

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAREPTA THERAPEUTICS, INC.,
Petitioners,

v.

GENZYME CORPORATION,
Patent Owner.

Case No. IPR2025-01195
Patent No. 7,704,721

PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL

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PATENT OWNER’S EXHIBIT LIST

Exhibit No.	Description
2001	Declaration of Katherine A. Helm
2002	Complaint, <i>Genzyme Corporation v. Sarepta Therapeutics, Inc., and Sarepta Therapeutics Three, LLC</i> , D.I. 1 (1:24-cv-00882-UNA)
2003	Second Amended Complaint, <i>Genzyme Corporation v. Sarepta Therapeutics, Inc., and Sarepta Therapeutics Three, LLC</i> , D.I. 81, (1:24-cv-00882-UNA)
2004	Second Amended Complaint, Ex. K, <i>Genzyme Corporation v. Sarepta Therapeutics, Inc., and Sarepta Therapeutics Three, LLC</i> , D.I. 81-2 (1:24-cv-00882-UNA)
2005	Second Amended Complaint, Ex. K, <i>Genzyme Corporation v. Sarepta Therapeutics, Inc., and Sarepta Therapeutics Three, LLC</i> , D.I. 81-3 (1:24-cv-00882-UNA)
2006	<i>Collabo Innovations, Inc. v. Sony Corp.</i> , 15-cv-1094-RGA, D.I. 43 (D. Del. Jan. 5, 2017)
2007	<i>Ansell Healthcare Prods. LLC v. Reckitt Benckiser LLC</i> , 15-cv-915-RGA, D.I. 105 (D. Del. Dec. 1, 2016)
2008	<i>RainDance Techs., Inc. v. 10X Genomics, Inc.</i> , 15-cv-152-RGA, D.I. 27, 37 (D. Del. Feb. 29, 2016)
2009	Notice of Service of Plaintiff’s Initial Claim Chart, <i>Genzyme Corporation v. Sarepta Therapeutics, Inc., and Sarepta Therapeutics Three, LLC</i> , D.I. 59 (1:24-cv-00882-UNA)
2010	Notice of Service of Stipulation to Extend Time, <i>Genzyme Corporation v. Sarepta Therapeutics, Inc., and Sarepta Therapeutics Three, LLC</i> , D.I. 68 (1:24-cv-00882-UNA)
2011	So Ordered re 77 Joint Stipulation to Amend Scheduling Order, <i>Genzyme Corporation v. Sarepta Therapeutics, Inc., and Sarepta Therapeutics Three, LLC</i> , D.I. 78 (1:24-cv-00882-UNA)
2012	Notices of Service for Interrogatories and Requests for Production, <i>Genzyme Corporation v. Sarepta Therapeutics, Inc., and Sarepta Therapeutics Three, LLC</i> , D.I. 28 (1:24-cv-00882-UNA)
2013	A.R. Kucernak et al., <i>Avoid Using Phosphate Buffered Saline (PBS) as an Electrolyte for Accurate OER Studies</i> , 9 ACS Energy Lett. 3939–3946 (2024)
2014	Oral Order on April 5, 2016 Denying Motion to Stay, <i>RainDance Technologies, Inc. et al v. 10X Genomics, Inc.</i> (1-15-cv-00152)

I. Introduction

Patent Owner Genzyme Corporation (“Genzyme”) respectfully requests discretionary denial of the Petition filed by Petitioner Sarepta Therapeutics, Inc. (“Sarepta”). There are several reasons why discretionary denial is warranted here.

First, Genzyme has unequivocal settled expectations relating to U.S. Patent No. 7,704,721 (the “’721 patent”). Interim Processes for PTAB Workload Management, 2 (Mar. 26, 2025) (“IPWM”). The ’721 patent issued on April 27, 2010, more than fifteen years before Sarepta filed its Petition. The ’721 patent is the parent of U.S. Patent No. 9,051,542, (the “’542 patent”). Sarepta admits it knew of the ’542 patent, which lists the ’721 patent on its cover, at least two years ago from monitoring prior litigation that began in 2021. *See Genzyme Corp. v. Novartis Gene Therapies, Inc.*, 21-cv-01736 (D. Del. Dec. 10, 2021) (the “Novartis Litigation”); *infra* § II.B. That litigation also gave rise to two IPRs on the ’542 patent that were denied institution on the merits in detailed decisions. *Novartis Gene Therapies, Inc. v. Genzyme Corp.*, IPR2023-00608, Paper 20 (PTAB Aug. 30, 2023) (EX1017); *Novartis Gene Therapies, Inc. v. Genzyme Corp.*, IPR2023-00609, Paper 22 (PTAB Aug. 30, 2023) (EX1018). Thus, Sarepta knew, or should have known about the ’721 patent, yet waited years to file its Petition.

