrants review. *See* 35 U.S.C. § 315(c) (joinder provision, relating to *inter partes* reviews, requires, as an initial matter, a determination that the petition accompanying the joinder motion warrants institution of review). We have jurisdiction under 35 U.S.C. § 314, which provides that review may be authorized only if “the information presented in the petition . . . and any [preliminary] response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a).

In the Mylan IPR, we instituted review of claims 1–7 of the ’208 patent on the following grounds:

Reference[s]	Statutory Basis	Claims challenged
’285 patent ²	§ 102(e)	1–7
’285 patent	§ 103	1–7
’285 patent, EC-Naprosyn label ³ , and Howden 2005 ⁴	§ 103	1–7

The Instant Petition challenges the same claims of the ’208 patent as those we instituted in the Mylan IPR, based on the same asserted prior art,

² U.S. Patent 8,557,285 B2, filed Aug. 23, 2011, issued Oct. 15, 2013 to John R. Plachetka (Ex. 1005, “the ’285 patent”).

³ Prescription Drug Label for EC-Naprosyn[®] and other Naprosyn[®] formulations (Ex. 1009, “EC-Naprosyn label”).

⁴ C.W. Howden, *Review article: immediate-release proton-pump inhibitor therapy—potential advantages*, 22 ALIMENT. PHARMACOL. THER. 25–30 (2005) (Ex. 1006, “Howden 2005”).

and three proposed grounds of unpatentability that are identical to the three grounds instituted in the Mylan IPR. *Compare* Pet. 3-4, *with* the Mylan IPR, Paper 2 (the “Mylan Pet.”), 32–60.

Dr. Reddy’s relies on the same declarations that Mylan submitted in the Mylan IPR. *See* Pet. 4. Therefore, Dr. Reddy’s Petition relies on the same arguments and evidence—including the same witness declarations—that supported our decision to institute review in the Mylan IPR. *Compare* Pet. 4, *with* Mylan Pet. 3, 17–60.

Patent Owners’ Preliminary Response raises the same arguments against institution that Patent Owners raised in the Mylan IPR, except that Patent Owners additionally argue that we should deny the Petition because the district court in the co-pending litigation determined that the claims of the ’208 patent are invalid as indefinite. *Compare* Mylan IPR, Paper 7, *with* Prelim. Resp. 9–16; *see* Prelim. Resp. 6–9.

We previously determined, upon consideration of Mylan’s Petition and Patent Owners’ Preliminary Response thereto, that the record in the Mylan IPR established a reasonable likelihood that Mylan would prevail with respect to claims 1–7 on the grounds outlined above. Mylan IPR, Paper 9. Given the identical grounds and evidence presented in the present proceeding, we likewise determine that Dr. Reddy’s Petition warrants institution on the grounds presented. We rely on, and incorporate by reference, the reasoning set forth in our Decision on Institution in the Mylan IPR, and institute an *inter partes* review of the challenged claims based on the same grounds authorized, and for the same reasons discussed, in our decision to institute the Mylan IPR. *See id.* at 15–24 (reflecting reasons for instituting review). As to Patent Owners’ argument that we should deny

institution based on the district court's invalidity determination, we find that argument moot in view of our decision denying Patent Owners' motion to terminate this proceeding for the same reason. Paper 20.

B. Granting Motion for Joinder

Dr. Reddy's timely filed its Motion for Joinder on July 2, 2018, within one month of the institution of the Mylan IPR, as required by 37 C.F.R. § 42.122(b). Patent Owners have not opposed joining Dr. Reddy's as a Petitioner to the Mylan IPR.

A Petitioner in an *inter partes* review may be joined as a party to another *inter partes* review, subject to the provisions of 35 U.S.C. § 315(c), which provides:

(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.

By regulation, the Director's discretion has been delegated to the Board. 37 C.F.R. § 42.4(a).

