

July 2, 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 Owner

Inter Partes Review IPR2018-001341
Patent No. 9,393,208 B2

MOTION FOR JOINDER
PURSUANT TO 35 U.S.C. § 315(c) AND 37 C.F.R. § 42.122(b)

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I. STATEMENT OF PRECISE RELIEF REQUESTED

Petitioner Dr. Reddy's Laboratories, Inc. ("DRL" or "Petitioner") respectfully requests joinder and/or consolidation of the above-captioned *inter partes* review of U.S. Patent No. 9,393,208 ("the '208 Patent") ("the DRL IPR") with IPR2018-00272 ("the Mylan IPR"), filed December 4, 2017 by Mylan Pharmaceuticals Inc. ("Mylan"). The Mylan IPR was instituted on June 14, 2018. *Mylan Pharms., Inc. v. Pozen Inc. and Horizon Pharma USA, Inc.*, IPR2018-00272, slip op. at 24 (PTAB June 14, 2018) (Paper 9).

The DRL IPR is substantially the same as the Mylan IPR. The DRL IPR involves the same patent, the same claims, and presents the same grounds of unpatentability, using the same evidence, as the Mylan IPR (except where DRL-specific substitutions were required). The DRL IPR challenges the claims as anticipated and/or obvious over the same prior art, based on the same arguments, and relies on the same experts, Drs. David C. Metz, M.D. and Michael Mayersohn, Ph.D. as the Mylan IPR. Mylan has consented to DRL's retention of its experts for purposes of this DRL IPR (and the previously filed DRL IPR2018-00894 on a closely related U.S. Patent No. 9,220,698.). *See Dr. Reddy's Laboratories, Inc. v. Pozen Inc. and Horizon Pharma USA, Inc.*, IPR2018-00894,

Paper 9 at 1.

Joinder is appropriate because DRL will take on a purely understudy role and thus joinder will not cause any delay in the Mylan IPR trial schedule. Mylan consents to this joinder. Thus joinder will not prejudice any of the parties to the Mylan IPR.

II. STATEMENT OF MATERIAL FACTS

On December 4, 2017, Mylan filed a Petition for *Inter Partes* Review of claims 1-7 of U.S. Patent No. 9,393,208. The Mylan IPR was accorded Case No. IPR2018-00272. The Mylan IPR asserted the following grounds of unpatentability:

Ground 1: Claims 1-7 are unpatentable as anticipated under 35 U.S.C § 102 by U.S. Patent No. 8,557,285 (“’285 patent”);

Ground 2: Claims 1-7 are unpatentable as obvious under 35 U.S.C § 103 over the ’285 patent; and

Ground 3: Claims 1-7 are unpatentable as obvious under 35 U.S.C § 103 over the ’285 patent in view of the EC-Naprocyn[®] label and Howden 2005.

On June 14, 2018, the PTAB instituted the Mylan Petition on all of the

asserted grounds of unpatentability. *Mylan Pharms. Inc. v. Pozen Inc. and Horizon Pharma USA, Inc.*, IPR2018-00272, slip op. at 24 (PTAB June 14, 2018) (Paper 9).

On July 2, 2018, DRL filed a Petition for *Inter Partes* Review, Case No. IPR2018-001341, and filed the present Motion for Joinder the same day.

The petition in the DRL IPR is substantially identical to the petition in the Mylan IPR and includes substantially the same exhibits and relies on the same experts, Drs. David C. Metz, M.D. and Michael Mayersohn, Ph.D., as the Petition in the Mylan IPR.

Mylan, DRL, Dr. Reddy's Laboratories, Ltd., Lupin Ltd., and Lupin Pharmaceuticals, Inc. are defendants involved in pending litigations regarding the '208 patent in the District of New Jersey.¹

III. APPLICABLE LEGAL STANDARD

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:

¹ For a list of related matters involving the '208 patent, see DRL's Petition for *Inter Partes* review, pages 1- 2, submitted earlier today with this joinder motion.

(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). The PTAB has indicated that a motion for joinder should set forth the reasons joinder is appropriate, identify any new grounds of unpatentability asserted in the petition, and 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 April 24, 2013) (Paper 15).

IV. ARGUMENT

A. Joinder is timely

DRL's request for joinder is timely because it was filed on July 2, 2018,

which is less than one month after the June 14, 2018 institution of the Mylan IPR.

This Motion for Joinder is therefore filed “no later than one month after the institution date of any *inter partes* review for which joinder is requested.” 37 C.F.R. § 42.122(b).

Furthermore, the Petition for *Inter Partes* Review filed concurrently with the present Motion for Joinder is not time barred under 37 C.F.R. § 42.101(b) because “[t]he time period set forth in § 42.101(b) shall not apply when the petition is accompanied by a request for joinder.” *Id.*

B. Joinder is appropriate because both IPRs present the same grounds of unpatentability concerning the same claims of the same patent

Joinder is appropriate here because DRL has presented the same arguments in the DRL IPR as are present in the Mylan IPR. In particular, both the DRL IPR and the Mylan IPR allege the same three grounds of unpatentability:

Ground 1: Claims 1-7 are unpatentable as anticipated under 35 U.S.C § 102 by U.S. Patent No. 8,557,285 (“’285 patent”);

Ground 2: Claims 1-7 are unpatentable as obvious under 35 U.S.C § 103 over the ’285 patent; and

Ground 3: Claims 1-7 are unpatentable as obvious under 35 U.S.C § 103 over the '285 patent in view of the EC-Naprocyn[®] label and Howden 2005.

