

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAREPTA THERAPEUTICS, INC.,
Petitioners,

v.

GENZYME CORPORATION,
Patent Owner.

Case No. IPR2026-00270
Patent No. 12,298,313

PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL

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PATENT OWNER’S EXHIBIT LIST

Exhibit No.	Description
2001	Declaration of Katherine A. Helm
2002	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-00882) D.I. 78 – Joint Stipulation to Amend Scheduling Order
2003	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-00882) D.I. 59 – Notice of Service of Plaintiff’s Initial Claim Charts on Infringement
2004	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-00882) D.I. 68 – Notice of Service of Defendant’s Initial Invalidity Contentions
2005	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-00882) D.I. 28 - Notice of Service of Plaintiff’s First Set of Requests for Production of Documents and Things
2006	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-00882) D.I. 35 - Notice of Service of Defendant’s First Set of Requests of Production of Documents and Things to Plaintiff and First Set of Interrogatories and Initial Disclosures
2007	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-00882) D.I. 37 - Notice of Service of Plaintiff’s Second Set of Interrogatories and Second Set of Requests for Production of Documents and Things
2008	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-00882) D.I. 45 – Notice of Service of Plaintiff’s First Set of Interrogatories and Third Set of Requests for Production of Documents and Things
2009	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-00882) D.I. 67 - Notice of Service of Defendant’s Second Set of Requests of Production of Documents and Things to Plaintiff and First Set of Interrogatories
2010	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-00882) D.I. 83 - Notice of Service of Defendant’s Amended Second Set of Requests of Production of Documents and Things to Plaintiff and First Set of Interrogatories
2011	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-00882) D.I. 87 - Notice of Service of Defendant’s Third Set of Requests of Production of Documents and Things to Plaintiff
2012	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-

Exhibit No.	Description
	00882) D.I. 91 – Notice of Service of Plaintiff’s Responses to Defendants Third Set of Requests for Production of Documents and Things
2013	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-00882) D.I. 92 - Notice of Service of Plaintiff’s Fourth Set of Requests for Documents and Things
2014	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-00882) D.I. 99 – Notice of Service of Plaintiff’s Fifth Set of Requests for Documents and Things
2015	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-00882) D.I. 102 – Notice of Service of Defendant’s Fourth Set of Requests of Production of Documents and Things to Plaintiff
2016	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-00882) D.I. 110 – Notice of Service of Plaintiff’s Sixth Set of Requests for Production of Documents and Things
2017	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-00882) D.I. 76 – Second Amended Complaint
2018	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-00882) - Defendant’s Supplemental Initial Invalidity Contentions
2019	U.S. Patent No. 11,698,377
2020	Prosecution History Excerpts for U.S. Patent No. 11,698,377
2021	Van Vliet, Kim et al., Adeno-Associated Virus Capsid Serotype Identification: Analytical Methods Development and Application, 159 <i>Journal of Virological Methods</i> 167–177 (2009)
2022	Bark, Steven et al., High-Temperature Protein Mass Mapping Using A Thermophilic Protease, 123 <i>J. Am. Chem. Soc.</i> 1774-76 (2001)
2023	<i>Genzyme Corporation v. Sarepta Therapeutics Inc.</i> (1:24-cv-00882) D.I. 162 – Markman Order (April 27, 2026)

I. Introduction

The Board should discretionarily deny the *inter partes* review (“IPR”) Petition challenging U.S. Patent No. 12,298,313 (“’313 patent”) filed by Petitioner Sarepta Therapeutics, Inc. (“Sarepta”). This Petition is a textbook case for discretionary denial under 35 U.S.C. § 314(a): it would spawn a costly, duplicative parallel proceeding that serves no purpose other than to give Sarepta a second bite at the apple of unpatentability.

Sarepta is responsible for the duplication and inefficiency it now asks this Board to reward. Sarepta was informed of the ’313 patent’s issuance on May 1, 2025 (Ex. 2017, ¶ 57)—prior to its May 13 issuance—and Sarepta had every opportunity to file a Post-Grant Review (“PGR”) petition challenging the ’313 patent in December 2025, when it filed petitions challenging related U.S. Patent Nos. 11,698,377 (the “’377 patent”) and 12,123,880 (the “’880 patent”) (collectively the “LC-MS Patents”). *Sarepta Therapeutics, Inc. v. Genzyme Corp.*, IPR2026-00167, 168 (PTAB Dec. 2, 2025).

