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' OPPOSITION TO PATENT'S OWNER'S BRIEF REQUESTING DISCRETIONARY DENIAL

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I. INTRODUCTION

The Director should deny Patent Owner's Brief Requesting Discretionary Denial (Paper 13, "DD Brief") and institute this Petition (Paper 4, "Petition"). Patent Owner's brief is largely an attempt to further argue its opposition to Zydus's motion requesting joinder. Issues of joinder are irrelevant to discretionary considerations. Patent Owner had its opportunity to submit an opposition to Zydus's motion for joinder. Now Patent Owner conflates the issues to hide its lack of substantive arguments concerning discretionary considerations. Patent Owner's brief should be rejected for this reason alone.

Notwithstanding Patent Owner's improper attempt to conflate joinder and discretionary denial, Patent Owner's assertions regarding the timing of the filing of the Petition are incorrect. The Petition is timely. Zydus properly sought joinder with PGR2026-00013 ("Ascendis PGR") pursuant to 35 U.S.C. §325(c) and 37 C.F.R. §42.222(b). Neither the statute nor the rule state that a party may not join an earlier filed proceeding when otherwise time barred. Further, in the Ascendis PGR, the Board has already determined that 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.

There is not a sufficient basis for discretional denial, and Patent Owner does

not provide one. A weighing of the Fintiv factors strongly supports institution and there are no other factors that warrant discretionary denial. There are no settled expectations. No other forum has reviewed the patentability or validity of the claims. The General Plastic factors favor institution.

For at least all the reasons stated above, and more fully discussed below, Patent Owner's request for discretionary denial should be denied.

II. ARGUMENT

A. Patent Owner's Assertion that Zydus's Petition and Motion for Joinder are Untimely has Already Been Fully Briefed and is Irrelevant to Discretionary Denial

Patent Owner's leading argument—that Zydus's Petition and Motion for Joinder are untimely—is irrelevant to the issue at hand which is discretionary denial. "The Board first determines whether to institute a proceeding before considering a motion for joinder." *Elong Int'l USA Inc. v. Feit Electric Co., Inc.*, IPR2025-00258, Paper 16, at 2 (PTAB June 25, 2025) (precedential). *See also id.* ("discretionary considerations are first reviewed for the Petition on its own, and then reviewed if joinder were to be granted."). *Elong* distinguishes discretionary considerations from joinder issues, stating that discretionary considerations are to be reviewed "first"

"before" considering issues of joinder.[1] Inexplicably, Patent Owner has centered its discretionary denial arguments on issues of joinder. *See, e.g.,* DD Brief at 4 ("Zydus's joinder request does not excuse the time bar"), 5 ("Zydus's late-filed petition and request for joinder also add complexity"), 6 ("instituting the petition through joinder could result in procedural hurdles and additional complexity"). Patent Owner's joinder arguments are irrelevant to the issue of discretionary denial and should be rejected.[2]

Patent Owner asserts that "Zydus's joinder request does not excuse the time bar" and that "Zydus's petition for PGR was filed on June 6, 2026, over 15 months after the '106 patent issued and well past the nine-month statutory bar." DD Brief at 4. Patent Owner offers nothing more than what was argued in its opposition to Zydus's motion for joinder. Patent Owner's attempt to rehash its opposition to Zydus's motion for joinder is improper and should be ignored as an unauthorized sur-reply to Zydus's motion for joinder.

Patent Owner's presentation of joinder arguments in its discretionary denial

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[1] Patent Owner concedes this. DD Brief at 4 ("discretionary considerations are first reviewed for a petition as if joinder were not sought.").

