

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAREPTA THERAPEUTICS, INC.,
Petitioners,

v.

GENZYME CORPORATION,
Patent Owner.

Case No. IPR2026-00150
Patent No. 12,031,894

**PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW OF THE
DECISION GRANTING INSTITUTION**

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I. Introduction

Patent Owner Genzyme Corporation (“Genzyme”) respectfully requests Director Review and reversal of the Decision on Institution granting institution of *inter partes* review (“IPR”) of U.S. Patent No. 12,031,894 (“’894 patent”), filed by Petitioner Sarepta Therapeutics, Inc. (“Sarepta”). See Paper 16 (“DI”). 37 CFR § 42.75(c). Reversal is warranted to align the outcome of this Petition with the goals espoused in recent Director decisions and the results in five other IPRs filed by Sarepta. Sarepta filed seven IPR petitions challenging every patent asserted by Genzyme in the concurrent district court litigation—yet this is the only challenge to be instituted to date. Allowing this IPR to proceed would result in precisely the type of “unnecessary trial” that Director Review is designed to prevent. Director Review Process at 2.B (“The Director Review process provides a mechanism to correct errors at the institution stage, for example, to avoid unnecessary trials for patent owners”).¹

The Director’s grant of institution overlooked two significant issues previewed by Genzyme’s Discretionary Denial Request² (“Paper 12”): the Board’s

¹ <https://www.uspto.gov/patents/ptab/decisions/director-review-process>.

² Patent Owner’s Request for Discretionary Denial, IPR2026-00150, Paper 12 (Feb. 4, 2026).

denial of institution in several other proceedings concerning patents at issue in the parties' parallel district court litigation (Paper 12, 6-7) and the Board's recent informative decisions regarding the use of IPR to gain the upper hand in litigation (Paper 12, 8-9). 37 C.F.R. §§ 42.71(d); 42.71(c). Both support denial of institution.

First, this single instituted proceeding will only impose unnecessary burden on the Board, the district court, and Genzyme. Out of seven patents challenged by Sarepta in IPRs, this is the only challenge to be instituted, with one IPR petition still at the pre-institution stage. Thus, this IPR is not an alternative to the district court litigation. Rather, the district court case will continue with respect to this and the other asserted patents. Proceeding with this IPR would only saddle the Board, district court, and the parties with a duplicative dispute that may result in conflicting outcomes. Paper 12, 3-4. This risk is particularly acute here because Sarepta's IPR2026-00149 challenging related U.S. Patent No. 12,013,326 ("326 patent"), which is in the same family as the '894 patent, was not instituted. At the time of the Director's March 23, 2026 decision to "review[] [the Petition] for merits and non-discretionary considerations" (Paper 15), three of Sarepta's now-rejected IPRs were pending and had not yet been denied institution. Thus, events subsequent to the Director's decision on discretionary factors confirm that the most efficient course of action to avoid inconsistent outcomes is to deny institution of

the Petition. This would allow the district court to exclusively handle all patents-in-suit, including the '894 at issue here and its related '326 patent.

Second, Sarepta's strategy "is less about [IPR as] a litigation alternative and more about inconsistent positions to gain an upper hand in the overall litigation." *Ford Motor Co. v. AutoConnect Holdings, LLC*, IPR2025-01342, Paper 27 at 3 (Director May 12, 2026) (informative) ("*AutoConnect*") (quoting *Terumo BCT Inc. v. Haemonetics Corp.*, IPR2025-01374, Paper 20 (Director May 12, 2026) (informative)). Sarepta's "invalidity contentions in the related district court proceedings [] argued all the challenged claims are indefinite," but Sarepta's Petition made no attempt to reconcile its obviousness arguments with its indefiniteness contentions, or to explain how the asserted unpatentability grounds could prove allegedly indefinite claims obvious. *Id.* at 2-3; *see also* Paper 12 at 8 ("Sarepta's invalidity contentions in the district court litigation are far more expansive and include §§ 101 and 112 arguments"). According to the Director's recently designated decisions, "it is appropriate to deny institution" where Petitioner has taken such a posture. *Id.*

The Director's recent institution denials and informative decisions conflict with the institution decision here. Reversal of institution of this IPR will foster a streamlined adjudication of related patents in one forum. Genzyme respectfully requests Director Review and reversal of the DI granting IPR institution.