Second, discretionary denial under 35 U.S.C. § 325(d) is warranted. The claims of the ’721 patent relate to a “method of preventing aggregation of

recombinant adeno-associated virus (rAAV) virions in a purified *preparation* of rAAV virions” that includes “produc[ing] a preparation of virions with an ionic strength of at least 200 mM” (the “ionic strength element”). EX1001, 14:9-20 (claim 1). The ’542 patent claims a “*composition* for the storage of purified [rAAV] particles ... wherein the ionic strength of the composition is greater than 200 mM.” EX1010, 14:15-26 (claim 1). Thus, the claims of the ’721 and ’542 patent recite, respectively, a preparation and a composition, with the same ionic strength of at least 200 mM.

The prior institution denials for the related ’542 patent found that the art failed to establish obviousness where it was not known that ionic strength was a “result-effective variable” for rAAV aggregation. EX1017, 23-24; EX1018, 27 n.10. When addressing the ionic strength element in this Petition, Sarepta relies on the same disclosure, Evans (EX1020), that the Board previously found unpersuasive for proving the ionic strength element obvious for the ’542 patent. EX1017 at 23-24. Although Sarepta purports to rely on Konz (EX1008), not Evans, the Petition cites Konz only to the extent it “incorporates Evans by reference,” and thus relies on Konz in name only. Petition, 38-39, 57-58 (citing EX1020). Sarepta fails to explain why its arguments based on Evans warrant a different result for the ’721 patent than for the ’542 patent in IPR2023-00608 (the “608IPR”). IPWM, 2-3.

Third, the Petition’s deficiencies in evidentiary support are so apparent that the Board need not evaluate its merits to recognize that Sarepta cannot reasonably establish unpatentability. Sarepta’s Petition and the declaration of Dr. Mark A. Kay (EX1005, the “Kay Declaration”) recycle art and arguments already found unpersuasive by the Board in challenges of the related ’542 patent, and without adequate evidentiary support for proving obviousness. The Petition’s argument on aggregation and ionic strength improperly imports by reference 29 paragraphs of the Kay Declaration in violation of Rule. § 42.6(a)(3). Petition, 9 (citing EX1005, ¶¶ 36-64). A review of the ’721 patent is not an efficient use of the Board’s resources. Thus, discretionary denial is appropriate.

II. Genzyme’s “Settled Expectations” Warrant Discretionary Denial

A. The ’721 Patent Issued Fifteen Years Before Sarepta Filed Its Petition

The ’721 patent issued on April 27, 2010, more than fifteen years before Sarepta filed its Petition on June 26, 2025 (EX1001 at 1), which creates a strong case for settled expectations. The Director has held that Petitions filed six or more years after patent issuance lead to a strong case for settled expectations of the Patent Owner. *Intel Corp. v. Advanced Cluster Sys., Inc.*, IPR2025-00794, Paper 13 at 2 (PTAB Aug. 14, 2025); *Dabico Airport Sols. Inc. v. AXA Power ApS*, IPR2025-00408, Paper 21 at 2 (PTAB June 18, 2025) (citing 35 U.S.C. § 286) (this “approach aligns with other approaches to settled expectations” including “for any

infringement committed more than six years prior to the filing of the complaint”).

In fact, before Sarepta filed its Petition, the ’721 patent expired on June 1, 2025, further supporting Genzyme’s settled expectations.

