

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAREPTA THERAPEUTICS, INC.,

Petitioner

v.

GENZYME CORPORATION,

Patent Owner

U.S. Patent No. 12,298,313

“Methods for Detecting AAV”

IPR2026-00270

**PETITIONER’S OPPOSITION TO PATENT OWNER’S
REQUEST FOR DISCRETIONARY DENIAL**

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. ARGUMENT	3
A. The <i>Fintiv</i> Factors and 35 U.S.C. § 314(a) Weigh Heavily Against Discretionary Denial.....	3
1. <i>Fintiv</i> Factor 1	3
2. <i>Fintiv</i> Factor 2	7
3. <i>Fintiv</i> Factor 3	10
4. <i>Fintiv</i> Factor 4	11
5. <i>Fintiv</i> Factor 5	12
6. <i>Fintiv</i> Factor 6	12
7. Petitioner’s <i>Sotera</i> Stipulation Is Broad and Will Prevent Duplication of Resources	17
B. 35 U.S.C § 325(d) Does Not Support Discretionary Denial.....	18
III. CONCLUSION	19

TABLE OF AUTHORITIES

Page

Cases

<i>Ansell Healthcare Prods. LLC v. Reckitt Benckiser LLC</i> , No. 15-cv-00915-RGA, D.I. 94 (D. Del. Nov. 7, 2016), D.I. 105 (D. Del. Dec. 1, 2016).....	6
<i>Apple Inc. v. Apex Beam Technologies LLC</i> , IPR2025-00896, Paper 10 (Director Sept. 3, 2025)	7
<i>Apple Inc. v. Fintiv, Inc.</i> , IPR2020-00019, Paper 11 (PTAB March 20, 2020)	12
<i>AT&T Servs. Inc. v. RightQuestion, LLC</i> , IPR2025-00360, Paper 12 (Director July 29, 2025).....	10
<i>Azurity Pharms., Inc. v. Heron Therapeutics, Inc.</i> , PGR2025-00035, Paper 11 (Director July 11, 2025)	10
<i>Be Smarter, LLC v. Yonder, Inc.</i> , IPR2025-00970, Paper 14 (Director Sept. 26, 2025)	11
<i>Cerebrum Sensor Techs., Inc. v. Revvo Techs., Inc.</i> , 24-cv-245-JLH-SRF, D.I. 117 (D. Del. Oct. 17, 2025).....	6
<i>Clearlamp v. LKQ Corp.</i> , No. 1:12-cv-02533, 2016 WL 4734389 (N.D. Ill. Mar. 18, 2016).....	5
<i>Collabo Innovations, Inc. v. Sony Corp.</i> , No. 15-cv-1094-RGA, D.I. 37 (D. Del. Dec. 22, 2016), D.I. 43 (D. Del. Jan. 5, 2017)	6
<i>Ericsson Inc. v. Pegasus Wireless Innovation LLC</i> , IPR2025-00084, Paper 17 (Director June 6, 2025)	11
<i>Inmar Brand Sols., Inc. v. Quotient Tech. Inc.</i> , 23-cv-994-JFM, D.I. 141 (D. Del. Apr. 4, 2025)	6
<i>Lam Research Corp. v. Inpria Corp.</i> , IPR2025-00256, Paper 12 (Director July 2, 2025).....	11

<i>LifeVac, LLC v. DCSTAR Inc.</i> , IPR2025-00454, Paper 11 (Director July 11, 2025)	10
<i>Magnolia Med. Techs., Inc. v. Kurin, Inc.</i> , IPR2026-00097, Paper 17 (Director May 14, 2026)	2, 18
<i>Motorola Sols., Inc. v. Stellar, LLC</i> , IPR2024-01205, Paper 19 (PTAB Mar. 28, 2025)	17
<i>Nokia of Am. Corp. v. Pegasus Wireless Innovation LLC</i> , IPR2025-00037, Paper 14 (PTAB Apr. 25, 2025)	11
<i>RainDance Techs., Inc. v. 10X Genomics, Inc.</i> , No. 15-cv-00152-RGA, D.I. 37 (D. Del. Feb. 29, 2016), D.I. 38 (D. Del. Apr. 6, 2016)	6
<i>Samsung Elecs. Co. v. GenghisComm Holdings, LLC</i> , IPR2025-00780, 00781, Paper 11 (Director Aug. 14, 2025)	17
<i>Samsung Elecs. Co., v. Vasu Holdings, LLC</i> , IPR2025-00446, Paper 12 (Director July 10, 2025)	10
<i>Shenzhen Tuozhu Tech.</i> , IPR2025-00354, Paper 11	18
<i>Tesla, Inc. v. Intellectual Ventures II LLC</i> , IPR2025-00217, Paper 9 (Director, June 13, 2025)	7

