

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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SAREPTA THERAPEUTICS, INC.,

Petitioner

v.

GENZYME CORPORATION,

Patent Owner

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**U.S. Patent No. 12,013,326**

“Analytical Ultracentrifugation for  
Characterization of Recombinant Viral Particles”

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IPR2026-00149

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

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**LIST OF EXHIBITS**

| <b>Exhibit Number</b> | <b>Description</b>                                                                                                                                                                                                                                                      |
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| EX1042                | <i>Genzyme Corp. v. Sarepta Therapeutics, Inc. et al.</i> , C.A. No. 24-882-RGA (D. Del.), D.I. 78, So Ordered re 77 Joint Stipulation to Amend Scheduling Order                                                                                                        |
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| EX1044                | <i>Genzyme Corp. v. Sarepta Therapeutics, Inc. et al.</i> , C.A. No. 24-882-RGA (D. Del.), D.I. 81, Redacted Public Version, Second Amended Complaint                                                                                                                   |
| EX1045                | Petition for IPR2026-00270                                                                                                                                                                                                                                              |
| EX1046                | U.S. Patent No. 7,704,721                                                                                                                                                                                                                                               |
| EX1047                | U.S. Patent No. 9,051,542                                                                                                                                                                                                                                               |
| EX1048                | <i>CG Tech. Dev., LLC v. William Hill US Holdco, Inc. et al.</i> , C.A. No. 18-cv-533, D.I. 68, Order Granting Motion to Stay                                                                                                                                           |
| EX1049                | <i>Genzyme Corp. v. Sarepta Therapeutics, Inc. et al.</i> , C.A. No. 24-882-RGA (D. Del.), D.I. 108, Joint Claim Construction Chart                                                                                                                                     |
| EX1050                | <i>Genzyme Corp. v. Sarepta Therapeutics, Inc. et al.</i> , C.A. No. 24-882-RGA (D. Del.), Civil Docket                                                                                                                                                                 |

## **I. INTRODUCTION**

In this case, the integrity of Patent Office proceedings, in addition to the strength and simplicity of the merits of the Petition, weigh heavily against discretionary denial. During prosecution of U.S. Patent No. 12,013,326 (“the ’326 patent”), Patent Owner Genzyme characterized the invention of the ’326 patent as the “discovery” of a linear relationship between two properties of AAV particles when analyzed by analytical ultracentrifugation (“AUC”). Genzyme did so in order to overcome cited prior art that had formed the basis of two instituted IPRs against an earlier patent in the same family. The Examiner accepted Genzyme’s argument, and allowed the claims of the ’326 patent to issue.

What Genzyme failed to disclose, and the Examiner failed to appreciate, was that the linear relationship Genzyme argued was “previously unknown” had been disclosed in the prior art as early as 1978 by de la Maza and Carter, leaders in the field of AAV research. EX1007; EX1008. Genzyme led the Examiner astray by arguing that the named inventors were the first to recognize the linear relationship in 2015, and the Examiner was not aware of key prior art references material to patentability. Every ground in the Petition cites de la Maza, which was not previously presented to the Office.

Genzyme’s request for discretionary denial doubles down on its statements made during prosecution in an attempt to characterize de la Maza as merely

cumulative of references that were before the Examiner, and makes attorney argument about how a POSA would have understood the teachings in this reference. Genzyme has not submitted any expert declaration in support of its arguments. Sarepta's un rebutted expert testimony on the material disclosures in de la Maza weigh heavily against discretionary denial.

Additional factors also weigh against discretionary denial. There will be no redundancy with the District Court proceedings. The trial date is set after the Final Written Decision date in this case, and Sarepta has filed a *Sotera* stipulation. EX1042, 3; Paper 9. In addition, claims 4, 5, 17, 18, 19, 23, 28, and 29 of the '326 patent are challenged in the Petition but not asserted in the District Court proceedings. EX1043, 2; Paper 2, 6. Denial of the Petition would therefore leave these eight claims unadjudicated by either tribunal. The merits of the Petition are strong, and Sarepta's arguments and prior art are new.

Furthermore, Genzyme has asserted seven patents from three different patent families in the District Court litigation, covering multiple materially different technologies. EX1044. This complexity weighs against discretionary denial.