B. Sarepta Monitored the Litigation of the ’542 Patent, Which Listed the ’721 Patent on its Face, Years Prior to Filing This Petition

The ’542 patent, a continuation of the ’721 patent, shares nearly identical rAAV concentration, pH, and ionic strength claim elements with the ’721 patent. The ’542 patent was the subject of a prior infringement litigation filed by Genzyme in 2021 relating to Novartis’ rAAV product, Zolgensma[®]. Novartis challenged the ’542 patent in two IPR petitions, both denied institution on the merits. EX1017; EX1018. Because the ’542 patent has been in force since 2015 “and was the subject of an earlier proceeding in which the Board denied institution of inter partes review based on the merits ... settled expectations and arguments of inefficiency tip the balance in favor of discretionary denial.” *Google LLC v. Mullen Indus. LLC*, IPR2025-00197, Paper 14 at 4 (PTAB June 25, 2025). The settled expectations of the ’542 patent also apply to the ’721 patent.

Although “actual notice of a patent or of possible infringement is not necessary to create settled expectations,” Sarepta likely knew about and/or willfully disregarded the ’721 patent nearly two years before filing this petition. *Dabico*, IPR2025-00408, Paper 21 at 3. Sarepta has admitted to becoming aware of the ’542 patent, a continuation of the ’721 patent, on August 18, 2023, upon

issuance of the “Memorandum Opinion in District of Delaware Civil Action No. 21-cv-01736-RGA (D.I. 263)” on claim construction in the Novartis Litigation. EX2003, ¶¶ 58-59; EX2004, 16-17. Although Sarepta claims it became aware of the ’721 patent on July 26, 2024 (*id.*), the ’542 patent lists the ’721 patent on its face. Thus, Sarepta either knew of or willfully disregarded the existence of the ’721 patent by the August 18, 2023 date. EX2003, ¶ 559. Sarepta’s awareness, or willful disregard, of the ’721 patent is consistent with Genzyme’s case for settled expectations. *See DataDome S.A. v. Arkose Labs Holdings, Inc.*, IPR2025-00693, Paper 13 at 2 (PTAB Aug. 14, 2025) (finding settled expectations where a petitioner was aware of challenged patent for less than two years).

Further, Sarepta likely knew, or should have known, of the ’721 patent and its relevance to Sarepta’s rAAV gene therapy product, Elevidys[®], even before August 2023. The Novartis Litigation, which Sarepta admitted to monitoring, began in December 2021. The related ’542 patent was challenged in two IPRs filed in early 2023. Since Sarepta was monitoring the Novartis litigation, and the ’542 patent and its IPRs, which were notable events in that litigation, it would have been standard practice to review patents in the ’542 patent’s priority chain, including the ’721 patent. Additionally, the publicly available formulation module of Sarepta’s Biological License Application (“BLA”) for Elevidys[®], filed in 2022, cites a peer-reviewed publication co-authored by the inventors of the ’721 patent, John Fraser

Wright and Guang Qu. EX2005 (citing EX1047, “Wright (2005)”). Sarepta’s BLA states that the “extent of AAV aggregation is a critical concern for safety and efficacy in a drug product. It has been reported in the literature that ionic strength is critical for the minimization of AAV aggregation (Wright 2005).” *Id.* Wright (2005) describes the discovery—disclosed and claimed in the ’721 patent—that “an ionic strength of ≥ 200 mM was required to prevent aggregation” for high concentration rAAV particle compositions. EX1047, 6. The disclosure of Wright (2005) substantially overlaps with the disclosure of the ’721 patent. *Compare* EX1001, Figs. 1-3, Tables 1-3 *with* EX1047, Figs. 1-2, Tables 1-3. Because Sarepta knew of the Wright (2005) publication by 2022, at the latest, Sarepta likely knew or should have known of the corresponding ’721 patent before August 2023.

Moreover, Elevidys[®] was approved on June 22, 2023 (EX2003, ¶ 42), “without [Sarepta] challenging this patent” until years later, and nearly a year after Genzyme filed its initial complaint asserting the ’721 patent. *SIG Sauer Inc. v. Lone Star Future Weapons, Inc.*, IPR2025-00410, Paper 13 at 2 (PTAB June 26, 2025) (finding settled expectation where petitioner continued product development for years without challenging the patent). Sarepta’s “awareness of [the patent] and failure to seek early review of the patent[] favors denial” of institution based on settled expectations. *iRhythm Techs., Inc. v. Welch Allyn, Inc.*, IPR2025-00363, Paper 10 at 3 (PTAB June 6, 2025).