Statutes

35 U.S.C. § 101	9
35 U.S.C. § 112	3, 9
35 U.S.C. § 314(a)	3
35 U.S.C. § 325(d)	18

LIST OF EXHIBITS

Exhibit Number	Description
EX1041	<i>Genzyme Corp. v. Sarepta Therapeutics, Inc. et al.</i> , C.A. No. 24-882-RGA (D. Del.), D.I. 78 (May 29, 2025), So Ordered re 77 Joint Stipulation to Amend Scheduling Order
EX1042	<i>Genzyme Corp. v. Sarepta Therapeutics, Inc. et al.</i> , C.A. No. 24-882-RGA (D. Del.) (Sept. 15, 2025), Plaintiff's Supplemental Claim Charts on Infringement Pursuant to Paragraph 4(C) of the Default Standard for Discovery, Redacted Public Version
EX1043	U.S. Patent No. 12,123,880
EX1044	U.S. Patent No. 11,698,377
EX1045	<i>Genzyme Corp. v. Sarepta Therapeutics, Inc. et al.</i> , C.A. No. 24-882-RGA (D. Del.), D.I. 74-5 (May 27, 2025), Certificate of Service, Second Amended Complaint
EX1046	<i>Genzyme Corp. v. Sarepta Therapeutics, Inc. et al.</i> , C.A. No. 24-882-RGA (D. Del.), D.I. 80 (June 30, 2025), Exhibit 1 and 2 to Plaintiff's Unopposed Motion to File Second Amended Complaint, Redacted Public Version
EX1047	Van Vliet <i>et al.</i> , "Adeno-associated virus capsid serotype identification: Analytical methods development and application." <i>Journal of Virological Methods</i> 159.2 (2009): 167-177
EX1048	Bark <i>et al.</i> , "High-temperature protein mass mapping using a thermophilic protease." <i>Journal of the American Chemical Society</i> 123.8 (2001): 1774-1775
EX1049	U.S. Patent No. 11,698,377 Prosecution History Excerpts
EX1050	<i>Genzyme Corp. v. Sarepta Therapeutics, Inc. et al.</i> , C.A. No. 24-882-RGA (D. Del.), D.I. 166 (May 13, 2026), Order.

I. INTRODUCTION

The strong merits of the Petition and other factors weigh heavily against discretionary denial. There will not be redundancy with the District Court proceedings. Petitioner has filed a broad *Sotera* stipulation. Paper 7. In addition, claims 1, 7-13, and 20 of the '313 patent are challenged in the Petition but not asserted in the District Court proceedings. EX1042, 2; Paper 2, 9; EX1050, 1. Denial of the Petition would therefore leave claims 1, 7-13, and 20 unadjudicated by either tribunal, allowing Patent Owner to assert them in a subsequent proceeding, and potentially leading to a subsequent challenge before this Board – an inefficient outcome. The '313 patent issued on May 13, 2025 – as a result, Patent Owner has no settled expectations that weigh in favor of discretionary denial. Finally, the merits of the Petition are strong, and Petitioner's arguments and prior art are new, despite Patent Owner's incorrect characterizations in its request for discretionary denial.

