

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 BRIEF REQUESTING DISCRETIONARY DENIAL

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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 .	
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/ .	
2003	<i>BioMarin Pharmaceutical Inc. v. Zydus Lifesciences Ltd.</i> , 1:26-cv-1005, D.I. 1 (D.N.J.)	

TABLE OF AUTHORITIES

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Cases

<i>Apple Inc. v. RFCyber Corp.</i> , PGR2022-00003, Paper 10 (P.T.A.B. Mar. 24, 2022)	4
<i>Elong Int’l USA Inc. v. Feit Electric Co., Inc.</i> , IPR2025-00258, Paper 16 (June 25, 2025).....	4
<i>Magnolia Med. Techs., Inc. v. Kurin, Inc.</i> , IPR2026-00097, Paper 17 (Dir. May 14, 2026)	7
<i>Mylan Pharms. Inc. v. Janssen Oncology, Inc.</i> , IPR2016-01332, Paper 21 (P.T.A.B. Jan. 10, 2017)	5
<i>Realtek Semiconductor Corp. v. Parkervision, Inc.</i> , IPR2025-0324, Paper 11 (P.T.A.B. June 25, 2025)	4
<i>Sony Corp. v. Raytheon Co.</i> , IPR2016-00209, Paper 14 (P.T.A.B. Mar. 29, 2016)	5

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I. INTRODUCTION

Patent Owner BioMarin Pharmaceutical Inc. (“BioMarin”) respectfully requests that the Director deny institution of Petitioners Zydus Lifesciences Limited, Zydus Lifesciences Global FZE, and Zydus Pharmaceuticals (USA) Inc. (“Zydus”)’s Petition challenging U.S. Patent No. 12,233,106 (“the ’106 patent”, Ex. 1001). Denial is appropriate for at least three reasons. First, Zydus failed to timely file its Petition within the nine-month window prescribed by Section 321(c), and its joinder request does not excuse that statutory bar. Moreover, joining Zydus to the Ascendis PGR is likely to invite unnecessary complexity to the proceeding.

Second, the same parties are litigating infringement and validity of the same patent in a parallel district court action that has not been stayed. As such, review here would be duplicative—rather than in place—of that litigation. Third, the ’106 patent covers the use of Voxzogo[®], an FDA-approved therapy that BioMarin developed for children with achondroplasia (a rare genetic condition). BioMarin’s years of investment in that therapy reflect precisely the innovation the patent system seeks to protect. BioMarin is a U.S.-based innovator that bore the risk and expense of bringing Voxzogo[®] to patients, while Zydus—a predominantly foreign generic manufacturer that invested nothing in that development—now seeks to appropriate the benefit of that investment through an untimely collateral attack on the resulting patent.

Under these circumstances, instituting review would be an inefficient use of the Board's limited resources. As such, Patent Owner respectfully requests the Director exercise its discretion and deny Zydus's Petition for PGR.

II. BACKGROUND

The '106 patent relates to an FDA approved drug marketed and sold by BioMarin known as Voxzogo[®]. BioMarin's Voxzogo[®] was first approved by the FDA in November 2021 for the treatment of achondroplasia in children 5 years of age and older. Ex. 2001, Press Release: FDA Approves First Drug to Improve Growth in Children with Most Common Form of Dwarfism, FDA (Nov. 19, 2021). Achondroplasia is a rare genetic condition causing "severely short stature and disproportionate growth." Voxzogo[®] was the first drug approved for the treatment of achondroplasia. On October 20, 2023, the FDA expanded the approval of Voxzogo[®] to children under 5 years of age. *See* Ex. 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).

In approving Voxzogo[®], the FDA recognized its importance to treating this rare disease: "Today's approval fulfills an unmet medical need for more than 10,000 children in the United States With this action, children with short stature due to achondroplasia have a treatment option that targets the underlying cause of their short stature." Ex. 2001. As such, BioMarin's years of investment in

researching and developing Voxzogo[®] to treat children with achondroplasia—and being the first to do so—is the exact innovation the patent system is designed to protect.

In February 2025, BioMarin filed a complaint against Zydus for patent infringement under, *inter alia*, 21 U.S.C § 355(j) (the “Hatch-Waxman Act”). Ex. 2003, BioMarin Compl. at 1; *see also BioMarin Pharmaceutical Inc. v. Zydus Lifesciences Ltd.*, 1:26-cv-01005 (D.N.J.). Importantly, the filing of the Complaint stems from Zydus’s submission of an Abbreviated New Drug Application (“ANDA”) to the FDA, which included a Paragraph IV certification that it intended to “market and sell in the United States a purported generic version of VOXZOGO[®] . . . prior to the expiration of the ’106 patent.” *Id.* at 3. Filing an ANDA with a Paragraph IV certification constitutes an artificial act of infringement. *See* 35 U.S.C. § 271(e)(2). Although the district court litigation has just begun, the parties have already exchanged interrogatories and document requests, and Zydus’s noninfringement and invalidity contentions are due September 3.