C. Genzyme’s Settled Expectations Are Not Outweighed by Other Considerations

No other considerations outweigh Genzyme’s settled expectations. First, Sarepta has failed to establish that the prior Board decisions relating to the ’542 patent “overlooked [the prior art’s] teaching” or “erred in a manner material to the patentability of the claims.” *Contra Tesla, Inc. v. Charge Fusion Techs., LLC*, IPR2025-00152, Paper 11 at 3 (PTAB June 12, 2025). The same claim elements addressed by the institution denials are challenged here for the ’721 patent. Indeed, Sarepta’s arguments use much of the art and argument that the Board previously rejected in the Novartis petitions. *Infra* § III. The Petition also lacks the evidentiary support required for Sarepta to meet its burden. *Infra* § IV.

Second, the parallel district court litigation, *Genzyme Corp. v. Sarepta Therapeutics, Inc.*, No. 24-cv-00882 (D. Del.), does not present such a “large number and vast scope of the patents” as to weigh against discretionary denial. *Compare Tesla, Inc. v. Intell. Ventures II, LLC*, IPR2025-00217, Paper 9 at 2-3 (PTAB June 13, 2025) (Declining to discretionarily deny a petition where the “district court proceeding involve[d] eleven patents spanning nine different families” covering a “diverse range of subject matter.”). The parallel patent infringement litigation relates to Elevidys®. Genzyme has asserted seven patents (EX2003, ¶¶ 1, 25-38) belonging to three patent families, which all relate to rAAV technologies, including rAAV compositions (*id.*, ¶¶ 25-28) and two types of

analytical methods for testing rAAV compositions (*id.*, ¶¶ 29-38). Indeed, the parallel litigation weighs against institution because it presents the most efficient avenue to address challenges to the '721 patent.

III. Discretionary Denial Is Further Warranted Under § 325(d)

Sarepta repackages failed arguments from prior IPR challenges for the related '542 patent to challenge the '721 patent, which warrants discretionary denial under § 325(d) under the Board's two-part framework. *See Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 7 (PTAB Feb. 13, 2020) (precedential) ("*Advanced Bionics*"); *see also Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) ("*Becton, Dickinson*"); *see also id.*, 22-23 (basing the § 325(d) discretionary denial on prosecution of a related patent).

Novartis' petition in the 608IPR challenging the '542 patent, which was denied institution on the merits, relied on the same buffer disclosure in Evans (EX1014, 23-47) for the ionic strength element that Sarepta relies on here. Petition, 38, 58 (citing EX1020). The Board found that Novartis could not show a likelihood of obviousness where it "fail[ed] to demonstrate the ionic strength was a recognized result effective variable" and "fail[ed] to establish a known relationship between ionic strength and viral particle aggregation." EX1017, 23-24; EX1018,

26-27 n.10. The Board further found the 608IPR failed to establish that Evans would have motivated a POSA to make a high ionic strength rAAV composition. *Id.* Similarly, the Petition fails to demonstrate why a POSA would have made high ionic strength rAAV compositions based on Auricchio, Potter, and Konz/Evans. *Infra* §§ IV.

A. Sarepta’s Ionic Strength Argument Relies on Disclosure in Evans Found Unpersuasive by the Board in IPR2023-00608

The Petition fails under *Advanced Bionics* part one. Sarepta relies on the same art as the petition in the 608IPR, Evans (EX1020), to argue that the ionic strength element is obvious. *Advanced Bionics*, 10; *Becton, Dickinson* at 18, 22; EX1017, 23-24. Sarepta’s Grounds purport to refer to Konz (EX1008) and not Evans. Petition, 38, 58. The Petition, however, is misleading. Konz is merely a vehicle to introduce the buffer disclosure of Evans, which was the principal reference in the 608IPR. Sarepta admits it relies on Konz because it “incorporates Evans by reference, and Evans, in turn, discloses formulation buffers that meet this limitation of the claims.” Petition, 38-39, 57-58. Notably, the Petition’s ionic strength element section cites only Evans’s disclosure. *Id.* (citing EX1020 but not EX1008). Sarepta’s use of Konz is subterfuge for the Board to consider art and arguments that it previously evaluated and rejected.