Finally, Genzyme cannot credibly claim to have settled expectations in a patent that issued in 2024. And any purported "delay" in challenging the '326 patent was brought about by Genzyme, not Sarepta. Genzyme waited to assert the '326 patent in the District Court case until after the PGR filing deadline had passed.

Sarepta promptly filed its IPR Petition challenging the '326 patent thereafter.

For these reasons, Genzyme's motion should be denied.

## **II. ARGUMENT**

### **A. 35 U.S.C § 325(d) Does Not Support Discretionary Denial**

The '326 patent presents a quintessential case for IPR. Before filing the application that led to the '326 patent, Genzyme was faced with two IPR petitions challenging the claims of U.S. Patent No 10,429,288 ("the '288 patent"), which issued from a grandparent application in the same family as the '326 patent. Paper 2, 17-18. The claims of the '288 patent are generally directed to sedimentation velocity analytical ultracentrifugation ("SV-AUC") methods for characterizing full and empty capsids in preparations of rAAV particles. *See* EX1015, 54:20-58:47. The two IPR petitions challenged all claims of the '288 patent as anticipated and/or obvious in light of Le Bec, which had not been cited during prosecution. EX1016; EX1018, 2-3; EX1019, 2.

In response, Genzyme disclaimed claims 4 and 10-14. EX1021, 2. In January 2024, the Board granted institution of both IPRs on all remaining claims. EX1020, 41; EX1021, 28. On March 4, 2024, the Board granted the parties' motion to terminate the IPRs due to settlement of the district court litigation. EX1022, 3.<sup>1</sup>

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<sup>1</sup> Genzyme speculates that "[h]ad the IPRs not settled, the Board would likely

While the IPRs for the '288 patent were pending, Genzyme filed the continuation application that led to the '326 patent, seeking narrower claims in the same family. EX1001, (22). The '326 patent claims are limited to methods of determining the size of fragmented genomes in a preparation of rAAV particles, and methods for determining the molar concentration of each species in a mixture of rAAV particles. EX1001, 55:13-57:6.

During prosecution of the '326 patent, the Examiner rejected the pending claims as anticipated and/or obvious over Le Bec in combination with McLaughlin, Berkowitz (2007), or Cole. EX1002, 172-78. Genzyme argued that the key to the '326 patent was the discovery of the “linear relationship between sedimentation coefficients and molecular weights of genomes,” which allowed the inventors to determine the molecular weight (or size) of fragmented genomes using

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have been required to reconsider institution.” Paper 10, 19. But if Genzyme truly believed institution was in error, it likely would not have settled the litigation. And although the '288 patent IPR materials were before the Examiner during prosecution of the '326 patent, Genzyme failed to disclose and the Examiner did not appreciate the de la Maza teachings regarding the linear relationship between AAV particle density and genome size – which Genzyme used to distinguish the earlier cited prior art and obtain allowance of the challenged claims in this proceeding.

sedimentation coefficient data obtained via AUC. EX1002, 142-43. The *only* distinction Genzyme drew between the '326 patent claims and Le Bec was that the “linear relationship between sedimentation coefficients and molecular weights of genomes was not disclosed in Le Bec.” *Id.*, 150-51. Genzyme reiterates this narrow purported discovery in its discretionary denial request, claiming that “the inventors discovered a previously unknown linear relationship between the molecular weight and AUC sedimentation coefficient of rAAV particles.” Paper 10, 10-11.

De la Maza, which was not before the Examiner during prosecution, taught this allegedly distinguishing characteristic in a 1978 book chapter, more than 35 years before the '326 patent priority date. Specifically, de la Maza explicitly teaches the correlation between “[t]he density of the incomplete virus particles” and “the size of the incomplete DNA” within the particles. EX1007, 203. As de la Maza explains in a subsequent article discussing the 1978 work, “the particle density has an approximately *direct linear relationship* to the strand length.” EX1008, 3202 (emphasis added).

