

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 PGR2026-00055
U.S. Patent No. 12,233,106

**ASCENDIS PHARMA A/S's OPPOSITION TO
PETITIONER ZYDUS'S MOTION FOR JOINDER**

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Pursuant to the Board’s authorization of June 25, 2026, Petitioner in PGR2026-00013, Ascendis Pharma A/S (“Ascendis”), files this Opposition to Petitioner Zydus Lifesciences Ltd.’s (“Zydus”) Motion for Joinder of PGR2026-00055 with PGR2026-00013. Zydus’s motion should be denied for several reasons.

First, Zydus’s PGR petition is time-barred under 35 U.S.C. § 321(c). As the Director explained in *Elong*, the Board must “first determine[] whether to institute a proceeding” before considering joinder. *Elong Int’l USA Inc. v. Feit Elec. Co., Inc.*, IPR2025-00258, Paper 16 at 2 (Act. Dir. June 25, 2025) (precedential). Zydus’s petition is ineligible for institution (and, therefore, joinder) because it was filed after the statutory deadline. Congress provided a joinder exception to the IPR time- bar, but not to the PGR filing deadline. The inquiry should end there.

Second, joinder would not advance the purposes of AIA review. “Unlike court proceedings, AIA reviews are not solely about resolving ‘a private dispute’ ... The Office institutes review to reconsider its own decision and correct a possible error in the original patent grant—not to shield a particular petitioner from infringement liability.” *Magnolia Med. Techs., Inc. v. Kurin, Inc.*, IPR2026-00097, Paper 17 at 6 (Dir. May 14, 2026) (precedential) (internal citation omitted). That public interest objective is already being served in PGR2026-00013, where the Board is reviewing the very same patent. Zydus’s decision to copy Ascendis’s instituted grounds does not independently justify institution or joinder. *Apple Inc.*

v. Squires, 166 F.4th 1349, 1353 (Fed. Cir. 2026) (“[n]o law compels institution.”).

Nor is Zydus deprived of a forum: it can litigate the ’106 patent’s validity in district court. *See e.g.*, Zydus Petition at 88.

Third, joinder would frustrate the PTO’s strong public policy favoring settlement. Trial Practice Guide (“TPG”), § N (“[t]here are strong public policy reasons to favor settlement between the parties to a proceeding”). Absent joinder, Ascendis and BioMarin can settle and jointly seek termination of the PGR. Joining Zydus would give a non-party veto power over that result, contrary to the PTO’s policy.

Fourth, adding Zydus and its expert would reduce—not enhance—efficiency. Although Zydus alleges its expert would participate only if Ascendis exits the case, that proposal raises significant uncertainties regarding briefing, expert testimony, and cross-examination.

Accordingly, Zydus’s request is time-barred, unnecessary to further any AIA objective, contrary to the PTO’s policy favoring settlement, and procedurally inefficient. Joinder should be denied.

I. JOINDER IS FORECLOSED BY 35 U.S.C. §§ 321(C) AND 325(C).

There is no dispute that Zydus’s petition is untimely: it was filed on June 5, 2026, nearly 16 months after the ’106 patent’s February 25, 2025, grant date. Title 35 U.S.C. § 321(c) prohibits a PGR petition filed later than “9 months after the

date of the grant of the patent.” *Id.* Zydus’s petition is therefore time-barred under § 321(c). And because “[t]he Board first determines whether to institute a proceeding before considering a motion for joinder,” the first decision here must be denial of institution. *Elong* at 2.