As the moving party, Dr. Reddy's 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 that joinder is appropriate; (2) identify any new grounds of unpatentability asserted in the petition; (3) explain what impact (if any) joinder would have on the trial schedule for the existing review; and (4) address specifically how briefing and discovery may be simplified. *See* "Frequently Asked Questions H5,"

<https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/ptab-e2e-frequently-asked-questions#H5>.

Dr. Reddy's represents that it raises only those patentability issues that already are before us in the Mylan IPR. Mot. 5–6. Dr. Reddy's also represents that it relies on the same declarations Mylan submitted in the Mylan IPR. *Id.* at 1. In light of the substantial identity of Dr. Reddy's Petition and Mylan's Petition, we agree that Dr. Reddy's raises no new grounds of unpatentability or issues.

Dr. Reddy's also argues that joinder will not affect the schedule of the Mylan IPR. *Id.* at 6. Dr. Reddy's agrees to a passive role, explaining that it will not (1) file additional papers, (2) file additional pages to Mylan's papers, (3) present any new, additional, or supplemental arguments, (4) cross-examine Patent Owners' experts or attempt to offer a rebuttal expert of its own, and (5) present any arguments at oral hearing. *Id.* at 7. Dr. Reddy's will cease its passive role only if Mylan ceases to participate in the proceeding. *Id.*

In light of Dr. Reddy's arguments and representations, we are persuaded that it is appropriate to join Dr. Reddy's as a Petitioner to the Mylan IPR, and that joinder will lead to the more efficient resolution of the proceedings. We are satisfied that joinder will not unduly complicate or delay the proceedings. For these reasons, we grant Dr. Reddy's Motion for Joinder, subject to the requirements set forth in the Order below.

III. CONCLUSION

Having considered the information presented in the Petition, we institute an *inter partes* review of claims 1–7 of the '208 patent based on the

same grounds instituted in the Mylan IPR. We also grant Dr. Reddy's Motion for Joinder.

IV. ORDER

It is

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to:

Claims 1–7 of the '208 patent under 35 U.S.C § 102(e) as anticipated by the '285 patent;

Claims 1–7 of the '208 patent under 35 U.S.C § 103 as obvious over the '285 patent; and

Claims 1–7 of the '208 patent under 35 U.S.C § 103 as obvious over the combination of the '285 patent, the EC-Naprosyn label, and Howden 2005;

FURTHER ORDERED that Dr. Reddy's Motion for Joinder (Paper 3) is *granted*;

FURTHER ORDERED that Dr. Reddy's is joined as a Petitioner to IPR2018-00272;

FURTHER ORDERED that the grounds on which IPR2018-00272 was instituted are unchanged, and no other grounds are instituted in the consolidated proceeding beyond those set forth in IPR2018-00272, Paper 9;

FURTHER ORDERED that the Scheduling Order in place for IPR2018-00272 (Paper 27) shall continue to govern the joined proceeding;

FURTHER ORDERED that, throughout IPR2018-00272, any paper, except for a motion that does not involve the other party, shall be filed by Mylan as a single, consolidated filing on behalf of Mylan and Dr. Reddy's,

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pursuant to the page limits set forth in 37 C.F.R. § 42.24, and Mylan will identify each such filing as a consolidated filing;

FURTHER ORDERED that except as otherwise agreed by all parties, counsel for Mylan will conduct cross-examination and other discovery on IPR2018-00272 on behalf of Mylan and Dr. Reddy's, and that Patent Owners are not required to provide separate discovery responses or additional deposition time as a result of the joinder;

FURTHER ORDERED that IPR2018-01341 is terminated under 37 C.F.R. § 42.72, and all further filings this proceeding are to be made in IPR2018-00272;

FURTHER ORDERED that a copy of this Decision will be entered into the record of IPR2018-00272; and

FURTHER ORDERED that the case caption in IPR2018-00272 shall be changed to reflect that Dr. Reddy's has been joined as a Petitioner to that proceeding in accordance with the attached example.

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⁵ Petitioner Dr. Reddy's Laboratories, Inc., from IPR2018-01341, has been joined as a Petitioner to this proceeding.