Genzyme was aware of the foundational work conducted by de la Maza, co-author Barrier Carter, and others in Carter’s lab. Indeed, Genzyme cites a different article from the Carter lab twice in the '326 patent specification. EX1001, 43:26-29 (citing EX1012), 45:17-20 (same). Despite being aware of publications from the Carter lab, Genzyme never cited the contemporaneous de la Maza articles

characterizing AAV particles with fragmented genomes and explicitly teaching the direct linear relationship between particle density and genome size. Had de la Maza been disclosed during prosecution, the Examiner would not have accepted Genzyme's argument that the '326 patent inventors were the first to recognize the linear relationship between sedimentation coefficients and the molecular weights of fragmented genomes in AAV particles.

**1. Le Bec Discloses Nearly All Limitations Of The Challenged Claims**

Disclosure of Le Bec led to disclaimer or IPR institution for all claims of the '288 patent, the grandparent to the '326 patent. Genzyme does not dispute that Le Bec teaches nearly all limitations of the '326 patent claims. The only distinction over Le Bec identified by Genzyme during prosecution was the linear relationship between sedimentation coefficients and molecular weights of genomes. Paper 10, 12-13; EX1002, 175, 142, 150-151. Consideration of Le Bec during prosecution does not favor discretionary denial in this case because Genzyme's basis for overcoming Le Bec was taught by de la Maza, which was not presented to the Office.

**2. De La Maza Taught The Purportedly Newly Discovered Relationship In 1978**

As explained in the Petition, de la Maza teaches the linear relationship between the *density* of an AAV particle and the size of the genome inside the capsid. EX1007, 203; EX1008, 3194, 3202; EX1011, 449. In turn, a POSA would have

understood from the disclosure in de la Maza that there is a linear relationship between the *sedimentation coefficient* of an AAV particle and genome size. This relationship follows from the Svedberg equation, which would have been well understood by a POSA at the relevant time. Paper 2, 44; EX1004, ¶¶41-42.

As discussed in the Petition, a particle's sedimentation coefficient is defined by the Svedberg equation, named after 1926 Nobel Prize winner Theodor Svedberg:

$$s = M (1 - \bar{v}\rho) / (N_a f)$$

where  $s$  is the sedimentation coefficient of the particle,  $M$  is the molar mass of the particle,  $\bar{v}$  is the partial specific volume of the particle (inverse of particle density),  $\rho$  is the density of the solvent,  $N_a$  is Avogadro's number, and  $f$  is the frictional coefficient of the particle. Paper 2, 11; EX1004, ¶¶38-39.

As discussed in the supporting Declaration of Dr. Steven Berkowitz, because AAV particles have approximately the same size and shape, regardless of the size of the genome inside the capsid, the frictional coefficient for AAV particles is approximately constant for empty particles, particles containing full genomes, and particles containing fragmented genomes. EX1004, ¶41. Likewise, solvent density  $\rho$  is constant for a given solution at a given temperature. *Id.*, ¶42. Therefore, in a mixture of AAV particles "every parameter in the Svedberg equation is constant except for particle molar mass and partial specific volume (the inverse of density)." *Id.* De la Maza's experimental results confirm what the Svedberg equation predicts

mathematically: sedimentation coefficient is directly proportional to mass and density for all intact monomeric AAV particles, which have approximately the same size and shape, regardless of the size of the genome packaged inside. *Id.*, ¶¶100-103. Thus, de la Maza – viewed by a POSA with background knowledge in the art as to the Svedberg equation – teaches the purportedly “previously unknown linear relationship” (Paper 10, 10-11) between ***sedimentation coefficient*** and genome size.

There is no dispute that de la Maza was not disclosed to the Office during prosecution. Genzyme therefore attempts to cast de la Maza as cumulative to art presented during prosecution. In doing so, Genzyme makes the remarkable assertion that “the examination record already included multiple references teaching this same correlation [taught in de la Maza] between genome size and viral particle density.” Paper 10, 15. In the very next paragraph, however, Genzyme appears to walk this assertion back, arguing that the record “includes several disclosures ***indicating*** a correlation between genome size and viral particle density.” *Id.*, 15-16 (emphasis added). Genzyme cites Berkowitz (2007),<sup>2</sup> McLaughlin, and Le Bec as references

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<sup>2</sup> During prosecution, Genzyme distinguished Berkowitz (2007) as teaching AUC analysis of adenoviruses, not AAVs. EX1002, 149. However, Genzyme now attempts to characterize de la Maza (which studied AAVs) as cumulative because

teaching that particle density differences are sufficient to separate species in an adenovirus or AAV viral preparation via AUC. *Id.* To the extent these references merely “indicat[e]” a correlation between density and genome size, they are not cumulative of de la Maza’s *explicit* teaching of a direct linear relationship between AAV particle density and genome size. EX1007, 203; EX1008, 3202. Indeed, during prosecution Genzyme emphasized the importance of the “linear relationship” as the distinguishing feature over the prior art. EX1002, 143, 151. De la Maza is not cumulative of the art presented during prosecution.

