

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. 7,704,721

“Compositions and Methods to Prevent AAV Vector Aggregation”

IPR2025-01195

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

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LIST OF EXHIBITS

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EX1079	<i>Genzyme Corp. et al. v. Novartis Gene Therapies, Inc., et al.</i> , C.A. No. 21-1736-RGA (D. Del.), D.I. 251, Redacted Public Version, Defendants' Opening Brief in Support of Their Motion to Amend Their Answer, Defenses, and Counterclaims
EX1080	<i>Genzyme Corp. et al. v. Novartis Gene Therapies, Inc., et al.</i> , C.A. No. 21-1736-RGA (D. Del.), D.I. 259, Redacted Public Version, Plaintiffs' Opposition to Defendants' Motion for Leave to Amend Their Answer, Defenses, and Counterclaims
EX1081	<i>Genzyme Corp. et al. v. Novartis Gene Therapies, Inc., et al.</i> , C.A. No. 21-1736-RGA (D. Del.), D.I. 262, Redacted Public Version, Defendants' Reply Brief in Support of Their Motion for Leave to Amend Their Answer, Defenses, and Counterclaims
EX1082	<i>Genzyme Corp. et al. v. Novartis Gene Therapies, Inc., et al.</i> , C.A. No. 21-1736-RGA (D. Del.), D.I. 301, Redacted Public Version, Defendants' First Amended Answer and Counterclaims
EX1083	<i>Genzyme Corp. et al. v. Novartis Gene Therapies, Inc., et al.</i> , C.A. No. 21-1736-RGA (D. Del.), D.I. 301-1, Redacted Public Version, Exhibits to Defendants' First Amended Answer and Counterclaims
EX1084	<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
EX1085	<i>Genzyme Corp. v. Sarepta Therapeutics, Inc. et al.</i> , C.A. No. 24-882-RGA (D. Del.), D.I. 80, Redacted Public Version, Exhibit 1 and 2 to Plaintiff's Unopposed Motion for Leave to File Second Amended Complaint (Exhibit 1)
EX1086	<i>Genzyme Corp. v. Sarepta Therapeutics, Inc. et al.</i> , C.A. No. 24-882-RGA (D. Del.), D.I. 80-1, Redacted Public Version, Exhibit 1 and 2 to Plaintiff's Unopposed Motion for Leave to File Second Amended Complaint (Exhibit 2)

Exhibit Number	Description
EX1087	<i>Genzyme Corp. v. Sarepta Therapeutics, Inc. et al.</i> , C.A. No. 24-882-RGA (D. Del.) (April 16, 2025), Plaintiff's Initial Claim Charts on Infringement Pursuant to Paragraph 4(C) of the Default Standard for Discovery, Redacted Public Version

I. INTRODUCTION

In this case, important considerations of fairness and the integrity of the Board's proceedings, in addition to the strong merits of the Petition and other factors, weigh heavily against discretionary denial. Notably, at least one recent decision states that "the Office may consider unfair dealings as a factor when determining whether to exercise discretion to deny institution under 35 U.S.C. § 314(a)." *Tessell, Inc. v. Nutanix, Inc.*, IPR2025-00322, Paper 14, 2-3 (PTAB June 12, 2025). The patent at issue, U.S. Patent No. 7,704,721 ("the '721 patent") is the parent of U.S. Patent No. 9,051,542 ("the '542 patent"), which Petitioner has challenged in IPR2025-01194. During prior IPR proceedings brought by Novartis challenging the '542 patent, as set out in the Petition in this case, Patent Owner materially misrepresented the prior art and the state of the art.

Indeed, Patent Owner's discretionary denial request itself continues and extends these unfair dealings. Specifically, in the request, Patent Owner declines to respond to Petitioner's arguments regarding Patent Owner's material misrepresentations to the PTAB during the Novartis IPR proceedings. Instead, Patent Owner addresses these serious charges only in a single footnote, deferring any response until Patent Owner's Preliminary Response (POPR). Paper 8, 17 n.1. In this way, Patent Owner seeks to remove these issues from the discretionary denial proceedings, no doubt in the hope that a grant of discretionary denial will obviate

any further examination of its prior misrepresentations to the Board. The discretionary denial process should not be a mechanism for a patent owner to circumvent adjudication of its prior unfair dealings before the Board.

