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"

IPR2026-00166

PETITIONER'S OPPOSITION TO PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL

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I. MOTION TO WITHDRAW

Petitioner has moved to withdraw IPR2026-00166, challenging U.S. Patent No. 12,298,313 ("the '313 patent"), as prematurely filed before the expiration of the nine month post-issuance period. Paper 10. Petitioner's motion to withdraw is pending. Petitioner refiled its petition challenging the '313 patent on February 26, 2026, after expiration of that period. IPR2026-00270. Petitioner respectfully requests that the Board grant its motion to withdraw in this proceeding.

II. INTRODUCTION

Granting Petitioner's motion to withdraw will render Patent Owner's request for discretionary denial moot, and the Board need take no further action. However, given that the motion to withdraw has not yet been decided, Petitioner here provides responses to the additional arguments set out in Patent Owner's request for discretionary denial.

In this case, 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 7-10 of the '313 patent are challenged in the Petition but not asserted in the District Court proceedings. EX1042, 2; Paper 2, 9. Denial of the Petition would therefore leave claims 7-10 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. Finally, the merits of the Petition are strong, and Petitioner's arguments and prior art are new, despite Patent Owner's mischaracterizations in its request for discretionary denial.

The District Court litigation, furthermore, includes seven patents from three different patent families, covering multiple materially different technologies. EX1051 (asserting U.S. Patent Nos. 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"). This complexity weighs against discretionary denial.

Petitioner, furthermore, has withdrawn its proposed claim construction in the District Court litigation for the single disputed term ("variants / variant") of the '313 patent, and agreed to Patent Owner's proposed construction for this term ("AAV mutant capsid protein[s]”). EX1058, 4. Notably, Petitioner applied Patent Owner’s proposed construction in its Petition. Paper 2, 26. Patent Owner’s arguments regarding any purported inconsistency between the Petition and the District Court litigation are therefore moot and should be disregarded.

III. 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 heavily against discretionary denial, and the Board should deny Patent Owner’s request under 35 U.S.C. § 314(a).

1. *Fintiv* Factor 1

Contrary to Patent Owner’s argument (Paper 9, 4), there is a strong likelihood that the District Court will stay the case. Petitioner has filed IPR petitions against all three LC/MS patents, including the ’313 patent challenged here, and against both AUC patents. The PTAB 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, given that the technology at issue in the ’721 and

’542 patents is distinct from that in the remaining five asserted patents in the District Court, a stay would potentially obviate the need for the District Court to consider the technology in the remaining five patents.

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).

In addition, *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; *Apple Inc. v. Apex Beam*

Technologies LLC, IPR2025-00896, Paper 10, 2-3. Whether or not Petitioner obtains a stay in the District Court, the proceedings are sufficiently complex to warrant denial of Patent Owner's discretionary denial request.

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.

2. *Fintiv* Factor 2

Fintiv Factor 2 weighs against discretionary denial in that the trial date is currently scheduled for June 14, 2027, after the projected date for a Final Written Decision, June 4, 2027, should IPR be instituted here. EX1041, 3.

Patent Owner's cited cases are inapposite. In *Samsung*, the final written decision date was ***five months after*** the scheduled trial date. *Samsung Elecs. Co. v. VB Assets, LLC*, IPR2025-00870, Paper 11, 2 (PTAB Oct. 10, 2025) ("In particular, the projected ***final written decision*** due date in the Board proceeding is ***December 10, 2026***. DD Req. 19. The ***district court's scheduled trial date*** is ***July 6, 2026*** . . . .") (emphases added).

In *Shenzhen*, the final written decision date was similarly ***after*** the scheduled trial date. *Shenzhen Tuozhu Tech. Co. v. Stratasys, Inc.*, IPR2025-00354, Paper 11, 2 (PTAB June 12, 2025). In addition, in *Shenzhen*, the discretionary denial decision was also based on the fact that the petitioner's invalidity arguments in the district court were "more expansive" than those advanced in the IPR petition, and included combinations of the prior art asserted in the IPR proceedings with unpublished system prior art. *See id.*, at 2-3. As a result, the discretionary denial decision noted that the petitioner's *Sotera* stipulation would not "moot" these additional prior art arguments in the district court. *See id*.