Genzyme also argues that de la Maza fails to disclose “a connection between the *sedimentation coefficient* and rAAV molecular weight.” Paper 10, 16 (emphasis original). Genzyme’s attorney argument is both unsupported by any expert testimony, and is scientifically incorrect. As explained in the Petition and Dr. Berkowitz’s accompanying declaration, a POSA would know that AAV particle size and shape remains approximately uniform regardless of the size of the encapsulated DNA. Paper 2, 43-45; EX1004, ¶¶165-169. Dr. Berkowitz’s opinion is supported by teachings from the de la Maza and Carter group regarding insertion of DNA into preformed capsids, as well as microscopy images showing full and

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“de la Maza and Berkowitz (2007) teach density-genome size correlation using identical AUC techniques.” Paper 10, 17. Genzyme cannot have it both ways.

empty AAV particles with the same size and shape. EX1004, ¶¶165-167; EX1012, Abstract, 72, 82; *see also* EX1026, 2, Figure 1; EX1041, 59, Figure 2. Due to the uniformity in the size and shape of AAV particles, regardless of the length of the genome inside, the linear relationship between *sedimentation coefficient* and genome size follows from the linear relationship between *density* and genome size, as taught in de la Maza. Paper 2, 44-45; EX1004, ¶169.

Genzyme is also incorrect that the Petition relies on a “flawed *assumption* that particle shape and friction are negligible” for AAV particles. Paper 10, 18-19. Dr. Berkowitz explains in detail the basis for his opinion that “a POSA in 2015 would have *known* that intact, non-aggregated AAV particles have approximately uniform size and shape because AAV virus assembly occurs via insertion of DNA into preformed spherical capsids composed of the same number of protein subunits.” EX1004, ¶41 (emphasis added). Thus, “a POSA would understand that empty AAV particles, particles containing fragmented genomes, and particles containing complete genomes are all approximately the same size and shape.” EX1004, ¶167.

Genzyme points to Berkowitz (2015) as contrasting SV-AUC with SE-AUC. Paper 10, 16. This is a red herring. De la Maza’s key teaching is about physical properties of AAV particles and the genomes packaged therein, regardless of the type of AUC used to obtain the experimental data. There is no dispute that for protein molecules generally, frictional properties such as size and shape may impact

a particle's sedimentation coefficient. EX1024, 216, 241. However, Genzyme ignores Dr. Berkowitz's thorough analysis in his declaration, summarized above, explaining that for mixtures of AAV particles, a POSA in 2015 would have known that particle size and shape are approximately the same regardless of the size of the encapsulated DNA. Thus, the frictional properties for AAV particles are constant. Dr. Berkowitz's expert opinions are un rebutted. No expert evidence supports Genzyme's attorney argument regarding the teachings of de la Maza.

Because de la Maza is new, noncumulative prior art, discretionary denial under §325(d) is inappropriate. *Oticon Medical AB v. Cochlear Ltd.*, IPR2019-00975, Paper 15, 20 (PTAB Oct. 16, 2019) (precedential as to §§ II.B and II.C); *Advanced Bionics, LLC v. Med-El Electromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, 8 (PTAB Feb. 13, 2020) (precedential) (proceeding to part two of the framework only if part one is satisfied).

### **3. The Petition Explains How Genzyme Misled The Examiner During Prosecution**

During prosecution, Genzyme misled the Examiner by arguing that the “linear relationship between sedimentation coefficients and molecular weights of genomes was not appreciated in the art prior to the present invention.” EX1002, 143. And Genzyme now attempts to mislead the Board with the same argument that the cited prior art references “do not linearly correlate sedimentation coefficient and

molecular weight.” Paper 10, 16-17. These arguments are incorrect in light of the disclosures in de la Maza, viewed by a POSA who would have had a working knowledge of the Svedberg equation and would have understood the basic physical properties of AAV particles. Paper 2, 7 (citing EX1007, 195 (Table 1), 196 (Figure 1)). Contrary to Genzyme’s argument (Paper 10, 18), Sarepta addressed in detail Genzyme’s misleading statements during prosecution. Paper 2, 1-3, 18-20.