III. THE PETITION SHOULD BE DENIED AS UNTIMELY

Section 321(c) mandates that “[a] petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent.” 35 U.S.C. § 321(c). The ’106 patent issued on February 25, 2025. The

nine-month statutory bar for filing a petition for post-grant review, therefore, was November 25, 2025. *See* 35 U.S.C. § 321(c). 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. Zydus’s petition, therefore, is untimely.

Zydus’s joinder request does not excuse the time bar. *See also Elong Int’l USA Inc. v. Feit Electric Co., Inc.*, IPR2025-00258, Paper 16 (June 25, 2025) (discretionary considerations are first reviewed for a petition as if joinder were not sought) (precedential). Indeed, Zydus itself “acknowledges that the ’106 patent issued more than 9 months ago,” but provides no reason why its petition should be exempt from the statutory bar. *See* Zydus Mot. for Joinder (“Mot.”) at 5; *see also Realtek Semiconductor Corp. v. Parkervision, Inc.*, IPR2025-0324, Paper 11, at 3 (P.T.A.B. June 25, 2025) (“Petitions filed by time-barred parties should proceed only in exceptional circumstances.”) (precedential). None of the cases cited by Zydus supports instituting a PGR not properly filed within nine months of patent issuance. *Id.* Rather, the Board has a history of denying institution where a petitioner failed to properly file a PGR before the nine-month statutory bar. *See, e.g., Apple Inc. v. RFCyber Corp.*, PGR2022-00003, Paper 10, at 3 (P.T.A.B. Mar. 24, 2022) (denying institution because the petition was filed more than nine months after the challenged patent was granted). Zydus’s failure to comply with the statutory time-bar compels denial of the petition.

Zydus's late-filed petition and request for joinder also add complexity to the proceedings. For example, Zydus's expert, Dr. Renee Bargman, has *adopted* Dr. Abuzzahab's opinions as her own. *See* Mot. at 9 (admitting that Dr. Bargman has "reviewed and *adopted* the opinions" set forth in Dr. Abuzzahab's declaration); EX1066 ("I have reviewed the Declaration of Dr. Mary Jennifer Abuzzahab, M.D., [and] I adopt the background, opinions, and conclusions set forth in the Abuzzahab Declaration as shown below."). Zydus attempts to argue that this is of no consequence to BioMarin because Zydus is "prepared to rely solely on the testimony of Ascendis's expert." Mot. at 9. But Zydus also asserts that, "if Ascendis settles prior to a final written decision," Zydus would then "elect to rely on its own expert." Mot. at 9. Zydus's position unquestionably adds complexity to the proceedings.

Allowing Zydus to rely on the testimony of Dr. Abuzzahab, only to swap in Dr. Bargman at the eleventh hour, would deprive BioMarin of due process. The only remedy, then, would be to allow BioMarin to depose Dr. Bargman to the extent Zydus's PGR is instituted and joined with the Ascendis PGR, which would necessarily occur after BioMarin's Patent Owner Response is due in the Ascendis PGR. But this would only add unnecessary complexity to the proceedings and could potentially result in duplicative discovery and delay, which further supports denying Zydus's Petition and joinder. *See, e.g., Mylan Pharms. Inc. v. Janssen*

Oncology, Inc., IPR2016-01332, Paper 21, at 11 (P.T.A.B. Jan. 10, 2017) (denying joinder because it was after the patent owner’s response and “would require adjusting the schedule”); *Sony Corp. v. Raytheon Co.*, IPR2016-00209, Paper 14, at 5 (P.T.A.B. Mar. 29, 2016) (“[B]ecause Patent Owner has already filed its Patent Owner Response in the [initial] IPR, Patent Owner would no longer benefit from many of the efficiencies that potentially could be achieved through joinder.”).

Moreover, even if BioMarin and Ascendis were to settle and terminate PGR2026-00013—as Zydus argues is the reason its petition should be instituted—Zydus’s untimely filed petition should not be allowed to move forward. Zydus argues it should be allowed to join the Ascendis PGR to “preserve Zydus’s rights in the event that the Ascendis PGR is settled.” But Zydus has no rights to PGR review because it filed its Petition after the 9-month statutory bar. As such, instituting the petition through joinder could result in procedural hurdles and additional complexity in terminating the PGR2026-00013 should BioMarin and Ascendis chose to settle.