Combining Auricchio and Potter with Evans does not differentiate Sarepta’s arguments from those previously rejected by the Board. *First*, the Petition fails to

establish that either Aurrichio or Potter disclose the claimed ionic strength for a method of preventing aggregation of rAAV. *Infra* §§ IV.C-D. *Second*, the Petition’s combination of Auricchio or Potter with Konz/Evans for the ionic strength element is cumulative with the Board’s prior consideration of Evans alone. The Petition merely states that “Aurrichio and Konz thus both meet this limitation” (Ground 1) or “Potter and Konz thus both meet this limitation” (Ground 2) without explaining why the inclusion of Aurrichio or Potter warrants a different outcome than Konz/Evans alone. Petition, 39, 58. Thus, the Petition’s reliance on Konz/Evans for the ionic strength element renders the combination of Aurrichio and Konz/Evans or Potter and Konz/Evans cumulative with what the Board rejected in the 608IPR. *Becton, Dickinson*, 21 (factor (b)).

**B. Sarepta Fails to Identify any Material Error in the Boards’
Institution Denial of IPR2023-00608**

The Petition also fails under *Advanced Bionics* part 2 by not “demonstrat[ing] that the Office erred in a manner material to the patentability of [the] challenged claims.” *Advanced Bionics*, 8; *see also Becton, Dickinson*, 23-25 (factors (d)-(e)). Sarepta baldly asserts that the “express teachings of Evans that Konz points to, and that Petitioner relies on here, are materially different from the disclosures of Evans that were contested and that the Board addressed in IPR2023-00608.” Petition, 17 (citing EX1017, 17-21). In reality, the Petition’s ionic strength arguments substantively rely on the same disclosure in Evans as the petition in the

608IPR and thus overlap substantially with arguments already rejected by the Board. *Becton, Dickinson*, 23 (factor (d)). Sarepta has not “pointed out sufficiently how the [Board] erred in its evaluation of the asserted prior art” (*id.*, 24 (factor(e)) or identified the “extent to which additional evidence and facts presented in the Petition warrant Reconsideration of the prior art.” *Id.*, 25 (factor (f)).

For example, the 608IPR petition states “Evans’s claim 5 composition comprising **250 mM of NaCl and 5mM of MgCl₂ has an ionic strength of 265 mM.**” EX1014, 35 (citing Evans, claim 5) (emphasis added); *see also id.* at 36-37 (citing Evans, 9:16-20, 11:13-19). The current Petition states “a POSA would have selected a formulation buffer such as the buffer disclosed in Konz (via Evans) . . . with an NaCl concentration from 25 mM to 250 mM, an MgCl₂ concentration from 0.5 mM to 2.5 mM, and a non-ionic surfactant.” Petition, 41 (citing Evans, 11:31-12:4, 14:15-28; EX1005, ¶¶ 327-28, 331). Thus, both the 608IPR and this Petition rely on the same disclosure in Evans of a buffer having at least 250 mM ionic strength attributable primarily to NaCl.

Neither the Petition nor Kay Declaration, however, explain *why*, out of all the buffers in Evans ranging from low (25 mM) to high (250 mM) ionic strength, a POSA would have chosen the >250 mM buffer. EX1005, ¶¶ 316-317, 390-391 (citing EX1020). Similarly, the Petition states that “Konz, and Evans as incorporated into Konz . . . is directed to methods of preventing aggregation.”

Petition, 32-33 (citing EX1008, 24:1-9, 25:29-30, 48:11-21, Table 12; EX1005, ¶ 282); 52 (citing EX1008, 24:1-9, 48:11-21, Table 12; EX1005, ¶ 366). But neither the Petition nor Kay Declaration explain where Konz discloses any specific high ionic strength buffer system from Evans for use in its aggregation analysis. *Id.* Where Konz discloses “formulation buffers,” they contain between 10 mM and 75 mM of NaCl. Ex. 1008, 25:20-27 (citing Evans), 30:15-19, 42:14-16. The 10 mM and 75 mM NaCl concentrations in Konz’s “formulation buffers” are far below the “NaCl concentration above 250 mM” cited by the Petition and would have much lower ionic strengths. This reinforces that Sarepta is citing Konz in name, but is really relying on Evans and not Konz. The Petition and Kay Declaration do not address why a POSA would ignore Konz’s lower ionic strength “formulation buffers” to choose Evans’s buffer.

