

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.,
Petitioner,

v.

BIOMARIN PHARMACEUTICAL INC.,
Patent Owner.

Case PGR2026-00055
Patent No. 12,233,106 B2

PATENT OWNER'S PRELIMINARY RESPONSE

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LIST OF EXHIBITS

Exhibit No.	Description	Previously Submitted
2001	Press Release: FDA Approves First Drug to Improve Growth in Children with Most Common Form of Dwarfism, FDA (Nov. 19, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-improve-growth-children-most-common-form-dwarfism .	X
2002	Press Release: U.S. Food and Drug Administration Approves BioMarin's VOXZOGO® (vosoritide) for Children Under 5 Years with Achondroplasia, BioMarin (Oct. 20, 2023), https://www.biomin.com/news/press-releases/u-s-food-and-drug-administration-approves-biominins-voxzogo-vosoritide-for-children-under-5-years-with-achondroplasia/ .	X
2003	<i>BioMarin Pharmaceutical Inc. v. Zydus Lifesciences Ltd.</i> , 1:26-cv-1005, D.I. 1 (D.N.J.)	X
2004	Correspondence with Honorable Board	

I. INTRODUCTION

Patent Owner BioMarin Pharmaceutical Inc. (BioMarin” or “PO”) respectfully submits this Preliminary Response to the Petition for Post-Grant review (Paper 4) (“Petition” or “Pet.”) filed by Petitioners Zydus Lifesciences Limited, Zydus Lifesciences Global FZE, and Zydus Pharmaceuticals (USA) Inc. (“Zydus” or “Petitioners”) against claims 1-14 of U.S. Patent No. 12,233,106 (“the ’106 patent”). For the reasons explained below, the Petition should be denied under 35 U.S.C. § 324(a).

II. ZYDUS’S MOTION FOR JOINDER SHOULD BE DENIED AS MOOT AND THE PETITION DENIED AS UNTIMELY

On June 5, 2026, Zydus filed an untimely petition for PGR of the ’106 patent nearly 15 months after its issuance and well past the nine-month statutory bar. *See* 35 U.S.C. § 321(c); *see generally* *Zydus Lifesciences Ltd. v. BioMarin Pharmaceutical Inc.*, PGR2026-00055, Paper 4 (P.T.A.B. June 5, 2026). Zydus attempts to excuse its delay by arguing that its untimely petition should nonetheless be granted because it seeks to join the already-instituted PGR filed by Ascendis Pharma A/S (“Ascendis”), PGR2026-00013 (“Ascendis PGR”). *See* PGR2026-00055, Paper 5, at 5-6 (P.T.A.B. June 5, 2026).

On September 16, 2026, however, Ascendis and BioMarin notified the Board that the parties had “executed a binding settlement term sheet” and

requested “authorization to file a Joint Motion to Terminate the proceeding.” *See* Ex. 2004, Correspondence to Honorable Board at 2; *see also* Press Release, BioMarin Announces Global Settlement with Ascendis Pharma A/S; Ascendis Will Pay Royalties to BioMarin on Yuviwel Sales in U.S., EU, Brazil and South Korea, BioMarin (Aug. 30, 2026), <https://www.biomin.com/news/press-releases/biomin-announces-global-settlement-with-ascendis-pharma-a-s-ascendis-will-pay-royalties-to-biomin-on-yuviwel-sales-in-u-s-eu-brazil-and-south-korea/>. The Board granted the parties authorization to file the joint motion. Ex. 2004 at 1. As such, BioMarin and Ascendis expect the Ascendis PGR to be terminated before the Board decides Zydus’s motion for joinder.

Assuming the Board grants Ascendis’s and BioMarin’s Joint Motion to Terminate the proceeding, the Ascendis PGR will no longer exist and, therefore, “cannot serve as a proceeding to which another proceeding may be joined.” *See Google Inc. v. Personal Web Techs. LLC*, IPR2014-00980, Paper 10, at 6 (P.T.A.B. Oct. 30, 2014). As such, Zydus’s motion for joinder should be denied as moot. *See id.* Without a proceeding to be joined, Zydus’s Petition for PGR—standing alone¹—is untimely and should be denied. *See id.* at 6 (denying the

¹ Even if the Ascendis PGR is not terminated, Zydus’s motion for joinder and petition should be denied as untimely for the reasons discussed in BioMarin’s opposition to Zydus’s motion for joinder. *See* PGR2026-00055, Paper 9, at 4-7 (P.T.A.B. Jul. 6, 2026).

petition as untimely); *see also* PGR2026-00055, Paper 9, at 3-4 (P.T.A.B. Jul. 6, 2026).

III. CONCLUSION

For the reasons stated above, Zydus's motion for joinder should be denied as moot and its Petition for PGR denied as untimely.

Respectfully submitted,

Dated: September 18, 2026

By: /Naveen Modi/
Naveen Modi (Reg. No. 46,224)
Counsel for Patent Owner

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that the foregoing Patent Owner's Preliminary Response contains, as measured by the word-processing system used to prepare this paper, 455 words. This word count does not include the items excluded by 37 C.F.R. § 42.24.

Respectfully submitted,

Dated: September 18, 2026

By: /Naveen Modi/
Naveen Modi (Reg. No. 46,224)
Counsel for Patent Owner

CERTIFICATE OF SERVICE

I hereby certify that on September 18, 2026, I caused a true and correct copy of the foregoing Patent Owner's Preliminary Response to be served via email on Petitioner at the following addresses:

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