For the reasons stated above, the Board should exercise its discretion and deny institution and joinder.

IV. ZYDUS'S ATTEMPT TO CONVERT PTAB REVIEW INTO LITIGATION LEVERAGE FAVORS DENIAL

A. *Fintiv* Factors 1–4: Zydus Cannot Guarantee a Stay of the District Court Litigation

The co-pending district court litigation is between the same parties and will be adjudicating infringement and validity of the same patent. *See generally* Ex. 2003; *see also BioMarin Pharmaceutical Inc. v. Zydus Lifesciences Ltd.*, 1:26-cv-1005 (D.N.J.). Zydus argues that because no stay has yet been requested or ordered, that factor 1 is therefore “at most neutral.” Mot. at 12. But Zydus also states—without citing any authority—that “the district court will likely stay the parallel litigation pending the outcome of the PGR.” Mot. at 11. Importantly, however, no stay to date has been granted. To the contrary, fact discovery is proceeding in that matter, including Zydus’s invalidity contentions that are due in less than three weeks.

The Board should not allow Zydus to use the PTAB as an alternative to the district court. As the Board has repeatedly recognized, 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. *Magnolia Med. Techs., Inc. v. Kurin, Inc.*, IPR2026-00097, Paper 17 at 2 (Dir. May 14, 2026) (precedential) (emphasis added). Indeed, the Director has warned against institution where a petitioner may be attempting to use PTAB review to “shield”

itself from infringement liability in a parallel litigation. *Id.* at 2-3, 6. Zydus’s petition is precisely that—an attempt to use the Board as an alternative to litigation and to stay the district court case in which it faces infringement liability. Mot. at 11. Instead of accepting Zydus’s invitation, the Board should exercise its discretion to deny institution.

Therefore, *Fintiv* factors 1-4 weigh in favor of denial.

**B. *Fintiv* Factor 5: Zydus’s Claims
Can Be Adjudicated at the District Court**

As discussed above, the parties here are the same as the parties in the parallel district court action. *See BioMarin Pharmaceutical Inc. v. Zydus Lifesciences Ltd.*, No. 1:26-cv-01005 (D.N.J.). Although Zydus acknowledges that fact, it nonetheless asks the Director to institute so it may “preserve Zydus’s rights in the event that the Ascendis PGR is settled.” Mot. at 2. But Zydus’s “rights” in adjudicating noninfringement and validity are preserved in the district court litigation to which it is a party. As such, *Fintiv* fact 5 weighs in favor of denial.

**C. *Fintiv* Factor 6: The Merits Do Not
Outweigh the Potential Procedural Complexities**

Zydus’s asserted merits do not change the calculus. Zydus argues that the merits are strong because “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” in the Ascendis PGR. Mot. at 14. But the

Board's considerations in that PGR were different than this PGR. Here, Zydus cannot show that its alleged invalidity theories are compelling enough to override the potential procedural complexities discussed above. Moreover, Zydus has another forum in which it can adjudicate the patent's validity—which was not the case in the Ascendis PGR.

The broader equities reinforce that conclusion. The '106 patent covers the use of Voxzogo[®], the first therapy approved to target the underlying cause of achondroplasia, which BioMarin developed at substantial risk and expense over many years and brought to more than 10,000 children in the United States who previously had no such option. Ex. 2001; Ex. 2002. That is precisely the innovation the patent system—and the AIA's balance between correcting erroneously granted claims and protecting settled patent rights—is meant to protect. Zydus, by contrast, is a predominantly foreign generic manufacturer that invested nothing in the research, development, or clinical validation of Voxzogo[®], and that seeks to capture the benefit of BioMarin's investment by filing an ANDA with a Paragraph IV certification and then mounting an untimely collateral attack on the same patent more than fifteen months after issuance. Ex. 2003 at 3; 35 U.S.C. § 321(c). Where a time-barred petitioner's asserted merits are neither compelling nor unavailable in another forum, the Board should not devote its limited resources to a proceeding that would devalue a validly issued patent

reflecting exactly the kind of investment-backed innovation Congress sought to encourage.

As such, *Fintiv* factor 6 weighs in favor of denial.

V. CONCLUSION

BioMarin respectfully requests that the Director deny the Petition.

Dated: August 18, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that I caused to be served on the counsel identified below a true and correct copy of the foregoing Patent Owner's Brief Requesting Discretionary Denial of Institution by electronic means on August 18, 2026:

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