Instead, Sarepta filed an improper, statutorily-barred, IPR against the ’313 patent. Whether it was to avoid the broad provisions of PGR estoppel, negligent error, or otherwise, it was wrong, and the IPR petition had to be withdrawn. *Sarepta Therapeutics, Inc. v. Genzyme Corp.*, IPR2026-00166 (PTAB Dec. 2, 2025). Even after being alerted to its fatal error (*see id.*, Paper 9 (filed Feb. 4,

2026)), Sarepta delayed re-filing this Petition (a carbon copy of IPR2026-00166) for three more weeks, waiting until the PGR time window lapsed.

Sarepta controlled when and what type of petition to file. Whether through mistake or intentional gamesmanship, Sarepta's failure to follow a well-known statutory prohibition on filing an IPR within the first nine months of a patent's term created this disorder. Instituting IPR in this case would penalize Genzyme by forcing it to engage in three sets of proceedings on the LC-MS patents—district court; the '377 and '880 patent IPRs; and the '313 patent IPR—each on different timelines. Meanwhile, Sarepta benefits from the narrower scope of estoppel afforded by an IPR versus a PGR.

Indeed, the *Fintiv* factors compel denial. Five of the six considerations (factors 1-3, 5, and 6) strongly favor denial. Trial in the parallel District of Delaware litigation, *Genzyme Corporation v. Sarepta Therapeutics, Inc.* 24-cv-00882 (D. Del.), is scheduled for June 2027—months before the projected Final Written Decision ("FWD") would be expected in September 2027. By the projected institution decision date, every phase of discovery in the parallel litigation between Genzyme and Sarepta will be complete or substantially in progress. Indeed, *Markman* proceedings have already occurred, the substantial document discovery completion deadline has passed, fact discovery will close next month, and expert reports will have been exchanged.

Sarepta's chicanery runs contrary to AIA policy and the Director's guidance favoring PGRs. *Azurity Pharms., Inc. v. Heron Therapeutics, Inc.*, PGR2025-00035, Paper 11 at 2 (PTAB Aug. 14, 2025) (citing *LifeVac, LLC v. DCSTAR Inc.*, IPR2025-00454, Paper 11 at 2 (Director July 11, 2025) (precedential)). It also inevitably creates inefficiencies and divided invalidity forums for the '313 patent. Sarepta's *Sotera* stipulation does not cure the problem it created. Sarepta's invalidity claims and defenses will continue to progress to trial unabated because Sarepta continues to pursue invalidity grounds outside the scope of its stipulation. It also means that the Board's FWD would issue months after a jury renders its verdict.

Rather than "providing [a] quick and cost-effective alternative[] to litigation" (H.R. Rep. No. 112-98, pt. 1, at 48 (2011)), institution of Sarepta's belated IPR filing would impose unnecessary costs on the parties, squander valuable Board and district court resources, generate duplicative proceedings, risk conflicting judgments, and needlessly prolong resolution of this dispute. This is the opposite of what Congress intended. For these reasons, Genzyme respectfully requests that the Director exercise discretion to deny institution and dismiss this Petition.

II. *Fintiv* and § 314(a) Favor Discretionary Denial

Discretionary denial under 35 U.S.C. §314(a) is essential to prevent the

waste of Board, district court, and party resources on duplicative serial and parallel proceedings. *Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 16 (PTAB Sept. 6, 2017) (“the goals of the AIA [are] namely, to improve patent quality and make the patent system more efficient by the use of post-grant review procedures.”). Applying a projected FWD date of September 8, 2027, five of the six *Fintiv* factors decisively favor denial: (1) the district court will not stay the case; (2) trial is scheduled months before the projected statutory deadline for a FWD; (3) the parties and district court have made and are continuing to make substantial investments in the district court proceeding; (5) the petitioner and district court defendant are the same party; and (6) the merits of the petition are weak. See *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) (“*Fintiv*”). The sole remaining consideration—(4) Sarepta’s *Sotera* stipulation—cannot overcome the overwhelming weight of the factors favoring discretionary denial, particularly the fact that the district court trial will occur months before the projected FWD issues.

A. *Fintiv* Factor 1 Favors Discretionary Denial Because the District Court Will Not Stay Its Case

The district court has not stayed its case, and there is no reason to believe it will. Months ago, two of the patents-in-suit, U.S. Patent Nos. 7,704,721 and 9,051,542, were challenged by Petitioner in IPRs that were both denied institution by the Director. *Sarepta Therapeutics, Inc. v. Genzyme Corporation*, IPR2025-

01194, 01195, Paper 15 (Director Nov. 20, 2025). Judge Andrews, the presiding District of Delaware Judge, is therefore unlikely to grant any stay, because Sarepta's IPR filings cover fewer than all the asserted patents and all asserted invalidity grounds in the district court case.