Here, in contrast, Petitioner's *Sotera* stipulation expressly encompasses "(1) the specific grounds raised in the Petition, (2) any grounds of invalidity arising under U.S.C. §102 or §103 involving patent or printed publication prior art that could have reasonably been raised before the Board with respect to U.S. Patent No. 12,298,313, or (3) any ground based on a combination of system prior art and the references asserted as part of a ground raised in the instituted IPR with respect to U.S. Patent No. 12,298,313." Paper 7, 2.

Samsung and *Shenzhen* are therefore readily distinguishable and do not support Patent Owner's arguments.

3. ***Fintiv* Factor 3**

Fintiv Factor 3 weighs against discretionary denial. The case is in its early stages. The projected institution decision date is June 4, 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. Petitioner has withdrawn its proposed construction of the single claim term in dispute, so there is no claim construction briefing or hearing for the ’313 patent. EX1058, 4.

Patent Owner’s cited cases again are inapposite. In *Be Smarter*, the trial was scheduled to take place more than two months before the final written decision. *See Be Smarter, LLC v. Yonder, Inc.*, IPR2025-00970, Paper 14, 2 (Director Sept. 26, 2025). And the challenged patent had been in force for eight years, creating settled expectations. *See id*.

Ericsson is similarly inapposite. In *Ericsson*, the trial was scheduled to take place about ***nine months*** before the final written decision date. *Ericsson Inc. v. Pegasus Wireless Innovation LLC*, IPR2025-00084, Paper 17, 12-13 (Director June 6, 2025). In addition, unlike in the present case, fact discovery and opening expert reports on invalidity were scheduled to be completed before the projected institution decision date. *See id*., 13. Moreover, the PTAB found that the eight month period between service of patent owner’s infringement contentions and filing of the petition weighed in favor of denial of the petition. *See id*., 13-14. Here, Petitioner filed this IPR less than three months after service of Patent Owner’s infringement contentions. EX1042.

In *Nokia*, the trial was scheduled for seven months before the final written decision. *Nokia of Am. Corp. v. Pegasus Wireless Innovation LLC*, IPR2025-00037, Paper 14, 9-10 (PTAB Apr. 25, 2025). Moreover, in contrast to the present case, by the time of the projected institution decision date in *Nokia*, fact discovery would have been completed and opening expert discovery served. *See id*., 11. In addition, the PTAB found in *Nokia* that the petitioner's seven month delay in filing the petition after being served with infringement contentions weighed in favor of discretionary denial. *See id*., 11.

Be Smarter, *Ericsson*, and *Nokia* thus do not support Patent Owner's request for discretionary denial.

4. *Fintiv* Factor 4

Fintiv Factor 4, which Patent Owner does not fully or accurately address, weighs against discretionary denial. As discussed above, the Petition challenges multiple claims that are not at issue in the District Court proceeding. Specifically, claims 7-10 of the '313 patent are challenged in the Petition but not asserted in the District Court proceedings. EX1042, 2; Paper 2, 9. In addition, as also 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 appropriate. The Petition relies on multiple prior art references, in different combinations, none of which was before the Patent Office during prosecution.

(a) Instituting This IPR Would Be Efficient and Conserve Judicial Resources

Instituting this IPR would be highly efficient and would meaningfully conserve judicial resources. As discussed above, Patent Owner has asserted seven patents from three different families in the District Court. This complexity weighs against discretionary denial. In addition, as also discussed above, the fact that the PTAB has declined to institute IPR2025-01194 and -01195 on discretionary grounds does not support discretionary denial here. These petitions challenged expired patents from the same patent family. The denial of these petitions should not decrease the likelihood of a stay, and does not affect the efficiencies to be gained by removing the other two patent families from the District Court to simplify the litigation.