Genzyme, moreover, is attempting to curtail innovation by an American company that is a leader in the field of gene therapy by asserting a patent that should never have issued directed towards a well-known analytical technique. Sarepta Therapeutics is a biotechnology company at the forefront of precision genetic medicine – with substantial research, development, and manufacturing operations in the United States, including facilities in Massachusetts and Ohio. Sarepta has invested heavily in the development and commercialization of gene therapy

products for the treatment of rare diseases, including FDA-approved therapies for Duchenne muscular dystrophy. The challenged patent is therefore being asserted against Sarepta in connection with domestic innovation and manufacturing activities. As a result, this proceeding implicates the public interest in ensuring that patents asserted against domestic innovators were properly granted in the first place. As *Magnolia Medical* explains, the Director's discretionary authority exists in part to ensure that IPR proceedings serve these broader public interests. *Magnolia Med. Techs., Inc. v. Kurin, Inc.*, IPR2026-00097, Paper 17 (Director, May 14, 2026), 6-7.

Patent Owner's argument that discretionary denial is appropriate because Petitioner did not file a petition for Post Grant Review (PGR) should be rejected out of hand. Filing a PGR on the '313 patent would have been inefficient because, by the time Petitioner received Patent Owner's infringement contentions for the LC/MS patents in the litigation, the period for filing PGRs for the '377 and '880 patents was over. As a result, filing a PGR on the '313 patent could have resulted in 35 U.S.C. § 112 issues being adjudicated by the PTAB, while 35 U.S.C. § 112 issues for the '377 and '880 patents would be adjudicated by the District Court, given that IPR proceedings for those patents could not adjudicate those issues. Nor does the fact that this IPR was filed approximately three months after IPR2026-00167 and

IPR2026-00168¹ weigh in favor of discretionary denial.²

II. ARGUMENT

A. The *Fintiv* Factors and 35 U.S.C. § 314(a) Weigh Heavily Against Discretionary Denial

As set out below, the *Fintiv* factors weigh against discretionary denial, and the Board should deny Patent Owner's request under 35 U.S.C. § 314(a).

1. *Fintiv* Factor 1

Fintiv factor 1 weighs against discretionary denial. The District Court litigation includes seven patents from three different patent families, covering multiple materially different technologies. EX1046 (asserting U.S. Patent Nos.

¹ Petitioner notes that on May 15, 2026, the Director issued summary denials of institution of IPR2026-00167 and IPR2026-00168 without issuing a substantive decision for either IPR. IPR2026-00167, Paper 13; IPR2026-00168, Paper 13. IPR2026-00270, challenging a different patent with different claims, should be evaluated independently of IPR2026-00167 and IPR2026-00168.

² The fact that Petitioner initially filed an IPR petition (IPR2026-00166) prematurely on the '313 patent before the nine month post-issuance period had run has no bearing on IPR2026-00270. Petitioner withdrew IPR2026-00166 and timely filed IPR2026-00270.

9,051,542 (“the ’542 patent”), 7,704,721 (“the ’721 patent”), 12,031,894 (“the ’894 patent”), 12,013,326 (“the ’326 patent”), 11,698,377 (“the ’377 patent”), the 12,123,880 (“the ’880 patent”) patent, and the ’313 patent). The ’721 patent and the ’542 patent, which have both expired, are from the first patent family, and are directed towards methods of preparing adeno-associated virus (AAV) compositions, and compositions for the storage of AAV. The ’894 patent and the ’326 patent are from a second patent family and are directed towards analytical ultracentrifugation (AUC) methods for AAV (“the AUC patents”). The ’377 patent, the ’880 patent, and the ’313 patent are directed towards liquid chromatography-mass spectrometry (LC/MS) methods for analysis of intact proteins (“the LC/MS patents”).

On May 6, 2026, the PTAB instituted IPR2026-00150, challenging the ’894 patent, one of the AUC patents.³ IPR2026-00150, Paper 16. The trial date is currently scheduled for June 14, 2027, about a month after the expected date for the Final Written Decision for IPR2026-00150, May 6, 2027. EX1041, 3. On May 6, 2026, the Director issued a summary denial of institution without substantive written decision of IPR2026-00149, challenging the ’326 patent, the other AUC patent.

³ Patent Owner has filed a Request for Director Review of this institution decision. IPR2026-00150, Paper 19.