In addition, in an earlier litigation in which Patent Owner asserted the '542 patent against Novartis, the court granted Novartis's motion to amend its Answer to add inequitable conduct counterclaims, based in part on material misrepresentations to the Patent Office during prosecution, rejecting Patent Owner's arguments that such an amendment was futile. The case settled before the inequitable conduct issue could be adjudicated. *Genzyme Corp. et al. v. Novartis Gene Therapies, Inc., et al.*, C.A. No. 21-1736-RGA (D. Del.), D.I. 286, Oral Order. Although Patent Owner did not assert the '721 patent in this prior litigation, the allegations of inequitable conduct apply equally to the '721 patent, which is the parent of the '542 patent. Moreover, Patent Owner failed to inform the Board during the Novartis IPR proceedings challenging the '542 patent of the misrepresentations and withholding of conflicting data that took place during prosecution, demonstrating yet another instance of unfair dealings by Patent Owner.

Additional factors also weigh heavily against discretionary denial. There will not be redundancy with the District Court proceedings. The trial date is set for six months after the Final Written Decision date in this case, and Petitioner has filed a *Sotera* stipulation. EX1084, 3; Paper 6. In addition, claims 2-4 and 11 are

challenged in the Petition but not asserted in the District Court proceedings. EX1087, 2; Paper 2, 8. Denial of the Petition would therefore leave claims 2-4 and 11 adjudicated by either tribunal, allowing Patent Owner to assert these claims 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.

Patent Owner, furthermore, has recently asserted five additional patents in the District Court litigation, which now includes seven patents from three different patent families, covering multiple materially different technologies. EX1011; EX1085; EX1086. This complexity weighs against discretionary denial.

These considerations outweigh any settled expectations Patent Owner might assert based on the fact that the ’721 patent has recently expired or otherwise. At a minimum, there should be no settled expectations based on unfair dealings with this Board and with the Patent Office.

II. ARGUMENT

A. Patent Owner Has Repeatedly Engaged in Unfair Dealings

1. Prior IPR Proceedings Brought by Novartis

As set out in the Petition, during the prior IPR proceedings in which Novartis challenged the related ’542 patent, Patent Owner and its expert, Dr. Martyn Davies,

materially misrepresented the state of the prior art and, in particular, the disclosures of Potter. Paper 2, 14-17, 27-30; EX1005, ¶¶164-65, 260-68. Specifically, Patent Owner and its expert mischaracterized the disclosures of Potter that are relevant to a core element of the challenged claims, the concentration of viral genomes (vg/ml) in the claimed formulations. *Id.*

The sole independent claim of the '542 patent, subsequently disclaimed by Patent Owner during the Novartis IPR proceedings, recites a composition comprising “recombinant AAV vector particles at a concentration exceeding 1×10^{13} vg/ml up to 6.4×10^{13} vg/ml.” EX1010, 14:15-18. The limitation relating to the vg/ml concentration of the composition, was added during prosecution of both the '542 patent and the '721 patent to overcome rejections by the Examiner. Paper 2, 13; EX1002, 187, 297; *see also* IPR2025-01194, Paper 1, 13; EX1002, 166.

Patent Owner and Dr. Davies materially mischaracterized the concentration of the disclosed formulations in Potter. Paper 2, 14-17, 27-30; EX1005, ¶¶164-65, 260-68. Patent Owner and Dr. Davies argued that the formulations disclosed in Potter “contain virus particle concentrations *several orders of magnitude below the claimed concentration exceeding 10^{13} vg/ml.*” EX1016, 47-48 (emphasis added); EX1060, ¶121 (same). However, as set out in the Petition and Professor Kay’s declaration, Potter actually disclosed formulations with AAV particle concentrations (1.12×10^{13} vg/ml and 1.46×10^{13} vg/ml) that fall squarely within

the range recited in the '542 patent claims. Paper 2, 14-17, 27-30; EX1009, 9-12, Table II; EX1005, ¶¶164-65, 260-68.

