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Paper 47
Entered: August 14, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, INC.,
Petitioner

v.

POZEN INC. and HORIZON PHARMA USA, INC.,
Patent Owners.

Case IPR2018-00894
Patent 9,220,698 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. ("DRL" or "Petitioner") filed a Petition (Paper 1, "Pet.") on April 6, 2018, requesting an *inter partes* review of claims 1–7 of U.S. Patent No. 9,220,698 B2 (Ex. 1001, "the '698 patent"). Concurrently with the Petition, DRL filed a Motion for Joinder (Paper 3, "Mot.") to the *inter partes* review in *Mylan Pharms. Inc. v. Horizon Pharma USA, Inc.*, Case IPR2017-01995 (the "Mylan IPR" and Petitioner "Mylan"), an ongoing *inter partes* review, which we instituted on March 8, 2018. *See* IPR2017-01995, Paper 18. Pozen Inc. and Horizon Pharma USA, Inc. ("Patent Owners") filed an Opposition to Petitioner's Motion for Joinder (Paper 8, "Opp. to Joinder"), and DRL filed a Reply to Opposition to Motion for Joinder (Paper 9, "Reply to Opp. to Joinder"). Patent Owners did not file a preliminary response.

In the Motion for Joinder and Reply to Opposition to Petitioner's Motion for Joinder, DRL confirms that it seeks review of the same claims at issue in the Mylan IPR, based solely on the grounds of unpatentability we authorized in the Mylan IPR. Mot. 1; Reply to Opp. to Joinder 1–2. DRL commits to rely on the declarations and testimony of Mylan's experts. Reply to Opp. to Joinder 2.

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 DRL 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* IPR2017-01995, Paper 18. Thus, we institute an *inter partes* review of claims 1–7 of the '698 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 the joined proceedings. Mylan IPR, Paper 19.

A. Additional Related Proceedings

DRL identifies the following pending litigation related to the '698 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. 1–2.

II. ANALYSIS

A. Instituting Review of Claims 1–7 of the '698 Patent

We address whether joinder is appropriate only after determining that the Petition warrants the institution of an *inter partes* 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 authority 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 '698 patent on the following grounds:

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

The Instant Petition challenges the same claims of the '698 patent as those challenged in the Mylan IPR, based on the same asserted prior art and grounds of unpatentability. *Compare* Pet. 3–4, *with* the Mylan IPR, Paper 2 (the "Mylan Pet."), 34–59.

DRL filed expert declarations by Drs. Solny and Bergstrom to support its Petition, but subsequently committed to relying on the same declarations that Mylan submitted in the Mylan IPR. *See* Pet. 4; Reply to Opp. to Joinder 1–2. Therefore, DRL'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* Reply to Opp. to Joinder 1–2, *with* Mylan Pet. 3, 19–59.

[1] U.S. Patent 8,557,285 B2, filed Aug. 23, 2011, issued Oct. 15, 2013 to John R. Plachetka (Ex. 1005, "the '285 patent").

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

[3] C.W. Howden, *Review article: immediate-release proton-pump inhibitor therapy–potential advantages*, 22 ALIMENT PHARMACOL. THER. 25–30 (2005) (Ex. 1006, "Howden 2005").

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 18. Given the identical grounds and evidence presented in the present proceeding, we likewise determine that DRL'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 20–29 (reflecting reasons for instituting review).

B. Granting Motion for Joinder

DRL timely filed its Motion for Joinder on April 6, 2018, within one month of the institution of the Mylan IPR, as required by 37 C.F.R. § 42.122(b).[4] Patent Owners oppose joining DRL as a Petitioner to the Mylan IPR (Opp. to Joinder 3), Mylan does not (Reply to Opp. to Joinder 1).

A Petitioner in *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.

[4] Patent Owners argue that DRL's Petition is time barred under 35 U.S.C. § 315(b). Opp. to Joinder 1. However, the one-year time limitation for filing a petition "shall not apply to a request for joinder" under § 315(c). 35 U.S.C. § 315(b). Patent Owners' argument, thus, is without merit.

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