

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ZYDUS LIFESCIENCES LIMITED, ZYDUS
LIFESCIENCES GLOBAL FZE, and ZYDUS
PHARMACEUTICALS (USA) INC.,
Petitioners

v.

BIOMARIN PHARMACEUTICAL INC.
Patent Owner

Case No. PGR2026-00055
Patent 12,233,106

**PETITIONERS' REPLY TO ASCENDIS'S OPPOSITION
TO PETITIONERS' MOTION FOR JOINDER**

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Petitioners Zydus Lifesciences Limited, Zydus Lifesciences Global FZE, and Zydus Pharmaceuticals (USA) Inc. (collectively, “Zydus”) respectfully submit this Reply to Ascendis’s Opposition to Zydus’s Motion for Joinder (“Opposition”). The Opposition provides no explicit authority precluding the filing of the Petition with the proper and timely filed Motion for Joinder (here “the Motion”). In addition, the Motion does not create undue complexity—in fact, there is no additional burden or complexity on Ascendis at all. If Patent Owner has concerns, Zydus agrees to adhere to the conditions proposed on pages 9-10 of Patent Owner’s Opposition to Zydus’s Motion for Joinder. It is thus appropriate to allow Zydus to join the proceedings under those conditions, and therefore Zydus’s Motion should be granted.

I. ARGUMENT

A. Zydus’s Petition and Motion are Timely

Zydus’s Petition and Motion are timely under 35 U.S.C. §325(c) and 37 C.F.R. §42.222(b). The Opposition asserts that joinder is foreclosed by 35 U.S.C. §§321(c) and 325(c). However, neither statute states that a party may not join an earlier filed proceeding when otherwise time barred. Had Congress intended to bar petitioners from joining after the nine-month time period of 35 U.S.C. §321(c), it would have provided explicit language so stating in 35 U.S.C. §325(c). Moreover, Ascendis cites no explicit authority precluding joinder of a party to a PGR because the petition to be joined is outside of the nine-month window prescribed by 35 U.S.C. §321(c).

While Section 321(c) states a PGR petition “may only be filed not later than” 9 months after the patent grant, Section 311(c) states an IPR petition “shall be filed after the later of either (1) the date that is 9 months after the grant of a patent; or (2) if a post-grant review is instituted . . . the termination of such post-grant review.” 35 U.S.C. §§321(c), 311(c). Both provisions, however, are silent with respect to joinder, and neither addresses the situation where the nine-month date has passed but an IPR is not available due to a pending PGR. The silence as to restrictions on joinder and the gap between when proceedings may be initiated indicate that joinder may be permitted outside the nine-month window prescribed by 35 U.S.C. §321(c). If joinder were not permitted during that period, it would create a time period where a patent is not eligible for any new review before the PTAB; a potential challenger would have no available recourse. This cannot be what Congress intended.

The Opposition suggests that Zydus is wrong to contend that “there is no statute or rule” precluding joinder for time-barred PGR petitioners. Opposition, 3. The Opposition goes on to state that Section 325(c) imposes its own prerequisites: a PGR petition must be “properly filed” and must “warrant[] the institution of a post-grant review under section 324.” *Id.* The purpose of joinder under 35 U.S.C. § 325(c) is to allow additional parties to participate in an already-instituted proceeding. The Opposition only points to the allegedly untimely filing of the Petition but provides no substantive reason why the Petition was not “properly filed.” The timeliness issue

is addressed by 37 C.F.R. §42.222(b), which permits requests for joinder “no later than one month after the institution date of any post-grant review for which joinder is requested.” Ascendis’s interpretation of the statute effectively eliminates joinder under 37 C.F.R. §42.222(b), because institution decisions are due six months after a PGR petition is accorded a filing date and thus nearly always issue after the nine-month date. Again, this cannot be what Congress intended.

As to “warranting institution,” the Board has already determined that the petition warrants institution. The Zydus petition relies on the identical grounds and arguments of the Ascendis petition, and the Board instituted the PGR in the proceeding involving Ascendis. Thus, the Zydus petition also warrants institution.

Like with IPRs, the nine-month period in 35 U.S.C. §321 is a statutory deadline for initiating a petition, but it does not restrict the Director’s authority under 35 U.S.C. §325(c) to join petitions outside a statutory bar. The statutory language of 35 U.S.C. §325(c) explicitly grants discretion to the Director.

B. Joinder Does Not Undermine AIA Policy or Public Interest

The Opposition incorrectly asserts that joinder would contravene AIA policy and public interest. Opposition, 4-5. As stated in the Motion, and undisputed by Ascendis, the Board “routinely grants motions for joinder” where the party seeking joinder introduces identical arguments and grounds raised in the existing proceeding. Motion, 3-4. If joinder contravened AIA policy or public interest, the Board would

not routinely grant joinder in IPR proceedings and the statute would not contemplate joinder. This is true even when there is a statutory bar to an IPR petition filing.