II. Institution Overlooked the Burden Created by Instituting Only One of Seven IPRs Challenging Patents in the Parallel Litigation

As detailed in Genzyme’s Discretionary Denial briefing (Paper 12, 2), institution of this IPR does not advance “the goals of the AIA—namely, to improve patent quality and make the patent system more efficient by the use of post-grant review procedures.” *General Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 16 (PTAB Sept. 6, 2017). Sarepta filed eight serial and parallel petitions concurrent with the district court litigation—not as an alternative to litigation, but as a tool to gain leverage. Paper 12, 7-9. The Director’s institution decision in this one IPR overlooked Genzyme’s arguments previewing the risk of creating duplicative, and potentially inconsistent, outcomes that should result in discretionary denial. *Id.*, 1-3, 7-9.

A. An IPR Trial Concerning the ’894 Patent Presents a Significant Risk of Duplicative and Conflicting Outcomes

Sarepta has filed eight IPR challenges on seven patents—every patent asserted by Genzyme in the concurrent district court litigation. Aside from the instant Petition, five petitions were denied institution, and a sixth was withdrawn by Sarepta for its failure to comply with the statute governing IPR challenges. Sarepta refiled the withdrawn petition, making eight total IPRs challenging seven patents, as illustrated by the table below.

Family	Patent No.	IPR No.	Filed	Status
Compositions and Methods to Prevent AAV Vector Aggregation	9,051,542	2025-01194	June 26, 2025	Discretionary Denial Nov. 20, 2025
	7,704,721	2025-01195	June 26, 2025	Discretionary Denial Nov. 20, 2025
Analytical Ultracentrifugation for Characterization of Recombinant Viral Particles	12,013,326	2026-00149	Nov. 25, 2025	Denied Institution May 6, 2026
	12,031,894	2026-00150	Nov. 25, 2025	Instituted May 6, 2026
Methods for Detecting AAV	12,298,313	2026-00166	Dec. 2, 2025	Withdrawn Mar. 25, 2026 ³
	12,298,313	2026-00270	Feb. 26, 2026	Pending
	11,698,377	2026-00167	Dec. 2, 2025	Denied Institution May 15, 2026
	12,123,880	2026-00168	Dec. 2, 2025	Denied Institution May 15, 2026

Sarepta’s filing strategy reflects an abuse of the IPR process, with its lower burden of proof and limited petitioner estoppel provision, as a vehicle to improve its leverage in district court litigation. Paper 12, 8-9. For example, months after filing its statutorily barred IPR petition of U.S. Patent No. 12,298,313 (the “’313 patent”), Sarepta withdrew that petition, but only after Genzyme highlighted its

³ Sarepta moved to withdraw its IPR2026-00166 on February 26, 2026, the same day it filed IPR2026-00270 challenging the same patent.

impropriety.⁴ Rather than filing an earlier post-grant review (“PGR”) challenge, Sarepta filed, in serial, a second IPR petition challenging the ’313 patent, IPR2026-00270. Sarepta could have raised all of its grounds for invalidity in a timely filed PGR but deliberately chose the narrower IPR vehicle, presumably to limit its estoppel exposure, even though Sarepta was statutorily barred. Because of its delayed filing, the pending ’313 patent IPR presents numerous factors weighing in favor of discretionary denial, including the fact that the district court trial is scheduled to occur months before a Final Written Decision and that the case will be at an advanced stage well before an institution decision is due.⁵

Sarepta’s pending challenge of the ’313 patent is also likely to fail on the merits. Sarepta’s petition of the ’313 patent presents similar merits arguments to the denied petitions challenging U.S. Patent Nos. 11,698,377 and 12,123,880,

⁴ Patent Owner’s Request for Discretionary Denial, *Sarepta Therapeutics, Inc. v. Genzyme Corp.*, IPR2026-00166, Paper 9 (Feb. 4, 2026); Petitioner’s Motion to Withdraw, IPR2026-00166, Paper 10 (Feb. 26, 2026).

⁵ Patent Owner’s Request for Discretionary Denial, *Sarepta Therapeutics, Inc. v. Genzyme Corp.*, IPR2026-00270, Paper 8 at 6-10 (May 5, 2026).

which are related to the '313 patent.⁶ Thus, the IPR of the '313 patent is likely to result in the sixth institution denial for Sarepta.

