

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAREPTA THERAPEUTICS, INC.,
Petitioners,

v.

GENZYME CORPORATION,
Patent Owner.

Case No. IPR2026-00167
Patent No. 11,698,377

PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL

TABLE OF CONTENTS

Table of Authorities	ii
Patent Owner’s Exhibit List.....	iv
I. Introduction	1
II. <i>Fintiv</i> and § 314(a) Favor Discretionary Denial	2
A. <i>Fintiv</i> Factor 1 Favors Discretionary Denial Because the District Court Will Not Stay Its Case	3
B. <i>Fintiv</i> Factor 2 Favors Discretionary Denial Because Trial Is Scheduled Days After the Projected Final Written Decision Date	4
C. <i>Fintiv</i> Factor 3 Favors Discretionary Denial Because The Parties Have Expended Considerable Resources in the District Court	5
D. <i>Fintiv</i> Factor 5 Favors Discretionary Denial Because Sarepta Is Petitioner and District Court Defendant	6
E. <i>Fintiv</i> Factor 6 Favors Discretionary Denial	7
1. Instituting this IPR Would Be Inefficient, Duplicative, and Risk Conflicting Outcomes.....	7
2. The Petition Fails to Assert Compelling Merits of Unpatentability	9
F. Sarepta’s <i>Sotera</i> Stipulation Does Not Outweigh the Other Factors	12
III. Conclusion.....	13

TABLE OF AUTHORITIES

Page(s)

Cases

<i>Amazon.com, Inc. v. Audio Pod IP, LLC</i> , IPR2025-00768, Paper 15 (Director Aug. 14, 2025).....	8, 9
<i>Ansell Healthcare Prods. LLC v. Reckitt Benckiser LLC</i> , No. 15-cv-915-RGA, D.I. 105 (D. Del. Dec. 1, 2016)	3
<i>Apple Inc. v. Fintiv, Inc.</i> , IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020)	<i>passim</i>
<i>Be Smarter, LLC v. Yonder, Inc.</i> , IPR2025-00970, Paper 14 (Director Sept. 26, 2025)	5, 6
<i>Collabo Innovations, Inc. v. Sony Corp.</i> , No. 15-cv-1094-RGA, D.I. 43 (D. Del. Jan. 5, 2017)	3
<i>Ericsson Inc. v. Pegasus Wireless Innovation LLC</i> , IPR2025-00084, Paper 17 (Director June 6, 2025)	6
<i>General Plastic Indus. Co. v. Canon Kabushiki Kaisha</i> , IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017).....	2
<i>Motorola Sols., Inc. v. Stellar, LLC</i> , IPR2024-01205, Paper 19 (PTAB Mar. 28, 2025)	12
<i>Nokia of Am. Corp. v. Pegasus Wireless Innovation LLC</i> , IPR2025-00037, Paper 14 (PTAB Apr. 25, 2025)	6
<i>RainDance Techs., Inc. v. 10X Genomics, Inc.</i> , No. 15-cv-152-RGA, D.I. 37, 38 (D. Del. Apr. 6, 2016)	3
<i>Samsung Elecs. Co. v. ICashe, Inc.</i> , IPR2025-00641, Paper 12 (Director Aug. 14, 2025).....	8, 9
<i>Samsung Elecs. Co. v. SiOnyx, LLC</i> , IPR2025-00065, Paper 16 (Director June 6, 2025)	7

<i>Samsung Elecs. Co. v. VB Assets, LLC</i> , IPR2025-00870, Paper 11 (PTAB Oct. 10, 2025)	4, 7, 8, 9
<i>Sarepta Therapeutics, Inc. v. Genzyme Corp.</i> , IPR2025-00166, Paper 9 (Feb. 4, 2026)	7
<i>Sarepta Therapeutics, Inc. v. Genzyme Corporation</i> , IPR2025-01194, 01195 (Director Nov. 20, 2025)	3, 7
<i>Shenzhen Tuoazhu Tech. Co. v. Stratasy, Inc.</i> , IPR2025-00354, Paper 11 (PTAB June 12, 2025)	4, 12, 13
<i>Xerox Corp. v. Bytemark, Inc.</i> , IPR2022-00624, Paper 9 (PTAB Aug. 24, 2022)	10
Statutes	
35 U.S.C. § 311(c)	7
35 U.S.C. § 314(a)	1, 2
Other Authorities	
37 C.F.R. § 42.65(a)	10

