Trials@uspto.gov
Tel: 571-272-7822

Paper 36
Entered: April 1, 2019

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

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.