Genzyme argues that the ’288 patent IPRs were considered during prosecution of the ’326 patent, and contained the same arguments made in the instant Petition. However, that is not so. As Genzyme admits, the argument raised in the ’288 patent IPR referenced “a *hypothetical* system where the rAAV particles are uniform and have an identical frictional coefficient.” Paper 10, 18 (citing EX2024, 46). The evidence in the instant petition is not “hypothetical.” Again, Dr. Berkowitz explains how a POSA in 2015 would have known that empty AAV particles, AAV particles containing fragmented genomes, and AAV particles containing complete genomes are all approximately the same size and shape, citing to multiple references that were not considered during prosecution, including de la Maza, Myers, Gao, and Lock. EX1004, ¶¶41, 165-169 (citing EX1007, EX1012, EX1026, and EX1041). With this knowledge, the linear relationship between *sedimentation coefficient* and genome size follows from the linear relationship between *density* and genome size disclosed in de la Maza for AAV particles, according to the Svedberg equation.

Finally, Genzyme argues that a POSA would have understood Le Bec, McLaughlin, and/or Berkowitz (2007) to contain de la Maza's explicit teaching of a direct linear relationship between particle density and genome size. Paper 10, 15-16. But if that is so, the Examiner erred in allowing the challenged claims. The Examiner's failure to appreciate the mathematical relationship between rAAV particle density and sedimentation coefficient, as set forth in the Svedberg equation, resulted in error material to the patentability of the '326 patent claims.

The Board should deny Genzyme's request under 35 U.S.C. § 325(d).

**B. 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 Genzyme's request under § 35 U.S.C. 314(a).

*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 (PTAB Jun. 13, 2025); *Apple Inc. v. Apex Beam Technologies LLC*, IPR2025-00896, Paper 10, 2-3 (PTAB Sept. 3, 2025). Whether or not Sarepta obtains a stay in the District Court, the proceedings are sufficiently complex to warrant denial of Genzyme's discretionary denial request.

Specifically, in addition to the two AUC patents (the '326 and '894 patents) that Sarepta has challenged in IPR2026-00149 and IPR2026-00150, Genzyme has asserted five additional patents from two other patent families, spanning a diverse range of subject matter. EX1044, ¶1. The current District Court case now involves seven patents from three patent families spanning technologies from methods and compositions to prevent viral particle aggregation, to liquid chromatography/mass spectrometry methods, to AUC methods. EX1044, ¶¶25-38. The complexity that these diverse patent families and technologies present to the District Court weighs against discretionary denial.

Moreover, Judge Andrews may well stay the District Court proceedings should IPRs be instituted. Sarepta has filed IPRs for five of the seven patents-in-suit that have not yet been resolved. *See* IPR2026-00149, IPR2026-00150, IPR2026-00166,<sup>3</sup> IPR2026-00167, IPR2026-00168. And the two patents-in-suit (the '721 and '542 patents) Genzyme cites in its request for which institution of IPR was discretionarily denied both expired in 2025. EX1046, EX1047. Sarepta's outstanding challenges to five of seven patents-in-suit would significantly simplify

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<sup>3</sup> Sarepta has moved to withdraw its petition in IPR2026-00166 as prematurely filed before the expiration of the nine month post-issuance period. Sarepta has refiled this petition now that the period has expired. EX1045.

the issues for trial by invalidating five of seven patents, particularly considering that there are no issues of ongoing infringement or accumulating damages for the expired '721 and '542 patents. In any event, Judge Andrews has previously granted motions to stay where pending IPRs challenged less than all of the asserted patents. EX1048, *CG Tech. Dev., LLC v. William Hill US Holdco, Inc. et al*, 18-cv-533, D.I. 68, 2 (D. Del. Aug. 29, 2019) (“The pending IPRs have the potential to significantly simplify the issues for trial by invalidating all asserted claims of [three of four asserted] patents. Therefore, the first factor supports granting a stay.”).