[2] Patent Owner's arguments concerning joinder are also without merit. *See* §II.B., *infra*.

briefing violates 37 C.F.R. §42.6(a)(3). Throughout Patent Owner's brief, it cites Zydus's motion for joinder and responds to the arguments presented therein as a basis for discretionary denial. DD Brief at 4-5. However, the Board provides for separate briefing schedules for reviewing the distinct issues of discretionary denial and joinder. *See, e.g.,* 37 C.F.R. §42.122; Memorandum on Interim Processes dated March 26, 2025; *Elong*, IPR2025-00258, Paper 16. Further, 37 C.F.R. §42.6(a)(3) states that "[c]ombined motions, oppositions, replies, or other combined documents are not permitted." Patent Owner's presentation of arguments concerning joinder in its discretionary denial briefing violates the rule, memorandum, and precedent which provide clear demarcation between joinder and discretionary denial briefing. Patent Owner's request is improper and should be rejected.

B. Zydus's Petition and Motion are Timely

Notwithstanding the above, Zydus's Petition and Motion for Joinder are timely.[3] Zydus sought joinder with PGR2026-00013 ("Ascendis PGR") pursuant to 35 U.S.C. §325(c) and 37 C.F.R. §42.222(b). Zydus's Petition is substantively identical to the Ascendis Petition that the Director instituted on May 6, 2026. *See*

[3] Patent Owner's arguments concerning joinder are improper and irrelevant to discretionary considerations. *See* §II.A., *supra*. For completeness, Zydus demonstrates herein that Patent Owner's joinder arguments also lack merit.

EX1065; *see also* Petition at 1. As a copycat petition seeking joinder with an already-instituted proceeding presenting the same grounds and the same prior art, Zydus's Petition should be favored for institution.

1. Zydus's Petition and Motion are Consistent with Relevant Statutes and Rules

Zydus's Petition and Motion are timely under 35 U.S.C. §325(c) and 37 C.F.R. §42.222(b). Neither the statute nor the rule 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, while Patent Owner asserts that "[Zydus] provides no reason why its petition should be exempt from the statutory bar" and "the Board has a history of denying institution where a petitioner failed to properly file a PGR before the nine-month statutory bar" (DD Brief at 4), it 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).

Zydus's Petition and Motion for Joinder are appropriate under 37 C.F.R. §42.222(b) for at least five reasons. First, the Board has a long history of joining parties under the facts in this case where Zydus has committed to remain a silent understudy and not raise any new issues. *See, e.g., Sony Mobile Commc'ns AB et al.*, IPR2021-00663, Paper 17 at 29-33 (PTAB Jun. 10, 2021); *Samsung Elecs. Co., Ltd.*,

PGR2022-00045, Paper 9 at 9-12; and *Samsung Elecs. Co., Ltd.,* IPR2014-01518, Paper 10 at 6 (PTAB Mar. 18, 2015).

Second, there are no cases to date that Zydus is aware of that precludes 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). Applying such a condition on joinder would not make sense given the long history of the PTAB permitting joinder of parties to IPR proceedings when outside the one-year bar date of 35 U.S.C. §315(b). And, there is no statute or rule that states that the nine-month window for filing a PGR applies to joinder requests. While Section 321(c) states that a PGR petition "may only be filed not later than" 9 months after the patent grant, Section 311(c) states that 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 address the intervening period after the nine-month date but when an IPR is not yet available due to a pending PGR.

Third, "[p]etitions for post-grant review are favored because they must be filed no later than nine months from the grant of the patent (35 U.S.C. §321(c)), are close in time to examination, and occur before expectations in the patent rights are strongly settled." *Multi-Color Corp. v. Brook & Whittle Ltd*., PGR2025-00025, Paper 10 at 2-3 (PTAB Jul. 16, 2025) (precedential). *See also, LifeVac, LLC v.*

DCSTAR Inc., IPR2025-00454, Paper 11 at 2 (PTAB Jul. 11, 2025). Here, the '106 Patent issued on February 25, 2025, *i.e.*, very close in time to examination and before expectation in patent rights are strongly settled and Ascendis filed its PGR petition within nine months of issuance.

Fourth, allowing joinder to a PGR, even if the patent issued more than 9 months before the request for joinder is filed, will increase efficiency of proceedings before the Patent Office. Specifically, this approach allows a motion for joinder to be accompanied by a substantively identical petition covering the same grounds for challenging the patent. It also increases the odds that a PGR will remain active until the Board issues a final written decision.