IPR2026-00149, Paper 14. The Court could choose to stay the case to avoid duplication and inefficient use of judicial resources – specifically, to avoid having the PTAB and the District Court evaluating different patents in the same family in parallel. A stay would permit the District Court to obtain the guidance of the PTAB on the AUC patent family. *Clearlamp v. LKQ Corp.*, No. 1:12-cv-02533, 2016 WL 4734389, at *6 (N.D. Ill. Mar. 18, 2016) (holding that a PTAB decision was “persuasive because it affords this court an opportunity to consider the PTAB’s expert reasoning based on the evidence presented to it”).

If the PTAB institutes IPR2026-00270, then the Court will have an additional reason to stay the District Court litigation – to obtain the expertise of the PTAB on the LC/MS patent family. *See id.*

The Director denied institution on discretionary grounds of Petitioner’s IPR petitions challenging the ’721 and ’542 patents. IPR2025-01194, Paper 15; IPR2025-01195, Paper 15. However, given that, as noted above, both of these patents have expired, Patent Owner can, at most, obtain damages and not injunctive relief for any infringement of these patents. As a result, Patent Owner will suffer no prejudice with regard to these two patents from the imposition of a stay to promote judicial efficiency, and the denial of these IPR petitions does not weigh against the likelihood of a stay. Moreover, the technology at issue in the ’721 and ’542 patents

is wholly distinct from that in the remaining five asserted patents in the District Court.⁴

⁴ Patent Owner's cited cases are not persuasive and are readily distinguishable. *See, e.g., Collabo Innovations, Inc. v. Sony Corp.*, No. 15-cv-1094-RGA, D.I. 37, at 2 (D. Del. Dec. 22, 2016), D.I. 43 (D. Del. Jan. 5, 2017) (denying motion for stay where no IPR had been sought on one of four asserted patents, where all four asserted patents covered essentially the same technology); *Ansell Healthcare Prods. LLC v. Reckitt Benckiser LLC*, No. 15-cv-00915-RGA, D.I. 94, at 2-3 (D. Del. Nov. 7, 2016), D.I. 105 (D. Del. Dec. 1, 2016) (denying motion for stay where no IPR had been sought on two of four asserted patents all from the same patent family); *RainDance Techs., Inc. v. 10X Genomics, Inc.*, No. 15-cv-00152-RGA, D.I. 37 (D. Del. Feb. 29, 2016), D.I. 38 at 23:22-24:2 (D. Del. Apr. 6, 2016) (denying motion for stay where IPR was pending on only one of five asserted patents in the same patent family); *Cerebrum Sensor Techs., Inc. v. Revvo Techs., Inc.*, 24-cv-245-JLH-SRF, D.I. 117 (D. Del. Oct. 17, 2025) (finding that the question of a stay was a "close one" where, *inter alia*, defendant planned to pursue system art invalidity defenses in the district court in parallel with IPR proceedings); *Inmar Brand Sols., Inc. v. Quotient Tech. Inc.*, 23-cv-994-JFM, D.I. 141 (D. Del. Apr. 4, 2025) (finding the dispositive factor to be that the defendant was "unwilling to provide certainty as

Fintiv Factor 1 should be viewed in light of recent opinions finding that the complexity of district court proceedings where multiple patents have been asserted spanning different patent families and involving a diverse range of subject matter weighed against discretionary denial. *Tesla, Inc. v. Intellectual Ventures II LLC*, IPR2025-00217, Paper 9, 2-3 (Director, June 13, 2025); *Apple Inc. v. Apex Beam Technologies LLC*, IPR2025-00896, Paper 10, 2-3 (Director Sept. 3, 2025).

Specifically, as noted above, the current District Court case now involves seven patents from three patent families spanning technologies from methods for preparing AAV compositions, and compositions for the storage of AAV, to AUC methods, to LC/MS methods. EX1040, ¶¶25-38. The complexity that these diverse patent families and technologies presents to the District Court strongly weighs against discretionary denial because the District Court could choose to stay the litigation and obtain the benefit of the PTAB's expertise on two out of the three patent families at issue in the litigation.