Compounding the inefficiency of proceedings between the Board and the district court if this IPR proceeds is the Director's institution denial of IPR2026-00149 challenging the '326 patent. The '326 patent is in the same family as the '894 patent and relates to similar technology. Sarepta's district court invalidity contentions group the '326 and '894 patents together. Ex. 2018, 14-43. Thus, the district court is likely to consider their validity in tandem. This will inevitably lead to duplicative, and potentially conflicting, efforts in both proceedings.

The Director has repeatedly held that it is inefficient to institute an IPR after it has denied institution as to other patents from the same parallel district court proceeding. *See Samsung Elecs. Co. v. VB Assets, LLC*, IPR2025-00870, Paper 11 at 2-3 (PTAB Oct. 10, 2025) ("there are six patents at issue in the parallel district court proceeding, the two patents challenged in these proceedings and four patents challenged in other petitions filed by Petitioner, in which institution was denied In view of this, Patent Owner persuasively argues that addressing all of the challenged patents in the district court proceeding would be 'the fastest and most

⁶ Notice of Decisions on Institution, *Sarepta Therapeutics, Inc. v. Genzyme Corp.*, IPR2026-00167, -00168, Paper 13 (Director May 15, 2026).

efficient resolution of the Parties’ many disputes.”); *Amazon.com, Inc. v. Audio Pod IP, LLC*, IPR2025-00768, Paper 15 at 3 (Director Aug. 14, 2025) (“the district court will be considering the validity of the patents challenged in [other IPRs where institution was denied], along with the validity of the patent challenged in IPR2025-00768, and referring IPR2025-00768 to the Board would be an inefficient use of Board resources and tips the balance to discretionary denial as to that patent too.”); *Samsung Elecs. Co. v. ICashe, Inc.*, IPR2025-00641, Paper 12 at 3 (Director Aug. 14, 2025) (same). The facts here—where an IPR challenging only one of seven patents being litigated in the district court action is likely to remain before the Board—present an extremely inefficient use of Board resources. This alone is a sufficient reason for the Director to reverse institution.

B. The District Court Is Even More Unlikely to Stay any Aspect of the Case Based on the Many Institution Denials

Sarepta has not requested a stay. Regardless, a stay of the district court litigation is even more improbable now than when the Director declined to discretionarily deny institution on March 26, 2026. Paper 12, 3. Now, five of six IPRs considered by the Director have been denied institution, and a sixth petition is likely to produce another institution denial. *Supra* § II.A. Thus, six of seven patents-in-suit will likely be exclusively before the district court.

Additionally, the Director denied institution of the petition challenging the related ’326 patent. *See* IPR2026-00149, Paper 14. Like the ’894 patent, the ’326

patent relates to analytical ultracentrifugation methods. Sarepta's district court invalidity contentions group the '326 and '894 patents together, such that the district court is likely to consider their validity in tandem. Ex. 2018, 14-43.

Judge Andrews, the judge presiding over the parallel litigation, and other District of Delaware judges have rejected stays even where multiple patents-in-suit were subject to instituted IPRs, but other patents remained for trial. *See Collabo Innovations, Inc. v. Sony Corp.*, No. 15-cv-1094-RGA, D.I. 43 (D. Del. Jan. 5, 2017) ("Some simplification will be achieved by the three IPRs, but the fourth patent and its claims will have to be litigated regardless."); *Ansell Healthcare Prods. LLC v. Reckitt Benckiser LLC*, No. 15-cv-915-RGA, D.I. 105 (D. Del. Dec. 1, 2016) (denying motion to stay when "[n]o IPR is sought on two of the four asserted patents."); *RainDance Techs., Inc. v. 10X Genomics, Inc.*, No. 15-cv-152-RGA, D.I. 37, 38 (D. Del. Apr. 6, 2016) (denying motion to stay when Board instituted IPRs on two of the six asserted patents). *See also Cerebrum Sensor Techs., Inc. v. Revvo Techs., Inc.*, No. 24-cv-245-JLH-SRF, D.I. 117 (D. Del. Oct. 17, 2025) (denying motion to stay where IPRs on two of three asserted patents were instituted and case would proceed on the third patent); *Inmar Brand Sols., Inc. v. Quotient Tech. Inc.*, No. 23-cv-994-JFM, D.I. 141 (D. Del. Apr. 4, 2025) (denying motion to stay where PTAB instituted IPRs on two of three asserted patents and denied institution on the third).