The recent referrals of co-pending IPRs challenging other Genzyme patents-in-suit for merits and non-discretionary considerations, including the related LC-MS patents, are unlikely to result in a district court stay. Judge Andrews 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.*, 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., 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). Thus, a stay is unlikely even if one or more of the recent referrals of co-pending IPRs challenging other Genzyme patents-in-suit, including the related LC-MS patents, are instituted.

B. *Fintiv* Factor 2 Favors Discretionary Denial Because the Final Written Decision Will Issue Months After the District Court Trial

Sarepta's decision to challenge the '313 patent via an IPR rather than a PGR means that the FWD is not projected to issue until September 2027—nearly three months after the scheduled jury trial. Sarepta could have filed a PGR concurrently with the IPRs challenging the '377 and '880 in December 2025, but instead filed an improper IPR of the '313 patent that violated 35 U.S.C. § 311(c)(1). It then withdrew that IPR and delayed filing the instant Petition until nearly three months after its statutorily prohibited challenge. Sarepta alone, whatever its motive, has caused the inefficiency wrought by three sets of proceedings, in two forums, all on different schedules. Genzyme should not be forced to suffer the costs and consequences of Sarepta's actions.

Sarepta was informed of the '313 patent's upcoming May 13, 2025 issuance on May 1, 2025. Ex. 2017, ¶ 57. It also prepared and erroneously filed the IPR2026-00166 petition challenging the '313 patent on December 2, 2025. Sarepta could have raised all of its grounds in a timely filed PGR, but deliberately chose

the narrower IPR vehicle, presumably to limit its estoppel exposure, even when it was statutorily barred. That move should not be countenanced, let alone rewarded. “[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.” *Azurity*, PGR2025-00035, Paper 11 at 2 (citing *LifeVac*, IPR2025-00454, Paper 11 at 2. PGRs have the further advantage of being a vehicle for challenging all statutory patentability grounds. A PGR challenging the ’313 patent would have provided the parties with a single proceeding to evaluate the patentability of the ’313 patent, allowing for a FWD before our trial. By deliberately foregoing a PGR, Sarepta not only delayed filing its Petition—it guaranteed the very fragmented proceedings that the *Fintiv* framework is designed to prevent.

Sarepta’s delay results in the scenario *Fintiv* warns against: “[i]f the court’s trial date is earlier than the projected statutory deadline,” (*Fintiv*, Paper 11 at 9), the Petition should be denied. The Director has routinely granted discretionary denial in analogous circumstances. *See, e.g., Samsung Elecs. Co. v. Vasu Holdings, LLC*, IPR2025-00446, Paper 12 at 2 (PTAB July 10, 2025) (granting discretionary denial because “it is unlikely that a final written decision ... will issue before the district court trial occurs,” “there is insufficient evidence that the district court is likely to stay its proceeding ... and there has been meaningful investment in the

parallel proceeding by the parties ... the parties have completed claim construction briefing, a *Markman* hearing has occurred, a claim construction order has issued, and fact discovery has closed.”); *AT&T Servs. Inc. v. RightQuestion, LLC*, IPR2025-00360, Paper 12 at 2 (PTAB July 29, 2025) (same). Factor 2 strongly favors discretionary denial.

C. *Fintiv* Factor 3 Favors Discretionary Denial Because the Parties Have Expended Considerable Resources in the District Court

The sheer volume of work already invested in the district court proceeding, which the parties are continuing to undertake, underscores the wastefulness of an additional IPR on a different schedule. The parties have already concluded substantial completion of document production and have engaged in numerous discovery-related tasks, including motion practice to compel discovery. The district court held a *Markman* hearing on April 22, 2026, and the Court issued a *Markman* order on April 27, 2026 deciding nearly all disputed claim terms. Ex. 2023. By the September 8, 2026 projected institution decision date, fact discovery—including all fact depositions—will have been closed for more than two months, the parties will have served opening expert reports and will be poised to serve rebuttal expert reports just days later, as the below chart shows. Ex. 2002.¹

¹ Future dates are from the current schedule and assume no extensions.