Fifth, if 37 C.F.R. §42.222(b) were interpreted to not allow a motion for joinder to be filed simultaneously with a petition, Zydus would be required to pursue other less-efficient avenues (*e.g.*, an *inter partes* review, which limits the types of grounds that can be brought (for example, no challenges under 35 U.S.C. §112) or *ex parte* reexamination, which would proceed on a separate track with different filing requirements). The PTAB's final decision is scheduled to issue well before the district court's trial in the parallel litigation based on current data.[4] *See* Section

[4] The parallel litigation is Case No. 1:26-cv-01005 (D.N.J.) filed February 2, 2026.

IV.B.4.a. Allowing for joinder aligns with the intent of the AIA to provide for efficient resolution of patentability issues in view of pending district court litigation.

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.

2. Joinder Does Not Undermine AIA Policy or Public Interest

It is undisputed by Ascendis that the Board "routinely grants motions for joinder" where the party seeking joinder introduces identical arguments and grounds raised in the existing proceeding. 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.

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.

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

3. Joinder Would Not Add Complexity to the Proceeding

Patent Owner asserts that the "late-filed petition and request for joinder also adds complexity to the proceedings." DD Brief at 5. Patent Owner provides no evidence of added complexity. Because Zydus relies on grounds of unpatentability that are identical to Ascendis's, the case is amenable to consolidated filings and discovery, which will simplify the briefing and discovery process. 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). As to the testimony of Dr. Abuzzahab and Bargman, the declarations are substantively the same. There is no reason for duplicative discovery as Zydus has agreed to rely upon the testimony of Dr.

Abuzzahab. It is only if BioMarin drops out of the proceeding that Dr. Bargman will be needed and then the proceeding will continue to follow the same schedule just with another expert.[5]

C. This is Patent Owner's Second Attempt to Seek Discretionary Denial

This is Patent Owner's second attempt to seek discretionary denial of proceedings challenging the '106 Patent, and this attempt, like the first one, does not warrant discretionary denial. *See* PGR2026-00013, Paper 6. The Director rejected Patent Owner's arguments and instituted the proceeding. *See* PGR2026-00013, Papers 12, 14.

A joinder petition is not an occasion to give Patent Owner successive opportunities to seek discretionary denial. The purpose of joinder under 35 U.S.C. §325(c) is to allow additional parties to participate in an already-instituted proceeding. This is especially true where, as here, the joinder petitioners' substantive

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[5] If Ascendis ceases to participate and Zydus is required to rely on Dr. Abuzzahab, there would be no impact on the Board's ability to complete its review in a timely manner. Moreover, there would only be a modest impact on Patent Owner, given that Zydus's contingent expert's opinions are virtually identical to those already introduced and relied upon by Ascendis's expert.

challenge is identical to the one the Director has already found meritorious.

Setting aside Patent Owner's irrelevant and meritless joinder arguments, all that remains is Patent Owner's patchwork discretionary denial analysis that completely overlooks key Fintiv factors, absence of settled expectations, absence of review by other forums, and absence of General Plastic concerns, discussed below. The Board already recognized the public's interest in patent quality by instituting review of the Ascendis PGR.

D. Fintiv Factors Do Not Warrant Discretionary Denial

Patent Owner summarily asserts that *Fintiv* factors 1-4 weigh in favor of denial of institution. DD Brief, pp. 7-8. Patent Owner is incorrect. *Fintiv* factors 1-4 weigh strongly in favor of institution.

Fintiv Factor 1—Patent Owner asserts that Zydus cannot guarantee a stay of the district court litigation. DD Brief at 7. While no stay has yet been granted in the parallel litigation, the district court will likely stay the parallel litigation pending the outcome of the PGR. According to Docket Navigator, the district court has granted stays pending resolution of IPR proceedings over 80% of the time. *See* EX1071. Given the fact that no stay has yet been requested or ordered, this factor is at most neutral to the analysis.