Given that six of seven patents-in-suit will likely proceed exclusively in the district court—including the closely related ’326 patent—a stay of the district court litigation is nearly inconceivable. Maintaining this lone IPR only imposes duplicative burden on the Board, district court, and parties without any efficiency gains, and serves no legitimate purpose under the AIA. Paper 12, 6-8.

III. Sarepta’s Petition Fails to Address Its District Court Indefiniteness Contentions

Sarepta’s failure to address how its district court indefiniteness contentions impact its obviousness grounds is a further basis for discretionary denial. Indeed, Sarepta could have filed a PGR to address all patentability issues in a single forum, which would have been a true alternative to litigation. *Id.*, 8-9 (citing Ex. 2018). A petitioner’s failure to explain inconsistent positions taken in district court litigation and an IPR is a basis for discretionary denial, as explained in the Board’s recently designated decisions. *E.g.*, *AutoConnect* at 2-3 (citing *Revvo Techs., Inc. v. Cerebrum Sensor Techs., Inc.*, IPR2025-00632, Paper 20 (Director Nov. 3, 2025) (precedential)); *Tesla, Inc. v. Intell. Ventures II LLC*, IPR2025-00340, Paper 18 at 4 (Director Nov. 5, 2025) (informative).

Genzyme’s Discretionary Denial Request noted that Sarepta had raised § 112 issues in its contentions. Paper 12, 8-9 (citing Ex. 2018). Sarepta’s contentions argue that the claims of the ’894 patent are indefinite because, among other things, “[d]ifferent experimental conditions or sedimentation velocity

methods may yield different results. The ['326 and '894 patents] provide insufficient clarity regarding the scope of the claimed methods.” Ex. 2018, 43 (citing *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014)). Sarepta’s Petition, however, never reconciles the obviousness arguments in the Petition with its indefiniteness contentions, nor does it address how the asserted prior art renders the claims obvious even if they are indefinite, as Sarepta alleges. Sarepta alleged that the skilled artisan would be unable to determine with reasonable certainty whether the “experimental conditions or sedimentation velocity methods” fall within the scope of the claims. Ex. 2018, 43. Sarepta’s Petition never explained how or why the cited experimental conditions and velocity methods from the purported prior art would render the claims obvious despite this alleged uncertainty.

As the petitioner, Sarepta bears the burden of explaining why a claim may be anticipated or obvious despite indefiniteness. *See AutoConnect* at 2-3. Sarepta failed to meet this burden by not addressing how its indefiniteness contentions impact its prior art patentability arguments. This failure underscores that Sarepta seeks to use the IPR process not as a litigation alternative, but as a tool to gain a tactical advantage in the overall dispute. Paper 12, 8-9. Indeed, this strategy aligns with its conduct in the challenge of the '313 patent in withdrawn IPR2026-00166

and late-filed IPR2026-00270. *Supra* § II.A. Thus, Sarepta's failure to address its indefiniteness contentions in its Petition is further basis to deny institution.

IV. Conclusion

The denial of institution as to five, and likely six, of seven challenged patents, including the related '326 patent, renders a stay of the district court litigation virtually inconceivable. Maintaining this IPR would result in two '894 patent validity disputes proceeding in parallel with the attendant inefficiencies and risk of inconsistent outcomes. Moreover, Sarepta's failure to reconcile its district court indefiniteness contentions with its obviousness grounds in this proceeding confirms that the Petition is directed not at serving as a litigation alternative, but at gaining a strategic advantage in the overall dispute. Accordingly, Genzyme respectfully requests that the Director reverse the institution decision and deny institution of *inter partes* review of the '894 patent.

Dated: May 20, 2026

/Blaine M. Hackman/

Blaine M. Hackman, Reg. No. 67,479
Counsel for Patent Owner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that today in

Sarepta Therapeutics, Inc., v. Genzyme Corporation, IPR2026-00150

I caused to be served a copy of:

**PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW OF
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