Date	District Court Deadlines	IPR Deadlines
<i>Feb. 26, 2026</i>		<i>Petition Filed</i>
Mar. 16, 2026	Joint Claim Construction Brief Filed	
Apr. 15, 2026	Substantial Completion of Productions	
Apr. 22, 2026	Markman hearing	
June 30, 2026	Fact Discovery Cutoff	
Aug. 5, 2026	Opening Expert Reports	
<i>Sep. 8, 2026</i>		<i>Projected Institution Date</i>
Sept. 16, 2026	Rebuttal Expert Reports	
Oct. 14, 2026	Reply Expert Reports	
Dec. 4, 2026	Completion of Expert Discovery	
Jan. 8, 2027	Dispositive/Daubert Motions Filed	
Feb. 5, 2027	Dispositive/Daubert Responsive Filings	
Mar. 5, 2027	Case Dispositive/Daubert Replies	
June 4, 2027	Pretrial Conference	
June 14, 2027	Jury Trial	
<i>Sep. 8, 2027</i>		<i>Projected FWD</i>

This significant investment in the district court proceeding prior to the institution date compels discretionary denial. The Director has consistently reached this conclusion on comparable—and even less developed—records. *See Azurity*, PGR2025-00035, Paper 11 at 2-3 (granting discretionary denial based on *Fintiv* factors 1-3, including the “substantial investment by the parties in the district court proceeding”); *Lam Research Corp. v. Inpria Corp.*, IPR2025-00256, Paper 12 at 2

(PTAB July 2, 2025) (“it is unlikely that a final written decision in this proceeding will issue before district court trial occurs. Furthermore, the parties have made meaningful investment in the district court proceeding ... the district court has held a *Markman* hearing and completion of fact discovery is scheduled to occur before the due date for an institution decision.”); *Be Smarter, LLC v. Yonder, Inc.*, IPR2025-00970, Paper 14 at 2 (Director Sept. 26, 2025) (granting discretionary denial because “the parties have exchanged infringement and invalidity contentions, and a *Markman* hearing is scheduled to occur before the due date for an institution decision.”); *Ericsson Inc. v. Pegasus Wireless Innovation LLC*, IPR2025-00084, Paper 17 at 14 (Director June 6, 2025) (“significant investment in the parallel district court proceeding has already occurred. A claim construction hearing was held in the parallel district court proceeding on March 13, 2025. Also, the parties have exchanged invalidity contentions.”); *Nokia of Am. Corp. v. Pegasus Wireless Innovation LLC*, IPR2025-00037, Paper 14 at 11-12 (PTAB Apr. 25, 2025) (finding factor 3 weighed in favor of discretionary denial when “[t]he parties have exchanged contentions and the district court has held its *Markman* hearing, fact discovery is (or soon will be) closed, and the parties are set to exchange initial expert reports.”). Here, the district court record is even more advanced than in many cases denied institution under *Fintiv*.

D. *Fintiv* Factor 5 Favors Discretionary Denial Because Sarepta is Petitioner and District Court Defendant

Factor 5 also favors discretionary denial. Sarepta Therapeutics, Inc. is the Petitioner and a defendant in the Delaware Litigation. The other defendant, Sarepta Therapeutics Three, LLC, is a wholly-owned subsidiary of Sarepta Therapeutics, Inc. Genzyme is the Patent Owner and the only plaintiff in the Delaware Litigation. When “Petitioner is the same party as the defendant in the district court case, and Patent Owner is the plaintiff there ... This factor weighs in favor of discretionary denial.” *Samsung Elecs. Co. v. SiOnyx, LLC*, IPR2025-00065, Paper 16 at 16 (Director June 6, 2025).

E. *Fintiv* Factor 6’s Other Circumstances Favor Discretionary Denial

Factor 6, which allows the Board to consider “other circumstances” that may impact its discretion, further favors discretionary denial. The Petition fails to provide any compelling reason to institute over the overwhelming factors favoring denial. Although the IPRs challenging the ’377 and ’880 patents were referred for merits consideration, and not discretionarily denied, the *Fintiv* analysis is different for the ’313 patent due to its delayed filing and much later institution and FWD dates. Thus, Factors 2 and 3 much more strongly favor denial here than for the earlier-filed IPRs. *Supra* §§ II.B-C. Given that the *Fintiv* factors are applied holistically (*Fintiv*, Paper 11 at 6), deficiencies in the merits of the Petition provide

an additional reason the Director should discretionarily deny this Petition.²

Notably, the Petition is silent on how its Grounds raise issues not already addressed during prosecution—a telling omission. The '313 patent claims priority to the '377 patent (Ex. 2019). Ex. 1001, (60). The prosecution history of the '377 patent is directly relevant to the claims of the '313 patent, because both patents recite “subjecting the denatured [adeno-associated virus] AAV particles to liquid chromatography/mass spectrometry (LC/MS) *intact protein analysis*.” Compare Ex. 1001, claim elements 1(b), 11(b), 20(c) with Ex. 2019, claim element 1(b). This shared “intact protein analysis” requirement was central to the Examiner’s allowance of the '377 patent.