*Fintiv* Factor 2 weighs against discretionary denial. Trial in the District Court is currently scheduled to begin on June 14, 2027, after the date for a Final Written Decision on June 4, 2027. EX1042, 3. “If the court’s trial date is at or around the same time as the projected statutory deadline or even significantly after the projected statutory deadline, the decision whether to institute will likely implicate other factors discussed herein, such as the resources that have been invested in the parallel proceeding.” *Apple, Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, 9 (PTAB Mar. 20, 2020) (precedential). The “other factors” favor institution as detailed herein.<sup>4</sup>

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<sup>4</sup> Genzyme’s cited cases are inapposite. In both *Samsung* and *Shenzhen*, trial was scheduled *before* the final written decision date. *Samsung Elecs. Co. v. VB*

*Fintiv* Factor 3 weighs against discretionary denial. The District Court case is in its early stages. Fact discovery is proceeding, and while the parties filed a joint claim construction chart shortly *after* Sarepta filed its Petition (not before, as Genzyme erroneously states, Paper 10, 5), the parties have no disputes over any terms in the challenged claims of the '326 patent. EX1049, 3. Since agreeing last year that the preambles of the '326 claims are limiting, the parties have spent no resources, and will spend no future resources, litigating claim construction issues related to the '326 patent. While the parties have exchanged written discovery, no fact depositions have been noticed, and the anticipated June 4, 2026 institution decision is over three weeks before the current fact discovery cutoff. EX1042, 3. Opening expert reports are not scheduled to be served until August 5, 2026, more than two months after the institution decision. *Id.*, 3. At bottom, limited resources have been spent litigating the '326 patent in the District Court, and limited additional resources will be spent prior to the June 4, 2026 institution decision date.

*Fintiv* Factor 4, which Genzyme does not address at all, weighs strongly against discretionary denial. Institution here will not result in overlap in parallel proceedings. First, Sarepta has challenged eight additional claims beyond those at

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*Assets, LLC*, IPR2025-00870, Paper 11, 2 (PTAB Oct. 10, 2025); *Shenzhen Tuozhu Tech. Co. v. Stratasys, Inc.*, IPR2025-00354, Paper 11, 2 (PTAB June 12, 2025).

issue in the District Court. *Compare* Paper 2, 6 (challenging claims 1-5, 7-9, 12-23, and 25-30) *with* EX1043, 2 (asserting claims 1-3, 7-9, 12-16, 20-22, 25-27, 30). These eight additional claims will not be reviewed in the District Court. Where additional claims are challenged in an IPR, but not in the underlying litigation, Factor 4 weights against institution. *Apple, Inc. v. Maxell, Ltd.*, IPR2020-00204, Paper 11, 17 (PTAB Jun. 19, 2020) (“[C]laims 2, 5, 7, 13, and 14 are being challenged here, but not in the underlying litigation, which favors institution. On balance, we view this factor as weighing against exercising discretion to deny.”); *Volkswagen Group of America, Inc., v. Arigna Technology, Ltd.*, IPR2021-01321 Paper 10, 8 (PTAB Feb. 15, 2022) (“[T]he additional claims at issue here, but not in the [parallel] proceeding, weigh against exercising our discretion to deny institution. Thus, we determine this factor weighs against denying institution.”)

Moreover, Sarepta has filed a broad *Sotera* stipulation, ensuring there will be no duplication in the two proceedings. Paper 9. Genzyme acknowledges that the *Sotera* stipulation is “highly relevant” to the discretionary denial analysis. Paper 10, 8. Sarepta’s *Sotera* stipulation covers the specific grounds raised in the Petition, any § 102 or § 103 grounds involving patent or printed publication prior art that could have reasonably been raised, and any ground based on a combination of system prior art and the references asserted as part of a ground raised in the instituted IPR. Paper 9. This stipulation, and Factor 4 generally, “weighs strongly in favor of not

exercising discretion to deny institution.” *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12, 18 (PTAB Dec. 1, 2020) (precedential as to § II.A).