2. *Fintiv* Factor 2

Fintiv Factor 2 weighs against discretionary denial. The trial date is currently

to estoppel in this case (with respect to either the instituted patents or the non-instituted patent)").

scheduled for June 14, 2027. The projected date for the Final Written Decision in IPR2026-00270 is September 7, 2027, about three months after the projected date for a Final Written Decision, June 4, 2027, should IPR be instituted here. EX1041, 3. However, given the institution of IPR2026-00150 and the possibility of a stay, the timing of the Final Written Decision does not weigh against discretionary denial.

Patent Owner's arguments regarding Sarepta's decision not to file a PGR on the '313 patent should be rejected out of hand. As discussed, Patent Owner asserted, and Petitioner challenged, three patents from the same family, the LC/MS family – the '313 patent at issue here, the '377 patent, and the '880 patent. The '377 patent issued on June 11, 2023. EX1044. The '880 patent issued on October 22, 2024, and the '313 patent issued on May 13, 2025. EX1001; EX1043. Patent Owner sued Petitioner in the District Court on all three patents, serving its Second Amended Complaint asserting the LC/MS patents for the first time in the litigation on May 27, 2025, and its infringement contentions for the LC/MS patents on September 15, 2025. EX1045; EX1042.

Petitioner timely filed its IPR petitions for the '377 and '880 patents on December 2, 2025, ensuring that the projected final written decision date for these IPRs would fall before the scheduled trial date of June 14, 2027. IPR2026-00167; IPR2026-00168. Petitioner prematurely filed its IPR petition for the '313 patent on

December 2, 2025 (IPR2026-00166), and refiled it on February 26, 2026. IPR2026-00270.

Notably, by September 15, 2025, both the '377 and the '880 patents were beyond the post-issuance nine month period during which filing a post grant review (PGR) petition would have been possible. Had Petitioner filed a PGR petition for the '313 patent at this time, inefficiencies and waste of judicial resources would have occurred. Specifically, the scope of a PGR on the '313 patent would have included 35 U.S.C. §112 and 35 U.S.C. §101 issues – issues that are not within the scope of the IPR petitions on the related '377 and '880 patents. Such an outcome could have led to duplicative proceedings in the PTAB and the District Court on 35 U.S.C. §112 and 35 U.S.C. §101 issues – the District Court would have decided these issues for the '377 and '880 patents, while the PTAB would have decided them for the '313 patent. Such an outcome would therefore have been highly undesirable.

Filing IPR petitions on all three related LC/MS patents was therefore indisputably the most efficient avenue. Petitioner's broad *Sotera* stipulation in IPR2026-00270 ensures no duplication of these issues in the District Court. Paper 7. Similarly, the District Court's determination of 35 U.S.C. §112 and 35 U.S.C. §101 issues will not be duplicative of the PTAB proceeding.

Patent Owner's cited cases do not support their argument. In the precedential

LifeVac decision, the Director affirmed that even denial of a PGR petition on the merits is generally irrelevant to a request for discretionary denial of a subsequent IPR challenging the same patent. *LifeVac, LLC v. DCSTAR Inc.*, IPR2025-00454, Paper 11 at 2 (Director July 11, 2025) (precedential) (stating that “petitions for *inter partes* review will generally not be discretionarily denied because of an earlier petition for post-grant review when the post-grant review was not instituted”). Patent Owner’s argument that Petitioner should be penalized for not having filed a PGR is therefore contrary to Patent Owner’s own cited precedent.⁵

3. *Fintiv* Factor 3

Fintiv Factor 3 weighs against discretionary denial. The case is in its early

⁵ In *Azurity*, which cites *LifeVac*, the PGR was denied on discretionary grounds, and there is no discussion of whether filing a PGR is favored over filing a timely IPR at the end of the nine month patent post-issuance period. *Azurity Pharms., Inc. v. Heron Therapeutics, Inc.*, PGR2025-00035, Paper 11 (Director July 11, 2025). In *Samsung*, the projected Final Written Decision date was nine or ten months after the scheduled trial date. *Samsung Elecs. Co., v. Vasu Holdings, LLC*, IPR2025-00446, Paper 12 at 2 (Director July 10, 2025). In *AT&T*, the Final Written Decision date was a year after the scheduled trial date. *AT&T Servs. Inc. v. RightQuestion, LLC*, IPR2025-00360, Paper 12 at 2 (Director July 29, 2025).