Over the course of four office actions in the '377 patent’s prosecution, the Examiner asserted two prior art references in anticipation and obviousness

² Indeed, given the inefficiencies occasioned by Sarepta’s filing decisions, potentially resulting in three sets of proceedings regarding the same patent family taking place on different timelines and in different forums, Genzyme also respectfully urges the Director to reconsider the decision to not discretionarily deny IPR2026-00167 and -168. *See, e.g., Apple Inc. v. Conversant Intell. Prop. Mgmt, Inc.* IPR2025-01493, Paper 15 (Director Feb. 18, 2026) (Reversing referral decision due to inefficient use of Office resources).

rejections: Van Vliet (Ex. 2021) and Bark (Ex. 2022). Ex. 2020, 3-7, 28-35, 56-63, and 75-77. In finding the claims of the '377 patent allowable, the Examiner specifically explained that “neither [Van] Vliet nor Bark teaches or fairly suggests directly subjecting a denatured AAV or viral particle to liquid chromatography/mass spectrometry (LC/MS) intact protein analysis, i.e., without using a protease.” *Id.*, 61, 76-77, 77. Van Vliet, for example, discloses the use of trypsin to digest AAV samples. Ex. 2021, 172-73 (“The samples were digested with trypsin” which is a “protease.”). Critically, the primary reference in Sarepta’s Grounds, Satkunanathan (Ex. 1005), suffers from the same deficiency: it discloses “digested purified and concentrated vector samples with trypsin before LC-MS/MS.” Petition, 16 (citing Ex. 1005, 930-31). Thus, like Van Vliet, Satkunanathan also discloses the use of a protease to digest AAV prior to mass spectrometric analysis—the same approach the Examiner ultimately found insufficient. By failing to address the prosecution history of the '377 patent, the Petition fails to explain how Satkunanathan’s teachings differ in any material respect from the prior art already considered and found wanting during examination.

With respect to Sarepta’s combination reference Shytuhina, which was developed for an enveloped Chikungunya virus-like particle, rather than rAAV particles, the threshold question is whether the Petition provides sufficient

evidence and reasoning to support its assertion that a person of ordinary skill in the art (“POSA”) would have been motivated to apply Shytuhina’s LC-MS method to the structurally distinct, nonenveloped AAV capsid. It does not.

Conclusory statements in a petition or supporting declaration that lack reasoned analysis or corroborating evidence “add[] little to the conclusory assertion for which [they are] offered to support, and [are] entitled to little weight.” *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (PTAB Aug. 24, 2022) (precedential) (citing 37 C.F.R. § 42.65(a)).

Shytuhina relates to the LC-MS analysis of a Chikungunya virus-like particle, which is a distinct viral particle from AAV. The Chikungunya virus-like particle is an enveloped virus particle. Ex. 1003, ¶¶ 265-266, 269. The AAV capsid is nonenveloped. *Id.*, ¶ 66; Ex. 1001, 52:55-56. The Petition and declaration contend that Shytuhina’s method is directly applicable to AAVs based on the similarities in protein mass ranges between AAVs and Chikungunya virus-like particles. Petition, 33, 48-49; Ex. 1003, ¶¶ 403, 594. The Petition and declaration also state that “[i]ntact LC-MS analysis of AAV capsid proteins would have been even more straightforward for a POSA than working with the glycoproteins Shytuhina analyzed. Glycoproteins are more variable and therefore more difficult to analyze than AAV capsid proteins by intact LC-MS.” Petition, 60, 66, 71; Ex. 1003, ¶¶ 713, 754, 808.