As to the public interest and private disputes, the Opposition cites *Magnolia Med. Techs., Inc. v. Kurin, Inc.*, IPR2026-00097, Paper 17 at 6 (Dir. May 14, 2026) for the proposition that the public interest is already being served in PGR2026-00013. *Id.* However, should BioMarin and Ascendis settle, then the public would not have the benefit of the Board resolving the patentability issues that were raised. This does not serve the public interest when the Board has already found that the petition in that proceeding shows it is “more likely than not” that at least one of the challenged patent claims is unpatentable. The Board should correct the Patent Office’s error (not merely resolve the private dispute between Ascendis and BioMarin) as this would serve the public interest to improve patent quality.

The Opposition further suggests that joinder undermines the spirit of AIA reviews and longstanding public policy favoring settlement. Citing *VusionGroup SA*, the Opposition suggests that absent joinder Ascendis and BioMarin remain free to settle and terminate PGR2026-00013. Opposition, 4 (citing *VusionGroup SA v. Hanshow Tech. Co. Ltd.*, IPR2024-00857, Paper 28 at 3 (PTAB July 14, 2025)). But *VusionGroup* merely states that there are policies that favor settlement. It does not address joinder whatsoever. Without joinder, the public does not get the benefit of the Board resolving what it has already determined is “more likely than not” an error

made by the Patent Office.

Finally, as to hardship on Zydus, the cost and time associated with district court litigation, as Ascendis is well aware, is a significant hardship as compared to the cost and time of joining a PGR proceeding.

C. Joinder Would Not Add Complexity to the Proceeding

The Opposition asserts that joinder would not improve efficiency, suggesting that there are unresolved questions regarding discovery. Opposition, 5. This is not correct. As long as the Ascendis PGR remains pending and Ascendis remains active following joinder, no additional briefing or discovery would be needed. Zydus will adopt an “understudy” role and would only assume the primary role if Ascendis ceases to participate in the PGR. *See, e.g., Mylan Pharmaceuticals Inc. v. Novartis AG et al.*, IPR2015-00268, Paper 17 at 5 (PTAB Apr. 10, 2015). Thus, for Ascendis, there should be no complexity issue at all. As to Patent Owner concerns, they may be resolved by the conditions suggested by Patent Owner. *See* Patent Owner Opposition to Motion for Joinder, 9-10. These are conditions to which Zydus can adhere. It is thus appropriate to join the proceedings under those conditions.

II. CONCLUSION

For the foregoing reasons, Zydus respectfully requests that its Petition be instituted and the proceeding be joined with *Ascendis Pharma A/S v. BioMarin Pharmaceutical Inc.*, PGR2026-00013.

Respectfully submitted,

Date: July 16, 2026

/Roger H. Lee/

Roger H. Lee (Reg. No. 46,317)

BUCHANAN INGERSOLL & ROONEY PC

1700 K Street, N.W., Suite 300

Washington, DC 20006

Tel (703) 838-6545 / Fax (202) 452-7989

roger.lee@bipc.com

Counsel for Petitioners

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITIONERS' REPLY TO ASCENDIS'S OPPOSITION TO PETITIONERS' MOTION FOR JOINDER** is being served on this 16th day of July, 2026 via electronic mail as follows:

Counsel for Patent Owner

Naveen Modi

Eric Dittmann

Isaac S. Ashkenazi

Chetan Bansal

Gabrielle Landes

PAUL HASTINGS LLP

PH-Ascendis-BioMarin-PGR@paulhastings.com

Counsel for Petitioner Ascendis Pharma A/S in PGR2026-00013

David H. Holman, Ph.D. (dholman-PTAB@sternekessler.com)

Pratibha Khanduri (pkhanduri-PTAB@sternekessler.com)

Olga A. Partington (opartington-PTAB@sternekessler.com)

Eric Steffe (esteffe-PTAB@sternekessler.com)

STERNE, KESSLER, GOLDSTEIN & FOX PLLC

1101 K Street, NW, 10th Floor

Washington, DC 20005

PTAB@sternekessler.com

Date: July 16, 2026

/Roger H. Lee/

Roger H. Lee (Reg. No. 46,317)

BUCHANAN INGERSOLL & ROONEY PC

1700 K Street, N.W., Suite 300

Washington, DC 20006

Tel (703) 838-6545 / Fax (202) 452-7989

roger.lee@bipc.com

Counsel for Petitioners