

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 PATENT OWNER'S OPPOSITION
TO PETITIONERS' MOTION FOR JOINDER**

TABLE OF CONTENTS

	Page
I. ARGUMENT	1
A. Zydus’s Petition and Motion Are Timely	1
B. Zydus’s Petition Was Properly Filed	2
C. Joinder Does Not Add Complexity to the Proceeding	4
D. Limitations on Zydus’s Participation in the Proceedings	5
II. CONCLUSION.....	5
CERTIFICATE OF SERVICE	

TABLE OF AUTHORITIES

Cases	Page(s)
<i>Apple v. RFCyber Corp.</i> , PGR2022-00003, Paper 10 (PTAB Mar. 24, 2022)	2
 Statutes	
35 U.S.C. §311(c)	3, 4
35 U.S.C. §321(c)	1, 3, 4
35 U.S.C. §325(c)	1, 2
 Other Authorities	
37 C.F.R. §42.53	4
37 C.F.R. §42.222(b)	1, 2, 3, 4

Petitioners Zydus Lifesciences Limited, Zydus Lifesciences Global FZE, and Zydus Pharmaceuticals (USA) Inc. (collectively, “Zydus”) respectfully submit this Reply to Patent Owner’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”). Zydus’s Motion does not create undue complexity. Nevertheless, in order to mitigate the Patent Owner’s concern, Zydus is willing to abide by the conditions proposed in pages 9-10 of the Opposition. 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 Zydus’s Petition and Motion are not timely under 35 U.S.C. §321(c). Opposition, 3-4. This is not correct. 35 U.S.C. §321(c) does not state that a party may not join a pre-existing timely filed PGR through joinder. Here, Patent Owner was aware of the filing of the Ascendis petition and the arguments made therein before the statutory bar had lapsed. Zydus is merely relying on that proceeding and the arguments made in the Ascendis petition.

The Opposition states that none of the cases cited in the Motion supports instituting a PGR filed more than nine months after the patent grant. Thereafter, the

Opposition cites *Apple v. RFCyber Corp.*, PGR2022-00003, Paper 10, at 3 (PTAB Mar. 24, 2022) as evidence of a long history of denying institution where a petitioner failed to file within the nine-month statutory bar. However, the Opposition cites to no explicit authority precluding joinder of a party to a PGR because the petition to be joined is outside of the nine-month window. As indicated in the Motion, the Board has a long history of joining otherwise barred parties. Motion, 6.

Further, the Board in *Apple* does not provide authority for denying joinder in the present case. In *Apple*, the Board's decision on joinder did not turn on the fact that petitioner filed its petition after the nine-month window. In that case, the petition was also filed after the one-month period allowed by 37 C.F.R. §42.222(b), and the Board declined to waive that one-month joinder period. *Apple*, PGR2022-00003, Paper 10, at 3-5. Further, the Board recognized that there was already a settlement between the parties to the first filed PGR. *Id.* at 6. Since the joinder motion was considered untimely and a settlement between the original parties had occurred, the petition was considered untimely. This is not the case here as Zydus filed its motion for joinder within the 30-day period permitted by 37 C.F.R. §42.222(b) and there is no stated settlement between Ascendis and Patent Owner.

B. Zydus's Petition Was Properly Filed

Section 325(c) states: "The Director may consolidate... if more than 1 petition... is properly filed against the same patent and the Director determines that

more than 1 of these petitions warrants the institution of post-grant review....” This language emphasizes that consolidation and joinder are discretionary and contingent upon the petitions “properly filed” and “warranting institution.” The statute does not specify that petitions must be filed within the nine-month window. Instead, it allows the Board to evaluate whether the petitions, regardless of timing, warrant institution and can be consolidated for efficiency. Had Congress intended the nine-month window to apply to joined petitions it would have provided so in the statute.

The Opposition incorrectly asserts that Zydus’s Petition was not properly filed. Opposition, 4-7. Ascendis submitted a PGR challenging the claims of the ’106 Patent within 9 months of the patent issuing, and the PGR was instituted on May 6, 2026. Zydus filed its Petition and Motion on June 5, 2026, under 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.” Patent Owner fails to provide a single case suggesting that Zydus’s Petition and Motion were improper.

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.

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 read out the express permission under 37 C.F.R. §42.222(b) and 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.

C. Joinder Does Not Add Complexity to the Proceeding

The Opposition asserts that joinder would add complexity to the proceeding. Opposition, 7-9. It does not. Reliance on Dr. Bargman’s declaration—adopting the opinions of Dr. Abuzzahab—does not create undue complexity or prejudice. The concern about depriving BioMarin of due process by allowing reliance on Dr. Abuzzahab’s opinions and later deposing Dr. Bargman can be addressed through appropriate procedural safeguards. The PTAB has authority under 37 C.F.R. §42.53 to set schedules and procedures for depositions and cross-examinations. The Board can, for example, permit BioMarin to depose Dr. Bargman, or to cross-examine Dr.

Abuzzahab if necessary, ensuring fairness without causing undue delay.

Zydus will stand by the declaration and cross-examination testimony of Dr. Abuzzahab. The declaration from Dr. Bargman explicitly states she has “reviewed and adopted” Dr. Abuzzahab’s opinions. It is only if Ascendis drops out of the proceeding that Dr. Bargman may be necessary and then Dr. Bargman will be available for cross-examination. No duplication is required.

D. Limitations on Zydus’s Participation in the Proceedings

In recognition that the Board may join the proceedings, the Opposition outlines conditions that should be imposed on the joined proceedings. Opposition, 9-10. Zydus acknowledges that the conditions proposed by the opposition—such as page limits, prior Board approval for actions, restrictions on discovery, and limitations on oral participation—are workable, acceptable, and can effectively address Patent Owner’s concerns about efficiency, complexity, and prejudice.

Zydus’s willingness to accept the proposed conditions demonstrates its good faith commitment to facilitating an efficient and fair consolidation of proceedings. This acceptance underscores that joinder can be achieved without compromising the rights of any party or creating undue complexity.

II. CONCLUSION

For the reasons provided above and in the Motion, Zydus respectfully requests that its Petition be instituted and this proceeding be joined with PGR2026-00013.

Respectfully submitted,

Date: August 6, 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 PATENT OWNER'S OPPOSITION TO PETITIONERS' MOTION FOR JOINDER** is being served on this 6th day of August, 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: August 6, 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