Sarepta states it “relies on background, state of the art references (that were also not before ... the PTAB during the prior IPR proceedings) to demonstrate that a POSA at the relevant date would have been well aware that ionic strength was a ‘results-effective variable’ for viral particle aggregation.” Petition, 18 (citing EX1030; EX1031; EX1032; EX1005, ¶¶ 37-64). But the Petition never explains how the cited references, which relate to non-analogous disinfection of drinking water and wastewater, expose any error in the Board’s prior consideration of Evans. Neither the Petition nor Kay Declaration identify anything specific that

would “outweigh Petitioner’s failure in this proceeding to show material error in the [Board’s] consideration.” *Biocon Pharma Ltd. v. Novartis Pharms. Corp.*, IPR2020-01263, Paper 12 at 18 (PTAB Feb. 16, 2021). Because the Petition’s ionic strength art and arguments are the same or substantially the same as those previously rejected by the Board, discretionary denial under § 325(d) is warranted.

IV. The Petition’s Failure to Comply with Rules 42.65(a), 42.6(a)(3), and 42.104(b)(4) Warrants Discretionary Denial

The Petition’s and Kay Declaration’s failure to “disclose the underlying facts or data” that support the argument that a POSA would have been motivated to make the claimed rAAV composition with an ionic strength ≥ 200 mM renders these arguments “entitled to little or no weight.” 37 C.F.R. § 42.65(a). The Petition also improperly incorporates by reference vast swaths of the Kay Declaration with no explanation. 37 C.F.R. § 42.6(a)(3). Finally, Dr. Kay’s calculations rely on speculation that the cited evidence does not support. 37 C.F.R. § 42.104(b)(4). These failures provide additional discretionary denial bases.

A. Dr. Kay Offers Only Conclusory Opinions that Auricchio or Potter with Evans Renders the Ionic Strength Element Obvious

As explained (*supra* § III), in denying institution of the 608IPR, the Board determined that Evans did not establish any clear relationship between ionic strength and maintained infectivity after storage, and that the “Petitioner *fail[ed]* to *establish ionic strength as a result-effective variable* for rAAV aggregation.”

EX1017, 23-24 (emphasis added). The Petition and Kay Declaration are similarly deficient. On ionic strength, Dr. Kay’s testimony is “conclusory and unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight.” *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (PTAB Aug. 24, 2022) (precedential) (citing 37 C.F.R. § 42.65(a)).

The Petition never states why Aurichio or Potter combined with Konz/Evans renders the claimed ionic strength obvious. Petition, 39, 58 (citing EX1005, ¶¶ 318, 392). The Kay Declaration merely states that “a POSA would have been motivated to preserve the[] general characteristics” of Auricchio or Potter including a “high ionic strength buffer,” “in choosing one of the Konz buffers.” EX1005, ¶¶ 285, 369. Neither document addresses the fundamental question: *why would POSA choose a high ionic strength buffer* based on the cited references? Sarepta’s hindsight-based circular reasoning assumes the desirability of a high ionic strength buffer without justifying it. By failing to explain and cite to evidence for why a POSA would have been motivated to combine Auricchio or Potter with Konz/Evans to make the claimed high ionic strength composition, Sarepta’s arguments should not be entitled to any weight. 37 C.F.R. § 42.65(a).

B. The Petition Improperly Incorporates by Reference Arguments Relating to Ionic Strength

The Petition improperly imports by reference four publications and 29 paragraphs of the Kay Declaration with two sentences. Petition, 9 (citing EX1030;

EX1031; EX1032; EX1041, EX1005, ¶¶36-64.). The Petition, however, fails to explain how these portions of the Kay Declaration support the contention that ionic strength was understood to influence rAAV aggregation. “Arguments must not be incorporated by reference from one document into another document.” 37 C.F.R. § 42.6(a)(3); *see also* PTAB Consolidated Trial Practice Guide, 35-36 (Nov. 2019) (“CTPG”). “The burden of production cannot be met simply by throwing mountains of evidence at the Board without explanation or identification of the relevant portions of that evidence.” *Parus Holdings, Inc. v. Google LLC*, 70 F.4th 1365, 1371 (Fed. Cir. 2023).