Patent Owner also incorrectly characterized the analytical method, electron microscopy, that Potter used to assess aggregation of the purified AAV preparations. Paper 2, 15-17; EX1005, ¶¶265-68. Patent Owner stated that Potter was “unavailing” to show that a POSA would have had a reasonable expectation of success because “visual methods cannot accurately detect the presence of aggregates.” EX1016, 68-69. It is incorrect, however, to describe electron microscopy as a “visual method” that “cannot accurately detect the presence of aggregates.” Paper 2, 16-17; EX1005, ¶¶266-68. Electron microscopy, commonly used in the art to assess aggregation of viral particles, including AAV, was described as a “gold standard analytical method” for characterizing viral particles. Paper 2, 15-17; EX1005, ¶¶71, 256, 266; EX1036, Abstract. It is similarly incorrect to say that electron microscopy “cannot accurately detect” AAV aggregates. *Id.*

2. Discretionary Denial Request

Patent Owner’s discretionary denial request evidences further unfair dealings. Patent Owner addresses its mischaracterizations of the state of the art and Potter in the Novartis IPR proceedings only in a single footnote. Paper 8, p. 17 n.1. Moreover, in this footnote, Patent Owner does not provide any substantive response, and instead expressly defers any such response to its POPR. Yet Patent

Owner does not hesitate for pages of its brief to address multiple other scientific issues, including other technical aspects of Potter. Paper 8, 13-18. Patent Owner's deferral of its substantive response to Petitioner's arguments regarding its misrepresentations during the Novartis IPR proceedings is a transparent and improper effort to avoid consideration of these representations by the Board in the hope that discretionary denial will be granted.

3. Inequitable Conduct During Prosecution

In the prior Novartis litigation, the court granted Novartis's motion to amend its Answer to add inequitable conduct counterclaims, rejecting Patent Owner's arguments that such an amendment was futile. *Genzyme Corp. et al. v. Novartis Gene Therapies, Inc., et al.*, C.A. No. 21-1736-RGA (D. Del.), D.I. 286, Oral Order. Novartis alleged that at least named inventor John Fraser Wright, along with two patent attorneys, intentionally withheld information material to patentability from the Patent Office. EX1082, ¶¶121-259. This withheld information was also material to the patentability of the '721 patent, the parent of the '542 patent. The '542 patent is a continuation of the '721 patent, and both patents claim priority to the applications at issue in the counterclaims. EX1001; EX1010.

First, Novartis alleged that the Applicants withheld data contradicting their representations that vector formulations having an ionic strength at the lower end of the claimed range prevented vector particle aggregation during storage, as measured

by dynamic light scattering (DLS). EX1082, ¶¶209-30, 246-59. Second, Novartis alleged that the Applicants withheld information revealing that additional data in the specification, purporting to show that the claimed formulations prevented aggregation as measured by filtration through a 0.22 µm filter, were seriously flawed, given that their assay lacked any meaningful control. EX1082, ¶¶231-59.

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

Petitioner's prior art combinations and arguments are new. None of the principal prior art that Petitioner relies on was before the Patent Office during prosecution of the '721 patent. Paper 2, 8. Moreover, none of Petitioner's prior art combinations are the same as any prior art combinations advanced by Novartis in its IPR proceedings challenging the related '542 patent. Paper 2, 5-6.

Petitioner here relies on the following combinations of prior art: (1) Auricchio and Konz; and (2) Potter and Konz. Paper 2, 8. Auricchio, Konz, and Potter were never before the Patent Office. Paper 2, 8. Auricchio and Konz were not cited by either party during the Novartis IPR proceedings challenging the related '542 patent. Paper 2, 5-6. As set out in detail in the Petition, Potter was cited in the Novartis IPR proceedings concerning the related '542 patent as background prior art by Novartis, and was materially mischaracterized by Patent Owner. *Id.*

Petitioner's arguments here are wholly different from those raised in the Novartis IPR proceeding challenging the related '542 patent, and, in fact, expressly

address certain deficiencies that the Board found in denying institution in those proceedings. In particular, contrary to Genzyme's arguments in its discretionary denial request, Petitioner's reliance on Konz, which incorporates Evans, is wholly different from Novartis's reliance on Evans in the Novartis IPR proceeding.