Patent Owner's cited cases again do not support its arguments. In *VB Assets*, unlike this case, there were six patents asserted in the district court – four patents for which institution had been denied on discretionary grounds on the basis of settled expectations, and two remaining patents being challenged in the IPR proceedings. *See VB Assets*, IPR2025-00870, Paper 11, 2-3. In *Amazon.com*, unlike in this case, there were six patents asserted in the district court, and institution of five out of the six was denied on discretionary grounds on the basis of settled expectations, leaving only one subject to challenge in IPR proceedings. *Amazon.com, Inc. v. Audio Pod IP, LLC*, IPR2025-00768, Paper 15, 2-3 (Director Aug. 14, 2025). Similarly, in *ICashe*, there were nine patents at issue in the district court – IPRs challenging seven of the nine had been denied on discretionary grounds on the basis of settled expectations, leaving only two subject to IPR challenge. *Samsung Elecs. Co. v. ICashe, Inc*., IPR2025-00641, Paper 12, 2-3 (Director Aug. 14, 2025).

Here, in contrast, seven patents have been asserted in the District Court – five of these are currently being challenged in IPR proceedings, and the two patents for which IPR has been denied on discretionary grounds have expired. Therefore, as discussed above, these two expired patents are unlikely to prevent the issuance of a stay in the District Court, and therefore are irrelevant to arguments regarding duplication of efforts between the PTAB and the District Court.

As discussed, Patent Owner has asserted, and Petitioner has challenged, three patents from the same family, the LC/MS family – the ’313 patent at issue here, the ’377 patent, and the ’880 patent. As mentioned above, the ’377 patent issued on June 11, 2023. EX1049. The ’880 patent issued on October 22, 2024, and the ’313 patent issued on May 13, 2025. EX1001; EX1048. 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. EX1050; 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 is indisputably the most efficient avenue – given that all three petitions will have the same scope and will decide the same issues. Petitioner’s broad *Sotera* stipulation 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.

(b) The Petition Asserts Extremely Compelling Merits of Unpatentability

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 9, 10. During prosecution of the '377 patent, the Examiner, as Patent Owner also acknowledges, focused on two prior art references, Vliet and Bark. EX1055; EX1056; EX1057, 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: "High-Temperature Protein Mass Mapping ***Using a Thermophilic Protease***." EX1056 (emphasis added). Vliet similarly discloses liquid chromatography using protein digests and gel separation. EX1055, 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." EX1057, 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." EX1057, 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. IPR2026-00166, 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 well taken. 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. EX1057. 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. EX1057, 1-8, 25-37.

In fact, the applicants attempted to distinguish HK97 from AAV on the basis of purported structural differences. EX1057, 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 (VPl, 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." EX1057 1-8, 25-37, 40-41.

Here, 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 structural proteins of Chikungunya include envelope proteins in addition to a capsid protein. These arguments are meaningless and should similarly be disregarded.

Patent Owner's argument regarding the prior art reference 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. *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.

8. Petitioner Has Withdrawn Its Proposed Construction for a Single Disputed Term of the '313 Patent in the District Court

As discussed above, Petitioner has withdrawn its proposed construction for a single disputed term of the '313 patent in the District Court and agreed to Patent Owner's proposed construction of the term. EX1058, 4. The term at issue, "variants / variant" appears in only two dependent claims of the '313 patent, claims 2 and 21. EX1001; EX1058, 4. Moreover, in the Petition, Petitioner applied Patent Owner's proposed construction of the term, "AAV mutant capsid protein[s]," which Petitioner has now agreed to in the District Court. Paper 2, 26; EX1058, 4. There is therefore no inconsistency between the Petition and the proceedings in the District Court concerning claim construction, and Patent Owner's arguments in this regard are moot.

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.

IV. CONCLUSION

Petitioner respectfully requests that the Board grant its motion to withdraw. In that case, Patent Owner's request for discretionary denial will be moot. In the alternative, if the Board reaches the merits of this request, Petitioner respectfully requests that the Board deny Patent Owner's request for discretionary denial.

Respectfully submitted,

March 4, 2026

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §42.6, I hereby certify that on March 4, 2026, the foregoing document, Petitioner's Opposition to Patent Owner's Request for Discretionary Denial, and Exhibits 1041-1058 were served via email on the following counsel of record:

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