In the interests of avoiding abuse and supporting fairness and efficiency, the Board is not required “to play archeologist with the record....” *3M Co. v. Evergreen Adhesives, Inc.*, 860 F. App’x 724, 725 (Fed. Cir. 2021) (internal quotations omitted); *see also* CTPG at 35-36; *Parus*, 70 F.4th at 1372 (internal quotations omitted) (holding that “the ‘prohibition against incorporation of arguments eliminates abuses that arise from incorporation and combination.’”); *Nearmap US Inc. v. Pictometry Int’l Corp.*, IPR2024-00729, Paper 9 at 21-22 (PTAB Oct. 10, 2024). Sarepta’s incorporation of arguments by reference for the ionic strength element circumvents the word count requirement and allows for two grounds for every claim. The Board should not consider any testimony incorporated by reference for this claim element. CTPG at 35-36.

C. The Petition's Reasons for Selecting Aurrichio's Ionic Strength Are Not Supported by the Aurrichio Reference

The Kay Declaration states that Aurrichio “discloses a method of producing high physical and high infectious titer rAAV2” and teaches “produc[ing] rAAV2 with greater stability during storage at 4°C.” EX1005, ¶¶ 286, 288 (citing EX1007, 1-5). To meet the ionic strength element of claim 1, Dr. Kay’s ionic strength calculations use Aurrichio’s elution solvent containing “0.4 M NaCl (400 mM)” that is used to purify the rAAV2. EX1005, ¶¶ 306-314 (citing EX1007, 2). But the elution solvent is not the same solvent that is in Aurrichio’s “purified preparation of rAAV virions” that Aurrichio tests for storage stability. Aurrichio explains that after elution, “the eluate was concentrated to about 1ml ... by centrifugation. To adjust the NaCl concentration to physiological levels, the filter device was refilled with PBS, pH 7.4, and the virus was concentrated to 1 ml again.” EX1007, 2. Thus, the NaCl levels in Aurrichio’s preparation were not the same as in the elution solvent, and the Kay Declaration never addresses this issue.

The Petition fails to “make clear [Sarepta]’s theory of the case” with respect to why Auricchio’s elution solvent is relevant to the rAAV preparation of claim 1. *Nearmap*, IPR2024-00729, Paper 9 at 21. “[I]t is not the Board’s responsibility to weave together Petitioner’s evidence into a cohesive case.” *Id.* (citing 37 C.F.R. § 42.22(a)(2)); *Parus*, 70 F.4th at 1371-72. Dr. Kay’s testimony, which fails to explain the choice of the elution solvent to meet the ionic strength element, “is

conclusory and unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight.” *Xerox*, IPR2022-00624, Paper 9 at 15 (citing 37 C.F.R. § 42.65(a)).

D. The Petition’s Ionic Strength Arguments Based on Potter Are Not Supported by Evidence

The Petition and Kay Declaration cite to examples in the Potter reference relating to “National Reference Standard rAAV” for the claim element reciting “wherein the concentration of rAAV virions in said preparation exceeds 1×10^{13} vg/ml up to 6.4×10^{13} vg/ml.”¹ Petition, 58-59; EX1005, ¶¶ 397-399 (citing EX1009, Table II). But for the ionic strength claim element, these same filings cite different rAAV solutions relating to heparin affinity chromatography eluted with 0.5M NaCl. Petition, 57; EX1005, ¶¶ 388-89; EX1009, 7. Notably, Potter’s examples are unrelated to ionic strength. Table I reports the total number of particles. EX1009, 7. Table II reports concentration as part/mL and infectious part/mL (*id.* at 9). The Petition and Kay Declaration are silent on this discrepancy.

¹ Sarepta alleges that Genzyme, and its expert, Dr. Martyn C. Davies, previously “mischaracterized the concentration of the disclosed formulations in Potter.” *E.g.*, Petition, 15. This is incorrect. As Genzyme will address in its Preliminary Response, Potter’s “formulation with a physical titer of about 1.12×10^{13} vp/ml” is *not* “the same as 1.12×10^{13} vg/ml.” *E.g.*, EX1005, ¶ 165.