stages. The projected institution decision date is September 8, 2026. Fact discovery does not close in the case until June 30, 2026, and opening expert reports are not due until August 5, 2026. EX1041, 3. Patent Owner's cited cases again are inapposite.⁶

4. *Fintiv* Factor 4

⁶ *Be Smarter, LLC v. Yonder, Inc.*, IPR2025-00970, Paper 14, 2 (Director Sept. 26, 2025) (challenged patent in force for eight years, creating settled expectations); *Ericsson Inc. v. Pegasus Wireless Innovation LLC*, IPR2025-00084, Paper 17, 12-14 (Director June 6, 2025) (noting that trial scheduled to take place about nine months before the final written decision date and finding that eight month period between service of patent owner's infringement contentions and filing of the petition weighed in favor of denial of the petition); *Nokia of Am. Corp. v. Pegasus Wireless Innovation LLC*, IPR2025-00037, Paper 14, 9-11 (PTAB Apr. 25, 2025) (noting that trial scheduled for seven months before the final written decision and finding that petitioner's seven month delay in filing the petition after being served with infringement contentions weighed in favor of discretionary denial); *Azurity*, Paper 12, 2 (projected final written decision date eleven months after trial date); *Lam Research Corp. v. Inpria Corp.*, IPR2025-00256, Paper 12, 2 (Director July 2, 2025) (projected final written decision date almost four months after trial date).

Fintiv Factor 4, which Patent Owner neither fully nor accurately addresses, weighs against discretionary denial. As discussed above, the Petition challenges multiple claims that are not at issue in the District Court proceeding. Specifically, claims 1, 7-13, and 20 of the '313 patent are challenged in the Petition but not asserted in the District Court proceedings.⁷ EX1042, 2; Paper 2, 9; EX1050, 1. In addition, as discussed above, Petitioner has filed a broad *Sotera* stipulation here, ensuring that there will be no duplication in the two proceedings. Paper 7.

5. *Fintiv* Factor 5

Fintiv Factor 5 is neutral, in that although the parties here are the same as those in the District Court proceeding, there will not be overlap between the issues in the IPR and those in the District Court (*see Fintiv* Factor 4 above). *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, 13-14 (PTAB March 20, 2020).

6. *Fintiv* Factor 6

Fintiv Factor 6 weighs heavily against discretionary denial. The merits of the Petition are strong, providing a further reason to find that discretionary denial is not

⁷ The District Court ordered Patent Owner to reduce its asserted claims from 95 to no more than 45 by June 1, 2026. EX1050, 1. As a result, an even smaller number of the claims challenged in this Petition are currently asserted in the District Court than when the Petition was originally filed.

appropriate. The Petition relies on multiple prior art references, in different combinations, none of which was before the Patent Office during prosecution.

The Petition sets out extremely compelling merits of unpatentability. None of the prior art cited in the Petition was before the Patent Office during prosecution of the '313 patent. Moreover, the prior art cited in the Petition is wholly different in kind from, and materially more pertinent than, the prior art considered by the Patent Office during prosecution.

Specifically, the Patent Office did not consider or discuss prior art that disclosed the core element of the claims of the '313 patent – namely, the use of LC/MS to analyze *intact* proteins, specifically, viral structural proteins, without the use of enzymatic digests or gel separation. EX1001 (*e.g.*, claim 1, directed towards LC/MS intact protein analysis of AAV capsid proteins in the absence of a gel separation step).

Patent Owner argues that the prosecution history of the '377 patent is relevant to the claims of the '313 patent because the claims of both patents are directed towards analysis of viral structural proteins using liquid chromatography/mass spectroscopy (LC/MS) intact protein analysis. Paper 8, 12. During prosecution of the '377 patent, the Examiner, as Patent Owner also acknowledges, focused on two prior art references, Vliet and Bark. EX1047; EX1048; EX1049, 1-8, 25-37, 55-65, 74-79. The title alone of Bark demonstrates that the principal prior art considered

by the Examiner during prosecution of the '377 patent did not disclose LC/MS intact protein analysis, but rather protein mapping using a protease, *i.e.*, non-intact protein analysis: “High-Temperature Protein Mass Mapping *Using a Thermophilic Protease.*” EX1048 (emphasis added). Vliet similarly discloses liquid chromatography using protein digests and gel separation. EX1047, 169.