Fintiv Factor 2—Patent Owner fails to specifically address this factor in its motion. This is because the district court has not yet set a trial date, and current data

suggests that the trial will likely occur after the PTAB reaches a final written decision in the related PGR. According to Docket Navigator, the district court's average time to trial excluding outlier cases and cases with stays is 28 months and the median time to trial is 27 months. *See* EX1072. The PTAB's final decision will issue prior to the district court's trial. As such, institution would not unduly prejudice Patent Owner and aligns with the efficient resolution of the patentability issues in view of the pending district court proceedings. Fintiv factor 2 strongly weighs in favor of institution.

Fintiv Factor 3— Patent Owner fails to specifically address this factor in its motion. There has been no depositions, expert reports, or claim construction proceedings in the parallel district court case. The absence of these critical litigation milestones indicates that the district court proceeding is still in its early stages and has not advanced to a point where it would significantly prejudice the patent owner if review is instituted now. This early stage of the district court case supports a finding that institution at this time would not unduly prejudice the patent owner and aligns with the goal of efficient dispute resolution. Fintiv factor 3 strongly weighs in favor of institution.

Fintiv Factor 4—Citing no evidence, Patent Owner speculates that the "co-pending district court litigation is between the same parties and will be adjudicating infringement and validity of the same." DD Brief at 7. However, Patent Owner fails

to mention that Zydus has already stipulated consistent with *Sotera Wireless, Inc. v. Masimo Corp*., IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020), "if the Board institutes post-grant review in this proceeding, PGR2026-00055 (and does not subsequently vacate institution), Zydus will not pursue in the related litigation, Case No. 1:26-cv-01005 (D.N.J.) filed February 2, 2026, an invalidity defense based on any ground that was raised or reasonably could have been raised in this post-grant review before the Board with respect to U.S. Patent No. 12,233,106." PGR2026-00055, Paper 5 at 13. Thus, there will be no "overlap between issues raised in the petition and in the parallel proceeding." *Apple v. Fintiv*, IPR2020-00019, Paper 11 at 6. This stipulation ensures that the issues to be adjudicated in this proceeding are distinct from those in the district court, thereby minimizing the risk of inconsistent rulings and reducing the potential prejudice to the patent owner. The lack of overlapping issues supports the institution of review at this stage. Fintiv factor 4 strongly weighs in favor of institution.

Prior to addressing the remaining Fintiv factors, Patent Owner asserts that "Congress created AIA reviews as a 'quick and cost-effective alternative to district court patent litigation'—not as a tool for leverage in a co-pending parallel litigation." DD Brief, pp. 7-8 (citing *Magnolia Med. Techs., Inc. v. Kurin, Inc.*, IPR2026-00097, Paper 17 at 2 (Dir. May 14, 2026) (precedential)). However, in *Magnolia*, Petitioner had the opportunity to litigate the issues fully and fairly before the district court, did

so, and lost, and then attempted to use the Office as a repeat challenge or second bite at the apple to undo its litigation loss. *Magnolia,* IPR2026-00097, Paper 17 at 10. The facts in that case have no applicability in the present case. Zydus is not requesting a second bite at the apple. The Director recognized that "the mere existence of co-pending litigation in and of itself may not necessarily raise concerns" (*id.* at 3), and the Fintiv factors heavily favor institution as explained herein.

Fintiv Factor 5—Although the parties in the district court and this proceeding are the same, the differences in the scope, issues, and procedural posture of the two proceedings suggest that the overlap is limited. The similarity of parties alone should not outweigh the overall considerations favoring institution at this stage.

Fintiv Factor 6—The present petition is essentially a copycat, mirroring the arguments and grounds raised in the Ascendis PGR petition that the Board has already instituted review on. The institution of review on the earlier petition indicates that the Board has already identified substantial questions regarding patentability and determined that it is "more likely than not" that at least one challenged claim is unpatentable. Given that the Board has already instituted review based on a prior petition, the overall merits of the patent challenge are strong. This factor weighs in favor of proceeding with review to promote judicial economy and consistency. Fintiv factor 6 strongly weighs in favor of institution.