Sarepta “has the responsibility to make plain its challenges to the disputed claims.” *Nearmap*, IPR2024-00729, Paper 9 at 20-21 (citing 37 C.F.R. § 42.104(b)(4)). The Petition fails to “make clear [Sarepta]’s theory of the case” with respect to why these two disclosures in Potter would be combined, and “it is not the Board’s responsibility to weave together Petitioner’s evidence into a cohesive case.” *Id.* at 21 (citing 37 C.F.R. § 42.22(a)(2)); *Parus*, 70 F.4th at 1371-72. The Kay Declaration also does not address why it cites different solutions from Potter for each claim element. Its testimony “is conclusory and unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight.” *Xerox*, IPR2022-00624, Paper 9 at 15 (citing 37 C.F.R. § 42.65(a)).

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

The Board should discretionarily deny institution of the Petition under 35 U.S.C. §314(a) based on the parallel Delaware litigation. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) (“*Fintiv*”). As *General Plastic Industrial Co. v. Canon Kabushiki Kaisha* explains, when “exercising discretion ... [the Board is] mindful of the goals of the AIA—namely, to...make the patent system more efficient....” IPR2016-01357, Paper 19 at 16 (PTAB Sept. 6, 2017). *Fintiv* factors 1, 3, 5 and 6 favor denial. The progress of the Delaware litigation and the weakness of the Petition would make instituting this

IPR an inefficient use of the Board's limited resources even though trial is scheduled for June 14, 2027 and Sarepta filed a *Sotera* stipulation.

Factor (1), the unlikelihood of a stay, favors discretionary denial. *Mylan Lab'ys. Ltd. v. Janssen Pharmaceutica NV*, IPR2020-00440, Paper 17 at 14 (PTAB Sept. 16, 2020) (denial favored where facts "indicate that no stay is likely"). The Delaware Litigation is pending before Judge Andrews. Sarepta has challenged only two of seven asserted patents from one of three families. Sarepta has not sought a stay and Judge Andrews has denied stays under similar circumstances. (EX2003, ¶¶ 1, 25-38). EX2006 (denying a stay because only 3 of 4 patents were challenged); EX2007 (denying a stay where 2 of 4 patents.); EX2008 and EX2014 (denying a stay where IPRs were instituted on 2 of 6 asserted patents). Factor (3) "the amount and type of work already completed in the parallel litigation by the court and the parties at the time of the institution decision," favors discretionary denial. *Fintiv* at 9-10. The parties have served infringement and invalidity contentions and filed and responded to multiple rounds of interrogatories and requests for production. EX2009, EX2010, EX2012. By the institution date, the parties will have filed a joint claim construction chart and opening and answering claim construction briefs. EX2011. 2-3. Therefore, the parties have expended considerable resources in the Delaware litigation, which favors discretionary denial. *Charter Commc'ns, Inc. v. Adaptive Spectrum & Signal Alignment, Inc.*,

IPR2025-00087, Paper 14, at 12-13 (PTAB May 5, 2025). Moreover, Sarepta delayed filing its Petition until eleven months after Genzyme filed its complaint and eight and a half months after service. *Id.* Sarepta also admitted that it was aware of the related '542 patent nearly two years prior to filing this petition. *Supra*, § II.B. These facts demonstrate Sarepta's lack of diligence and further favor discretionary denial. Factor (5) favors discretionary denial because both Petitioner and Patent Owner are parties in the Delaware Litigation. *See Samsung Elecs. Co. v. SiOnyx, LLC*, IPR2025-00065, Paper 16, at 16 (PTAB June 6, 2025). *See Samsung Elecs. Co. v. SiOnyx, LLC*, IPR2025-00065, Paper 16, at 16 (PTAB June 6, 2025). Factor (6) permits the Board to consider "other circumstances that impact the . . . exercise of discretion, including the merits." *Fintiv* at 6. The Petition recycles arguments and evidence from failed prior challenges of the related '542 patent, and it is not sufficiently supported by evidence to warrant institution. Discretionary denial would provide the most efficient outcome for the Board and parties.

VI. Conclusion

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

Dated: September 8, 2025

/ Blaine M. Hackman /
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Counsel for Patent Owner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that today in

Sarepta Therapeutics, Inc., v. Genzyme Corporation, IPR2025-01195

I caused to be served a copy of:

PATENT OWNER’S REQUEST FOR DISCRETIONARY DENIAL

EXHIBITS 2001-2014

upon:

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Date: September 8, 2025

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