Furthermore, the DRL IPR is substantially identical to the Mylan IPR. The DRL IPR contains the same arguments as the Mylan IPR and relies upon the same expert testimony and exhibits.

Thus, the parties in both the DRL and Mylan IPRs will be presenting the same arguments, and the PTAB will be considering the same issues, in both IPRs. Joinder is therefore the most just, speedy, and inexpensive way in which to proceed. *See* 37 C.F.R. § 42.1(b).

C. Joinder is appropriate because the DRL IPR proposes no additional grounds of unpatentability

As indicated above, there are no grounds of unpatentability presented in the DRL IPR that were not presented, and accepted by the Board for the purposes of institution, in the Mylan IPR.

D. Joinder will not impact the existing trial schedule

DRL will not request any alterations to the schedule in the Mylan IPR. In addition, because joinder will not introduce any new prior art, arguments, or grounds of unpatentability into the Mylan IPR, joining the DRL and Mylan

IPRs will not complicate the substantive issues already pending in the Mylan IPR.

E. Joinder will simplify briefing and discovery

To simplify briefing and discovery, the petitioners in the DRL IPR will adopt an “understudy role” in the joined proceedings.² *See, e.g., Akorn Inc. v. Allergan, Inc.*, IPR2017-00596, slip op. at 4 (PTAB March 31, 2017) (Paper No.

² Petitioner is willing to take a passive role. For example, Petitioner agrees not to file additional papers, not file additional pages to Mylan’s papers, not present any new, additional, or supplemental arguments, not cross-examine Patent Owners’ expert(s) or attempt to offer a rebuttal expert of its own, and not present any arguments at oral hearings. *See, e.g., Akorn Inc. v. Allergan, Inc.*, IPR2017-00596, slip op. at 4 (PTAB March 31, 2017) (Paper No. 10) (allowing joinder where movants take a “understudy role” without a separate opportunity to actively participate). Only if Mylan drops out of the proceedings for any reason – for example settlement with the Patent owner and termination of its IPR – will Petitioner cease its passive role.

10). So long as the Mylan remains a party, DRL agrees to consolidated filings³ for all substantive papers in the respective proceedings, except for motions that do not involve Mylan. DRL also agrees that cross-examinations will occur within the timeframe normally allotted by the rules to one party and will not need to be extended in light of the joinder. Furthermore, unless Mylan ceases to be a party in its IPR, DRL agrees that oral argument will be conducted by Mylan.

Accordingly, joinder will greatly simplify the proceedings, and neither the Board, the patent owner, nor Mylan will be prejudiced by joinder, given the present petitioners' willingness to be an "understudy" in the joined proceeding.

To this end, Petitioner notes that the Board has granted joinder in similar circumstances before in a number of cases. For example, in IPR2017-00596, Petitioner Akorn Inc. was granted joinder with a previously-filed IPR by Mylan

³ Petitioner agrees to consolidated filings for all substantive papers in the respective proceedings, except for motions that do not involve Mylan. Petitioner agrees to incorporate its filings with those of Mylan in a consolidated filing, subject to the ordinary rules for one party on page limits.

where the petitioner made the concessions noted above. *Akorn Inc. v. Allergan, Inc.*, IPR2017-00596, slip op. at 4-5 (PTAB March 31, 2017) (Paper No. 10); *see also Amerigen Pharm. Ltd. v. UCB Pharma GMBH*, IPR2016-01665, slip op. at 4-7 (PTAB December 7, 2016) (Paper No. 8); *West-Ward Pharmaceuticals International, Ltd. v. Novartis Pharmaceuticals Corporation*, IPR2018-00507, slip op. at 4-5 (PTAB April 3, 2018)(Paper No. 10); *Jiawei Technology (HK) Ltd. et al. v. Lighting Science Group Corp.*, IPR2018-00262, slip op. at 6-7 (PTAB June 6, 2018)(Paper No. 7); *Actavis Laboratories FL, Inc. et al. v. Ltd. et al. v. Janssen Oncology, Inc.*, IPR2017-00853, slip op. at 6-7 (PTAB April 12, 2017)(Paper No. 19); *Samsung Bioepis Co., Ltd. v. Genentech, Inc.*, IPR2017-02139, slip op. at 4-5 (PTAB February 22, 2018)(Paper No. 11).

V. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests that the Board institute the Petition for *Inter Partes* Review submitted concurrently herewith, and join this proceeding with *Mylan Pharmaceuticals Inc. v. Pozen Inc. and Horizon Pharma USA, Inc.*, Case IPR2018-00272.

Although Petitioner believes that no fee is required for this Motion, the Commissioner may charge any additional fees which may be required for this

Motion for Joinder

U.S. Patent No. 9,393,208

Motion to Deposit Account No. 506688.

Date: July 2, 2018

Respectfully submitted,

/s/ Alan Pollack

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105, I certify that I caused to be served a true and correct copy of the foregoing: **Petition for *Inter Partes* Review of U.S. Patent No. 9,393,208** by Federal Express next business day delivery on this day on the Patent Owners' correspondence address of record for the subject patent as follows:

Steven L. Highlander
Parker Highlander PLLC
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Courtesy copies of the **Petition for *Inter Partes* Review of U.S. Patent No. 9,393,208** have been sent by Federal Express next business day delivery on this day to:

(1) Patent Owner's:

Horizon Pharma USA, Inc. 150 South Saunders Road Lake Forest, IL 60045	Pozen Inc. 8310 Bandford Way Raleigh, NC 27615
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Date: July 2, 2018

/s/ Alan Pollack
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