These are precisely the type of conclusory assertions that are entitled to little or no weight. The Petition and declaration fail to cite any corroborating references, discuss necessary protocol changes, or address the well-known compatibility challenges associated with analyzing structurally distinct types of viral particles. Neither the Petition nor the supporting declaration provides any substantive basis for why it would be “straightforward” to adapt a method disclosed for enveloped Chikungunya virus-like particles to nonenveloped AAV capsids, or to combine Shytuhina’s intact protein method with the protease digestion method of Satkunanathan. Without such reasoned analysis, Sarepta’s bare assertions are entitled to no weight.

F. Sarepta’s *Sotera* Stipulation Does Not Outweigh the Other Factors

Sarepta’s *Sotera* stipulation cannot remedy the inefficiency of serial proceedings concerning the ’313 patent. A March 24, 2025 memorandum from then Chief Judge Boalick confirmed that although a *Sotera* stipulation remains “highly relevant” for discretionary factor considerations, it is “not ... dispositive by itself.” Boalick Memo at 2-3. The Director has found that *Sotera* stipulations do not outweigh the other *Fintiv* considerations particularly when trial is scheduled to occur before the Board issues its FWD. *See, e.g., Samsung Elecs. Co. v. GenghisComm Holdings, LLC*, IPR2025-00780, 00781, Paper 11 (Director Aug. 14, 2025); *see also id.* at Paper 7.

Maintaining this IPR proceeding in parallel to the district court litigation would be a paradigm of inefficiency and improperly reward Sarepta for its failure to follow 35 U.S.C. § 311(c). Sarepta's *Sotera* stipulation restricts it from raising arguments it could have raised under §§ 102 and 103 based on patents, printed publications, and system art. But that stipulation is far narrower than Sarepta's actual invalidity campaign. Sarepta's invalidity contentions in the district court litigation encompass §§ 101 and 112 arguments that cannot be addressed in its Petition and will proceed to trial regardless of any IPR outcome. Ex. 2018.

Sarepta's *Sotera* stipulation will not prevent it from pursuing its §§ 101 and 112 contentions with full force in the district court. *See, e.g., Motorola Sols., Inc. v. Stellar, LLC*, IPR2024-01205, Paper 19 at 3-4 (Director Mar. 28, 2025) (vacating institution decision despite *Sotera* stipulation because "Petitioner's invalidity arguments in the district court are more expansive"); *Shenzhen Tuozhu Tech. Co., Ltd. v. Stratasys, Inc.*, IPR2025-00354, Paper 11 at 2-3 (Director June 12, 2025) (denying institution despite *Sotera* stipulation based on petitioner's broad invalidity contentions in district court). Sarepta's *Sotera* stipulation thus falls far short of overcoming the many factors that compel denial of institution.

Discovery, expert reports, and trial preparation on invalidity will proceed because Sarepta's §§ 101 and 112 contentions require the same type of claim construction analysis, expert testimony, and factual development as its §§ 102 and

103 arguments. Sarepta's *Sotera* stipulation thus does not meaningfully reduce the burden on the parties or the court—it simply carves the invalidity case into two forums, doubling the adjudicative burden rather than reducing it.

Sarepta may contend that a PGR on the '313 patent would have created duplication because the district court would decide §§ 101 and 112 issues for the '377 and '880 patents while the Board decided them for the '313 patent. This is incorrect. The supposed efficiency of uniform IPR scope is illusory when the district court must still conduct a full invalidity trial on grounds outside the IPR's reach.

Sarepta's decision to file an IPR rather than a PGR was not motivated by efficiency but by the desire to preserve its §§ 101 and 112 arguments for the district court free from PGR estoppel. The Board should not reward this transparent forum-shopping by crediting Sarepta's self-serving efficiency arguments. Instituting this Petition would encourage other petitioners to delay filing a timely PGR to evade PGR estoppel. This is directly contrary to the Director's goal of encouraging PGR challenges early in a patent's term that can address all statutory patentability issues. By waiting to challenge via IPR, Sarepta created a piecemeal collection of proceedings on different timelines and in different forums.

III. Conclusion

For all of the foregoing reasons, the *Fintiv* factors overwhelmingly favor discretionary denial. Sarepta's belated, strategically motivated IPR filing would waste the resources of the Board, the district court, and the parties while offering no corresponding benefit. Genzyme respectfully requests that the Director exercise its discretion to deny institution and dismiss this Petition.

Dated: May 5, 2026

/ Blaine M. Hackman /
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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, IPR2026-00270

I caused to be served a copy of:

PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL

EXHIBIT NOS. 2002-2023

upon:

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electronic service to the email addresses above.

Date: May 5, 2026

/ Blaine M. Hackman /

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