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	[Reserved]
2020	[Reserved]
2021	Van Vilet, 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	[Reserved]

I. Introduction

Patent Owner Genzyme Corporation (“Genzyme”) respectfully requests discretionary denial of the *inter partes* review (“IPR”) Petition challenging U.S. Patent No. 11,698,377 (“’377 patent”) filed by Petitioner Sarepta Therapeutics, Inc. (“Sarepta”). There are several reasons why discretionary denial is warranted.

The *Fintiv* factors and the interests of judicial efficiency compel discretionary denial under 35 U.S.C. § 314(a). The parallel Delaware district court litigation satisfies five of the six *Fintiv* considerations (factors 1-3, 5, and 6), which strongly favor denial. Trial is scheduled within days of the projected final written decision (“FWD”), and the district court and parties have invested substantial time and resources in that litigation. Contentions and numerous interrogatories have been exchanged, claim construction proceedings and document production will be complete before the projected institution date, and fact discovery will close shortly thereafter. The Petition further fails to establish compelling merits to support institution.

The single remaining consideration—Sarepta’s *Sotera* stipulation—does not outweigh these compelling factors. Maintaining parallel district court and IPR proceedings would waste valuable Board and district court resources, result in duplicative efforts, risk conflicting judgments, and unnecessarily prolong

resolution of this dispute. The district court is the more appropriate forum to address all patents and invalidity theories comprehensively.

For these reasons, Genzyme respectfully requests that the Board deny institution and dismiss this Petition.

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

Discretionary denial under 35 U.S.C. §314(a) is appropriate here to ensure that the resources of the Board, the Delaware district court, and the parties are not wasted on parallel proceedings. *General 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 June 4, 2027, five of the six *Fintiv* factors favor denial of institution: (1) the district court will not stay the case; (2) trial is scheduled at approximately the same time as the projected statutory deadline for a FWD; (3) the parties and district court have made significant 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 remaining consideration, (4) Sarepta’s *Sotera* stipulation, does not outweigh the factors favoring discretionary denial.

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

The district court has not, and likely will not, stay its case. Months ago, two key 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 a stay since Sarepta’s IPR filings cover fewer than all the asserted patents in the district court case. *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 only two of the six asserted patents). Thus, factor 1 favors discretionary denial.

B. *Fintiv* Factor 2 Favors Discretionary Denial Because Trial Is Scheduled Days After the Projected Final Written Decision Date

The jury trial in the Delaware litigation is scheduled to begin June 14, 2027, Ex. 2002. This is only ten days after the June 4, 2027 final written decision due date. *Fintiv* dictates that “[i]f the court’s trial date is at or around the same time as the projected statutory deadline,” (*Fintiv*, Paper 11 at 9), the Petition should be denied.

The proximity of the trial date and FWD favors denial even though the scheduled trial date is slightly after the FWD date. See *Samsung Elecs. Co. v. VB Assets, LLC*, IPR2025-00870, Paper 11 at 2 (PTAB Oct. 10, 2025) (“[E]ven though a district court trial date that occurs after a projected FWD date reduces the possibility of conflicting decisions, that benefit does not outweigh the efficiencies gained by avoiding parallel proceedings under these circumstances.”). The Board has found that factor 2 favors denial where, like here, trial is projected for the same month the FWD is due. *Shenzhen Tuozhu Tech. Co. v. Stratasy, Inc.*, IPR2025-00354, Paper 11 at 2 (PTAB June 12, 2025) (“[I]t will be inefficient to maintain two parallel proceedings when the district court scheduled trial date and the projected final written decision due date are in close proximity.”).