In an effort to undercut Sarepta’s *Sotera* stipulation, Genzyme faults Sarepta for filing an IPR petition instead of a PGR. Paper 10, 7-8. But Genzyme is the party who delayed by waiting to file suit until after the PGR deadline. Genzyme filed the original complaint in the District Court proceeding on July 26, 2024, asserting the ’542 and ’721 patents. EX1050, 4 (D.I. 1, 4). Although Genzyme sent letters to Sarepta regarding the ’326 patent on July 26 and October 31, 2024, Genzyme did not assert the ’326 patent in District Court until May 27, 2025 – over two months after the PGR deadline. *Id.*, 9 (D.I. 74, 75). Sarepta did not “delay[] challenging the ’326 patent, [while] the Delaware case proceeded,” as Genzyme contends. Paper 10, 8. Rather, Sarepta acted promptly to file its IPR Petition less than six months after Genzyme added the ’326 patent to the Delaware case. Paper 2. Genzyme’s attempt to place the burden on Sarepta – and any entity receiving a notice letter – to undertake the time and expense of preparing and filing a PGR petition should be rejected. Genzyme, not Sarepta, is the one who delayed by strategically running out the clock on the PGR window before asserting the ’326 patent in the District Court. Such gamesmanship cannot circumvent Sarepta’s *Sotera* stipulation.

*Fintiv* Factor 5 is neutral, in that the parties here are the same as those in the District Court proceeding.

*Fintiv* Factor 6 weighs against discretionary denial. The merits of the Petition are strong, and the Board’s interest in the integrity of its proceedings is also at issue, providing a further reason to find that discretionary denial is not appropriate. Genzyme has repeatedly characterized the invention of the ’326 patent as the “discovery” of a linear relationship between AAV particle density and genome size – something a POSA would have understood from de la Maza, a reference that was not before the Patent Office during prosecution. Furthermore, the complexity of the District Court proceedings, with seven patents from three patent families spanning a broad range of technologies, further warrants denial of Genzyme’s discretionary denial request.

**C. Genzyme Has No Settled Expectations In A 2024 Issued Patent**

The ’326 patent issued on June 18, 2024. EX1001, (45). Sarepta petitioned for IPR the following year. Paper 2, 72. Genzyme cannot credibly claim settled expectations in a 1-year old patent. *See, e.g., Evenflo Company, Inc. v. Baby Jogger, LLC*, IPR2025-01122, Paper 9, 6 and Paper 12, 2 (Director Dec. 1, 2025) (denying discretionary denial request and instituting IPR where patent was less than two years old); *see also Dabico Airport Sols. Inc. v. AXA Power ApS*, IPR2025-00408, Paper 21, 3 (Director Jun. 18, 2025, designated informative Jan. 9, 2026) (“[T]he longer the patent has been in force, the more settled expectations should be,” citing the six year limitation on recovery for patent infringement in 35 U.S.C. § 286).

The articles Genzyme cites do not suggest otherwise. Rather than “highlight the importance of the patented invention,” (Paper 10, 20), the 2020 Beckman Coulter article describes Burnham 2015 as showing that SV-AUC experiments “are able to characterize the quality of viral vector productions (*ratio between empty and filled capsids*).” EX2021, 1 (emphasis added). Similarly, the 2018 Genethon publication co-authored by Le Bec cites Burnham 2015 as an example of using AUC for “*the determination of empty-to-full capsid ratio*.” EX2020, 166-167 (emphasis added). Neither of Genzyme’s proffered articles relate to the ’326 patent claims, which are limited to methods of determining the size of *fragmented genomes* or molar concentration of particles comprising *fragmented genomes*. EX1001, claims 1, 20.

Persons of ordinary skill in the field of gene therapy were aware of AUC methods for determining the ratio of empty and full capsids before the ’326 patent. *See, e.g.*, EX1006. Genzyme has provided no evidence of industry adoption or the purported importance of the *claimed* AUC methods directed to rAAVs with fragmented genomes. Genzyme has no settled expectations.

### III. CONCLUSION

Sarepta respectfully requests that the Board deny Genzyme’s request for discretionary denial.

March 4, 2026

Respectfully submitted,

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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, Sarepta's Opposition to Genzyme's Request for Discretionary Denial, and Exhibits 1042-1050 were served via email on the following counsel of record:

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