1. The Petition Addresses Deficiencies Found by the Board in the Prior IPR Proceedings Brought by Novartis

(a) Petitioner's Reliance on Konz Addresses Deficiencies in the Novartis IPR Proceedings

The Board, in the prior IPR proceedings regarding the related '542 patent rejected Novartis's arguments that certain limitations of claims 5 and 6 of the '542 patent were inherent in the disclosures of the prior art. EX1017, 22, 24; EX1018, 16-22, 26-27. Specifically, Novartis had argued that the limitations relating to the particle radius as measured by dynamic light scattering (DLS) and the recovery after filtration through a 0.22 μm filter were inherent. *Id.*

Here, Petitioner relies on Konz for its express disclosures of using DLS to assess aggregation and evaluating recovery after filtration through a 0.22 μm filter. Paper 2, 33, 36, 44-47, 52, 55, 63-64. Therefore, Petitioner not only relies on a principal piece of prior art that was never before the Patent Office or cited in the Novartis IPR proceedings, but also uses that prior art to address the specific deficiencies that formed a basis for the Board's decisions denying institution.

Patent Owner's arguments that Petitioner cites Konz exclusively for the

disclosures of Evans, incorporated by reference in its entirety in Konz, are therefore simply untrue. The disclosures of Konz regarding DLS and filtration through a 0.22 μm filter are not present in Evans. Indeed, Novartis cited Evans, yet relied on inherency arguments for these limitations, confirming that Evans does not contain these disclosures.

Moreover, Petitioner's reliance on Evans, as incorporated in Konz, is very limited. Paper 2, 17-18. Petitioner argues that, for each combination, the primary reference – either Auricchio or Potter – discloses a high ionic strength formulation that inhibits significant aggregation. Paper 2, 17-18, 34, 41, 53. Given the success of these formulations in inhibiting aggregation, a POSA, in combining these references with Konz, would select similar high ionic strength buffers disclosed in Konz, including those incorporated by reference from Evans. *Id.*

Patent Owner further misrepresents Petitioner's reliance on Konz in arguing that “the Petition's ionic strength element section cites only Evans's disclosure.” Paper 8, 9. In fact, no portion of Petitioner's argument relies solely on Evans's disclosure. Paper 2, 17-18. Patent Owner fails to cite the discussions in the Petition addressing the general motivation for each combination (Auricchio and Konz, Potter and Konz), which apply to *all* challenged claims. Paper 2, 31-34, 51-53. For example, for both combinations, the Petition states that the motivation to combine would include applying Konz's methods of assessing aggregation (DLS and

filtration through a 0.22 μm filter), which would be more efficient and cost effective for large scale preparation than the methods disclosed in Auricchio or Potter. *Id.*

(b) The Petition Demonstrates That Ionic Strength Was Well Known to Be a Result-Effective Variable

Petitioner further addresses another deficiency that the Board found with Novartis's petitions, namely, that Novartis had failed to demonstrate that optimizing the ionic strength of a solution would have been a matter of routine experimentation because Novartis had failed to establish that ionic strength was known to be a result-effective variable. EX1017, 23; EX1018, 27; Paper 2, 18. The Board stated that "Petitioner fails to establish a known relationship between ionic strength and viral particle aggregation." EX1018, 27.

The Petition and the supporting Kay declaration rely on prior art references demonstrating that at least since the 1970s, decades before the earliest possible priority date for the '721 patent, it was known that lowering ionic strength induced aggregation of viral particles. Paper 2, 9, 18; EX1005, ¶¶36-64. These references were never before the Patent Office during prosecution and were not at issue in the prior Novartis IPR proceedings. Despite Patent Owner's misleading attempt to dismiss these as "non-analogous," these references are highly probative of the question whether ionic strength was recognized as a result-effective variable for viral particle aggregation. *Id.* One of these references, for example, is titled,

“Aggregation of Poliovirus and Reovirus by Dilution in Water,” and discloses that “[p]oliovirus and reovirus were found to aggregate into clumps of up to several hundred particles when diluted 10-fold into distilled water from a stock preparation of minimal aggregation in 0.05 M phosphate buffer, pH 7.2, plus 22 to 30% sucrose.” EX1030, Abstract, 2; Paper 2, 9; EX1005, ¶37. These references showed that for both viruses tested, reduced ionic strength produced aggregation, directly addressing the deficiency the Board found in the prior proceedings. *Id.*