Patent Owner asserts that "Zydus cannot show that its alleged invalidity

theories are compelling enough to override the potential procedural complexities" and "Zydus has another forum in which it can adjudicate the patent's validity." DD Brief at 9. However, Patent Owner fails to provide any argument or evidence that there are procedural complexities. Moreover, Patent Owner's bald assertions cannot outweigh the public interest when the Board has already found that the petition 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. As to Patent Owner's assertion that there is another forum, this is the case with respect to almost all IPR and PGR cases, but the statute does not exclude a petitioner's ability to avail itself of the Board when there are other options to challenge the claims of a patent. Instead, the statute specifically contemplates a petitioner's ability to file a petition after it has been served with a complaint. *See* 35 U.S.C. §321(c). This argument makes no sense in light of the clear intent of Congress.

E. Other Discretionary Denial Factors Weigh in Favor of Institution

1. Absence of Settled Expectations Weighs in Favor of Institution

Patent Owner fails to address settled expectations. This is because Patent Owner does not have settled expectations as to the validity of the '106 Patent. The '106 Patent issued on February 25, 2025, *i.e.,* close in time to examination and

before expectation in patent rights are strongly settled. Further, Patent Owner has been aware of Ascendis's Petition previously filed within the nine-month statutory time frame. That the PGR has been instituted further demonstrates the absence of any settled expectations. This factor weighs in favor of institution.

2. Lack of Other Forums Reviewing Patentability or Validity Weighs in Favor of Institution

Patent Owner fails to address whether other forums have reviewed the '106 Patent. Aside from the Ascendis PGR, there has been no prior review or determination of the '106 Patent's patentability or validity. Allowing the review to proceed at this stage is consistent with the purpose of the PGR process—to provide a comprehensive and efficient mechanism for challenging patents that have not yet undergone adversarial scrutiny, thereby promoting patent quality and ensuring that only valid patents remain enforceable. This factor weighs in favor of institution.

3. The General Plastic Factors Weigh in Favor of Institution

Patent Owner fails to address the General Plastic factors. This is Zydus's first petition against the claims of the '106 Patent. Zydus has not coordinated with Ascendis or any other party regarding its Petition and has not discussed its Petition with any other party other than to seek Ascendis's position on whether it opposes its Motion for Joinder. Accordingly, the factors in *General Plastic Indus. Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 9-10 (PTAB Sept. 6, 2017), which relate to serial filings by the same party or by parties coordinating their filings,

are not relevant here and do not weigh in favor of denying institution. *See Sony Mobile Commc'ns AB et al.,* IPR2021-00663, Paper 17 at 11-15 (PTAB Jun. 10, 2021) (finding factors weigh "strongly" in favor of institution of petition where joinder was sought and the joining party had not previously filed a challenge to the claims of the patent); *Netflix, Inc. v. Broadcom Corp.*, IPR2020-01423, Paper 7 at 5-6 (PTAB Mar. 11, 2021). This factor weighs in favor of institution.

III. CONCLUSION

Patent Owner's request for discretionary denial should be denied.

Respectfully submitted,

Date: September 18, 2026

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APPENDIX A – EXHIBIT LIST

Exhibit No.	Description
1065	Notice of Decisions on Institution, *Ascendis USA, Inc. et al v. BioMarin Pharmaceutical Inc.*, PGR2026-00013, Paper 14.
1071	Docket Navigator Statistics on Motions to Stay Pending IPRs and PGRs (downloaded June 1, 2026)
1072	Docket Navigator Statistics on Time to Trial (downloaded June 1, 2026)

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITIONERS' OPPOSITION TO PATENT OWNER'S BRIEF REQUESTING DISCRETIONARY DENIAL** was served on this 18th day of September, 2026 via electronic mail as follows:

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