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

Instituting this proceeding would be highly inefficient in view of the parties' resources and time already invested in the Delaware litigation. Genzyme has served infringement contentions (Ex. 2003), and Sarepta has served invalidity contentions (Exs. 2004). The parties have served and responded to numerous rounds of interrogatories and requests for productions. Exs. 2005-2016. Claim construction proceedings are well underway. The parties exchanged claim terms, proposed constructions, and filed a joint claim construction chart, all before Sarepta filed its Petition. Ex. 2002. The parties have already filed their opening and answering claim construction briefs. *Id.* By June 4, 2026, the projected institution date, claim construction briefing will have concluded—the parties will have filed a joint claim construction brief and appeared for a claim construction hearing, presently scheduled for April 8, 2026. *Id.* The deadline for substantial completion of document production, April 15, 2026, is months prior to projected institution. *Id.* Fact discovery ends shortly thereafter, on June 30, 2026. *Id.*

Such significant investment in the district court proceeding prior to the institution date favors discretionary denial, regardless of whether trial may occur after the Board issues its FWD. *See Be Smarter, LLC v. Yonder, Inc.*, IPR2025-00970, Paper 14 at 2 (Director Sept. 26, 2025) (“it is not clear whether a final written decision in this proceeding will issue before the district court trial occurs.

The parties, however, have made meaningful investments in the district court proceeding . . . For example, 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.”).

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 in the Delaware Litigation, 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 Favors Discretionary Denial

Factor 6, which allows the Board to consider “other circumstances” that may impact its discretion, further favors discretionary denial.

1. Instituting this IPR Would Be Inefficient, Duplicative, and Risk Conflicting Outcomes

As explained above, the Board has already denied institution as to two of the patents in the Delaware litigation, U.S. Patent Nos. 7,704,721 and 9,051,542. *See* Ex. 2017; *Sarepta*, IPR2025-01194, 01195, Paper 15. The co-pending IPR proceeding challenging 12,298,313 (“’313 patent”), IPR2026-00166 is also likely to be denied institution because Sarepta filed that IPR petition before the ’313 patent was IPR-eligible. *Sarepta Therapeutics, Inc. v. Genzyme Corp.*, IPR2025-00166, Paper 9 at 2-4 (Feb. 4, 2026) (Patent Owner’s Request for Discretionary Denial) (explaining that because the petition was filed less than nine months after the ’313 patent issued, the IPR was filed prematurely under 35 U.S.C. § 311(c)).

The Board has repeatedly held that it is an inefficient use of its resources to refer a petition for consideration of its merits where, as here, it has already denied institution as to other challenged patents from the same parallel proceeding. *See VB Assets*, IPR2025-00870, Paper 11 at 2-3 (“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 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 inefficiency of instituting this proceeding is compounded by the likelihood that the IPR challenging the ’313 patent will be denied institution as premature. Even if Sarepta refiles its petition challenging the ’313 patent, the Petition is likely to be discretionarily denied institution because its projected FWD would fall months after the scheduled June 2027 trial. The ’313 patent claims priority to the ’377 patent, and Sarepta’s Petitions raise similar Grounds for both challenges. It would make little sense for the Board to invest its resources in instituting review of the ’377 patent while denying institution of the ’313 patent. This scenario would result in the district court and the Board considering similar

issues in parallel under different standards of review. Such an outcome strongly supports discretionary denial. *See, e.g., VB Assets*, IPR2025-00870, Paper 11 at 2-3; *Audio Pod*, IPR2025-00768, Paper 15 at 3; *ICashe*, IPR2025-00641, Paper 12 at 3.

2. The Petition Fails to Assert Compelling Merits of Unpatentability

The Petition does not provide a compelling reason to institute over the overwhelming factors favoring discretionary denial. The prosecution history of the '377 patent focused on the element “directly subjecting the denatured [adeno-associated viral] particle to liquid chromatography/mass spectrometry (LC/MS) *intact protein analysis*” in the independent claims. Ex. 1001, claim elements 1(b), 2(b). The 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 rejections: Van Vliet (Ex. 2021) and Bark (Ex. 2022). Ex. 1002, 1796-1800, 2113-2120, 2181-2188, and 2223-2225. In finding the claims of the '377 patents allowable, the Examiner 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.*, 2186, 2224-2225, 2261. 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.”). The primary reference in Sarepta’s Grounds, Satkunanathan (Ex. 1005) also discloses “digest[ing] purified and concentrated vector samples with trypsin before LC-MS/MS.” Petition, 18 (citing Ex. 1005, 930-31). Thus, Satkunanathan also discloses the use of a protease to digest AAV prior to mass spectrometric analysis. By failing to address the prosecution history of the ’377 patent, the Petition fails to identify teachings in Satkunanathan that were not considered during examination, including Van Vliet.