In fact, the Applicants distinguished these references, Bark and Vliet, on these bases during prosecution and amended the claims to avoid them as prior art, adding the limitations “wherein the method is performed in the absence of a gel preparation step” and “intact protein analysis.” EX1049, 9-24, 39-54. The Applicants stated, for example, “As discussed in Applicant’s remarks filed on November 9, 2021, neither Vliet nor Bark teaches or 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.” EX1049, 52.

As set out in detail in the Petition and in the expert declaration of Dr. Joshua J. Coon, one of Petitioner’s two principal references, Shytuhina, discloses the use of LC/MS for analysis of intact viral structural proteins. IPR2026-00270, Paper 2; EX1006; EX1003. Petitioner’s other principal reference, Satkunanathan, discloses LC/MS methods of analysis of AAV capsid proteins that a POSA would be motivated to combine with the teachings of Shytuhina, applying Shytuhina’s LC/MS

intact protein analysis to Satkunanathan's study of AAV capsid proteins, and would have a reasonable expectation of success. Paper 2; EX1005; EX1006; EX1003.

Patent Owner's arguments attempting to distinguish Shytuhina on the basis that Shytuhina discloses a viral particle that is not an AAV particle are not consistent with the understanding of a POSA. Paper 9, 12-13. On the contrary, as set out in the Petition and Dr. Coon's declaration, a POSA would readily apply the teachings of Shytuhina to Satkunanathan's study of AAV to arrive at all claims of the '313 patent. Paper 2; EX1003.

Notably, during prosecution, the pending claims of the '377 patent directed specifically to AAV were rejected over Bark, which discloses a ***bacteriophage***, HK97. EX1049. A bacteriophage, unlike AAV or the virus disclosed in Shytuhina (Chikungunya virus) does not infect mammalian cells. Nor did the Examiner's rejections over Bark depend on structural similarity between HK97 and AAV. EX1049, 1-8, 25-37.

In fact, the applicants attempted to distinguish HK97 from AAV on the basis of purported structural differences. EX1049, 23, 51 ("HK97 is a phage with only one major capsid protein which interlinks to form the viral capsid. *See* page 1774, paragraphs 5 and 6 of Bark. HK97 stands in stark contrast to AAVs, which have three capsid proteins (VP1, VP2, and VP3) with serotype-dependent sequences and masses"). The Examiner disregarded these arguments, maintaining the rejection

over Bark until Applicants amended the claims to add the limitation “intact protein analysis.” EX1049 1-8, 25-37, 40-41.

In contrast to its position during prosecution, Patent Owner advances the even more untenable argument that Chikungunya virus, a virus that, like AAV, infects mammalian cells, is meaningfully distinct from AAV for purposes of application of the analytical technique of LC/MS because the multiple different structural proteins of Chikungunya include envelope proteins in addition to a capsid protein. Patent Owner’s arguments here contradict its arguments during prosecution, which rested on HK97 having only a single structural protein, and should therefore be disregarded.

Patent Owner’s argument regarding the prior art reference (Zabrouskov) on which Petitioner relies for its challenge to claims 7-10 of the ’313 patent is similarly unpersuasive. As a preliminary matter, dependent claims 7-10 of the ’313 patent are directed towards “determining the sequence of one or more VPs [viral proteins].” EX1001. As set out in detail in the Petition and the supporting Declaration of Dr. Coon, Zabrouskov is directed to intact MS/MS protein analysis, which determines the sequence of the proteins being analyzed. Paper 2; EX1038; EX1003. As further set out in detail in the Petition and Coon Declaration, a person of ordinary skill in the art could readily have combined the intact MS/MS protein analysis of Zabrouskov with techniques of liquid chromatography that were well

known in the art at the relevant time. Paper 2; EX1038; EX1003.