While the IPR joinder statute expressly permits joinder, notwithstanding § 315(b)’s time bar, Congress included no comparable exception in the PGR statute. *Compare* 35 U.S.C. § 315(c) *with* § 325(c). Zydus therefore is wrong to contend that “there is no statute or rule” precluding joinder for time-barred PGR petitioners. Mot. at 6-7. Section 325(c) imposes its own pre-requisites: a PGR petition must be “properly filed” *and* must “warrant[] the institution of a post-grant review under section 324.” Zydus satisfies neither. Its petition was filed seven months after the § 321(c) deadline and thus was not properly filed. Nor can a time-barred petition warrant institution under § 324. Congress’s intent is clear: it created a joinder exception to the IPR time bar in § 315(c), but omitted any such exceptions from § 325(c). The Board must give effect to that choice. Zydus’s *motion* may have been “timely” under 37 C.F.R. § 42.222, but its’s *petition* fails the statutory mandates of §§ 321(c) and 325(c).

Zydus’s cited authority is inapposite. Mot. at 6. Two of the cited cases involve IPRs, where Congress expressly authorized joinder of time-barred petitions, and the lone PGR case did *not* involve a time-barred petition. None

supports joinder here.

II. JOINDER HERE WOULD CONTRAVENE AIA POLICY AND PUBLIC INTEREST.

Joinder would undermine both the spirit of AIA reviews and longstanding public policy favoring settlement. As Director Squires recently explained, “AIA [r]eviews [r]elate to the [p]ublic [i]nterest” and are not “solely about resolving ‘a private dispute’.” *Magnolia* at 6. The public interest is already being served in PGR2026-00013. Joining Zydus would not further the Board’s reconsideration of patentability; it would merely add another petitioner to an existing proceeding.

Joinder would also undermine the PTO’s “strong public policy reasons” favoring settlement. *See VusionGroup SA v. Hanshow Tech. Co. Ltd.*, IPR2024-00857, Paper 28 at 3 (P.T.A.B. July 14, 2025); TPG, § N . Absent joinder, Ascendis and BioMarin remain free to settle and seek termination of PGR2026-00013. Joining Zydus would allow a non-party to keep the proceeding alive despite a settlement. Nor is Zydus entitled to a PGR simply because it filed its petition. *Apple* at 1353; *Magnolia* at 7. Further, denial of joinder imposes no hardship on Zydus, as Zydus itself acknowledges that other avenues remain available (e.g., IPR or *ex parte* reexamination). Mot. at 8. And Zydus is free to litigate validity of the ’106 patent in district court. Petition at 89.

Zydus’s request for joinder embodies the very concern identified in *Magnolia*. AIA reviews were intended to provide an “*alternative* to district court

patent litigation for resolving disputes over patent validity.” *Magnolia* at 2. As a party already litigating the ’106 patent in district court, Zydus is not seeking an “alternative” to litigation; it is seeking to maintain an AIA proceeding in parallel with litigation “to gain litigation leverage.” *Id.* at 3.

III. JOINDER WOULD NOT IMPROVE EFFICIENCY.

Zydus argues that its proposed understudy role would improve efficiency, but it would do the opposite. Zydus’s proposal raises unresolved questions regarding expert discovery, threatening to complicate the established schedule in PGR2026-00013. For example, Zydus introduces a new expert without addressing how her testimony or cross-examination would be handled in PGR2025-00013. Nor does Zydus explain how its expert’s testimony would coexist with that of Ascendis’s expert. Although Zydus attests that its witness “adopts” as her own the opinions of Ascendis’s expert, the two experts have different professional backgrounds and experiences that could lead to different testimony and require separate cross-examinations. Joinder would add procedural complexity and uncertainty, not efficiency.

“Petitions filed by time-barred parties should proceed only in exceptional circumstances.” *Realtek Semiconductor Corp. v. ParkerVision, Inc.*, IPR2025-00324, Paper 11 at 3 (Act. Dir. June 25, 2025) (precedential). Zydus identified none. Joinder should be denied.

Respectfully submitted,

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CERTIFICATION OF SERVICE (37 C.F.R. § 42.6(e))

The undersigned hereby certifies that on July 7, 2026, a true and correct copy of **ASCENDIS PHARMA A/S's OPPOSITION TO PETITIONER ZYDUS'S MOTION FOR JOINDER** was served electronically via e-mail in its entirety on the following counsel:

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