The threshold question is whether Sarepta’s combination reference, Shytuhina, provides sufficient evidence and reasoning to support the Petition’s assertion that a POSA would have been motivated to apply Shytuhina’s LC-MS method—developed for an enveloped Chikungunya virus-like particle—to the structurally distinct, nonenveloped AAV capsid.

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, ¶¶ 275-276, 279. The AAV capsid is nonenveloped. *Id.*, ¶ 66; Ex. 1001, 52:51-52. The declaration contends that Shytuhina's method is directly applicable to AAVs based on the similarities in protein mass ranges between AAVs and Chikungunya virus-like particles. *Id.*, ¶¶ 422, 478. 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, 45, 50, 55; Ex. 1003, ¶¶ 525, 554, 591.

These statements are precisely the type of conclusory assertions that are entitled to little weight. The Petition and declaration fail to cite any corroborating references, discuss necessary protocol changes, or address compatibility issues associated with analyzing distinct types of viral particles. The Petition repeats the word "straightforward" (*id.*, 45, 50, 55) to convey that adaptation of Shytuhina's method to AAV would not require substantial modifications. But mere repetition cannot substitute for reasoning. Neither the Petition nor the supporting declaration provide any explanation for why it would be straightforward to adapt a method disclosed for Chikungunya virus-like particles to AAV, or to combine Shytuhina's method with the protease digestion method of Satkunanathan. Absent such reasoned analysis, Sarepta's conclusory assertions are entitled to no weight.

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

Sarepta’s *Sotera* stipulation would not obviate the inefficiency of two parallel proceedings concerning the ’377 Patent. A March 24, 2025 memorandum from then Chief Judge Boalick explained that although a *Sotera* stipulation remains “highly relevant” for discretionary factor considerations it is “not . . . dispositive by itself.” Boalick at 2-3. Indeed, the Director has found that *Sotera* stipulations do not outweigh the other *Fintiv* considerations.

Maintaining this IPR proceeding in parallel to the district court litigation would be highly inefficient. 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 Sarepta’s invalidity contentions in the district court litigation are far more expansive than the grounds addressed in its Petition, and include §§ 101 and 112 arguments. Ex. 2018.

Sarepta could have raised these arguments in a timely filed PGR, but instead opted to file an IPR with its more limited estoppel provisions. Sarepta’s *Sotera* stipulation will not bar it from pursuing unencumbered its §§ 101 and 112 contentions. *See, e.g., Motorola Sols., Inc. v. Stellar, LLC*, IPR2024-01205, Paper 19 at 3-4 (PTAB Mar. 28, 2025) (vacating institution decision despite *Sotera* stipulation because “Petitioner’s invalidity arguments in the district court are more expansive”); *Shenzhen Tuozhu Tech.*, IPR2025-00354, Paper 11 at 2-3 (denying

institution despite Sotera stipulation based on petitioner's broad invalidity contentions in district court). Thus, Sarepta's *Sotera* stipulation does not obviate the many factors that favor denial of institution.

III. Conclusion

For the foregoing reasons, Genzyme respectfully requests that the Petition be discretionarily denied, and no proceeding instituted.

Dated: February 4, 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, IPR2026-00167

I caused to be served a copy of:

PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL

EXHIBIT NOS. 2002-2018, 2021-2022

upon:

Sarepta Therapeutics, Inc. c/o:

robertwilson@quinnemanuel.com

annetoker@quinnemanuel.com

jimglass@quinnemanuel.com

via:

electronic service to the email addresses above.

Date: February 4, 2026

/ Blaine M. Hackman/

Blaine M. Hackman, Reg. No. 67,479

Dechert LLP

Three Bryant Park

1095 Avenue of the Americas

New York, NY 10036-6797

Tel: 212-698-3500

Fax: 212-698-3599

blaine.hackman@dechert.com

Counsel for Patent Owner,

Genzyme Corporation