In short, as set out in detail in the Petition and Coon Declaration, Shytuhina discloses precisely the use of LC/MS for intact protein analysis of viral structural proteins, in the absence of any gel separation step, to which the claims of the '313 patent are directed. Paper 2; EX1003. And Satkunanathan discloses LC/MS methods of analysis of AAV capsid proteins that a POSA would readily combine with Shytuhina's LC/MS analysis of intact viral structural proteins. Paper 2; EX1003. Patent Owner's arguments to the contrary should be given no weight.

7. Petitioner's *Sotera* Stipulation Is Broad and Will Prevent Duplication of Resources

As discussed above, Petitioner has filed a broad *Sotera* stipulation. Paper 7.

Patent Owner's cited cases are, again, inapposite. In *Samsung*, "the challenged patents ha[d] been in force for approximately eight and six years, creating strong settled expectations" and the trial was likely to take place about ten months before the final written decision projected issuance date. *Samsung Elecs. Co. v. GenghisComm Holdings, LLC*, IPR2025-00780, 00781, Paper 11, 2 (Director Aug. 14, 2025). *Motorola* is distinguishable on multiple grounds, including that the *Sotera* stipulation at issue there – unlike Petitioner's *Sotera* stipulation here – did not cover system art, and petitioner was asserting system art prior art combinations in the district court. *Motorola Sols., Inc. v. Stellar, LLC*, IPR2024-01205, Paper 19

at 3-4 (PTAB Mar. 28, 2025). In addition, in *Motorola*, the trial was scheduled to take place eleven months before the projected final written decision date, and the parties had served opening and rebuttal expert reports. *See id.*, 3. *Shenzhen* is similarly distinguishable, in that in *Shenzhen*, the Sotera stipulation did not cover system art, while the petitioner relied on system art combinations of prior art in the district court. *Shenzhen Tuozhu Tech.*, IPR2025-00354, Paper 11, 2-3.

As discussed above, instituting this Petition will serve judicial efficiency and promote conservation of judicial resources. Patent Owner's arguments to the contrary should be rejected. As also noted above, Genzyme is attempting to curtail innovation by Sarepta, an American company that is a leader in the field of gene therapy, by asserting a patent that should never have issued directed towards a well-known analytical technique. This proceeding therefore implicates the public interest in ensuring that patents asserted against domestic innovators were properly granted in the first place. As *Magnolia Medical* explains, the Director's discretionary authority exists in part to ensure that IPR proceedings serve these broader public interests. *Magnolia*, IPR2026-00097, Paper 17, 6-7.

B. 35 U.S.C § 325(d) Does Not Support Discretionary Denial

As discussed above, Petitioner's prior art combinations and arguments are new. None of the prior art that Petitioner relies on was before the Patent Office during prosecution of the '313 patent.

III. CONCLUSION

Petitioner respectfully requests that the Board deny Patent Owner's request for discretionary denial.

June 5, 2026

Respectfully submitted,

By: /Robert B. Wilson/

Robert B. Wilson (Reg. No. 45,227)
Anne S. Toker (Reg. No. 53,692)
James M. Glass (Reg. No. 46,729)
Quinn Emanuel Urquhart & Sullivan,
LLP
295 Fifth Avenue, 9th Floor
New York, New York 10016
Tel.: 212-849-7000
Fax: 212-849-7100

*Attorneys for Petitioner Sarepta
Therapeutics, Inc.*

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §42.6, I hereby certify that on June 5, 2026, the foregoing document, Petitioner's Opposition to Patent Owner's Request for Discretionary Denial, and Exhibits 1041-1050 were served via email on the following counsel of record:

Amanda K. Antons
amanda.antons@dechert.com

Katherine A. Helm
khelm@dechert.com

Blaine M. Hackman
blaine.hackman@dechert.com

June 5, 2026

Respectfully submitted,

By: /Robert B. Wilson/

Robert B. Wilson (Reg. No. 45,227)
Anne S. Toker (Reg. No. 53,692)
James M. Glass (Reg. No. 46,729)
Quinn Emanuel Urquhart & Sullivan,
LLP
295 Fifth Avenue, 9th Floor
New York, New York 10016
Tel.: 212-849-7000
Fax: 212-849-7100

*Attorneys for Petitioner Sarepta
Therapeutics, Inc.*