2. The Petition Identifies Patent Owner’s Material Misrepresentations in the Novartis IPR Proceedings

The Petition demonstrates that Patent Owner’s material misrepresentations of the state of the art, and the Potter reference in particular, contributed to an incorrect assessment of the merits of the Novartis IPR petitions. Paper 2, 14-17. In its decision denying institution, the Board relied on Patent Owner’s misrepresentations about the state of the art regarding the concentration of prior art AAV formulations, as measured in vg/ml. EX1017, 17-21; Paper 2, 17. Having improperly mischaracterized references such as Potter as disclosing only formulations with concentrations “orders of magnitude” below the claimed ranges, Patent Owner conveyed the false impression that the claimed concentration ranges were not known in the art, or, at least, not known in conjunction with high ionic strength formulations without significant aggregation. EX1017, 17-21. This misrepresentation left Patent

Owner free to argue that a POSA would have assumed the presence of large numbers of empty capsids in certain prior art formulations that would have reduced the stated concentrations to below the claimed ranges of vg/ml. *Id.* Thus, Petitioner has demonstrated an error in the Board's prior consideration of the '721 patent, resulting from Patent Owner's unfair dealings.

C. Petitioner Has Fully Complied with Rules 42.65(a), 42.6(a)(3), and 42.104(b)

As a preliminary matter, Patent Owner improperly seeks to dispute the scientific merits of the Petition during these discretionary denial proceedings. Patent Owner, for example, raises substantive technical arguments regarding whether Petitioner has demonstrated that ionic strength was known to be a result-effective variable, in the guise of challenging the evidentiary basis for the Petition. Paper 8, 13-18. Patent Owner here relies solely on attorney argument, in the absence of any supporting expert testimony. All such arguments should be disregarded as improper and irrelevant to the question of discretionary denial.

Moreover, while advancing numerous technical arguments in its request for discretionary denial, Patent Owner defers to its POPR any discussion of its material mischaracterization of Potter during the Novartis IPR proceedings, choosing instead to rely on future expert testimony for that particular issue. Paper 8, 17, n.1. Such gamesmanship constitutes further evidence of Patent Owner's ongoing unfair

dealings regarding the '721 patent, and should be rejected out of hand.

Nonetheless, Petitioner addresses Patent Owner's unsupported technical arguments below, including by pointing to the ample expert testimony submitted by Professor Kay in support of the Petition, and appropriately cited therein.

1. Professor Kay's Opinions Regarding Ionic Strength Are Supported by Ample Evidence

As discussed above, the Petition demonstrates that ionic strength was well known for decades to be a result-effective variable regarding viral particle aggregation. The Petition and Professor Kay, in particular, rely on three references, Floyd I, Floyd II, and Floyd III, all published decades before the earliest possible priority date for the '721 patent, which explore in detail the relationship between factors including ionic strength, pH, and multivalent ions – in short, most of the limitations recited in the '721 patent claims – and viral particle aggregation. Paper 2, 9, 18; EX1005, ¶¶36-64. Professor Kay addresses these references in a few paragraphs of his declaration, all appropriately cited in the Petition. *Id.*

As also discussed above, given the well known relationship between viral particle aggregation and ionic strength, Professor Kay expresses his opinion that a POSA would have understood references such as Auricchio and Potter to teach that high ionic strength buffers inhibited significant aggregation of rAAV particles in high physical titer (vg/ml) preparations. Paper 2, 34, 41, 53; EX1005, ¶¶285, 330,

368-69. In each of these references, the authors purified a high physical titer rAAV preparation in a high ionic strength buffer, and demonstrated the absence of aggregation. *Id.* Professor Kay concludes from these disclosures in the context of the well known connection between ionic strength and viral particle aggregation, that a POSA would have sought to preserve the high ionic strength buffers of Auricchio and Potter in combining these references with Konz. *Id.*

2. The Petition Does Not Improperly Incorporate Arguments by Reference

The petition does not improperly incorporate arguments by reference. Patent Owner improperly cherry picks a single citation from the Petition, failing to disclose the context. Paper 8, 14-15. The cited portion of the Petition expressly explains that, as discussed above, ionic strength had been known for decades to be a result effective variable for viral particle aggregation: “Factors that influence aggregation of viral particles, including the effects of ionic strength, pH, and the presence of ions such as Na⁺, and multivalent ions such as Mg²⁺, have been studied since at least the 1970s. EX1030; EX1031; EX1032; EX1041, 6; EX1005, ¶36. The Floyd studies showed that dilution of viral particle preparations, which reduces ionic strength, can result in aggregation. EX1030, Abstract, 2; EX1005, ¶¶37-64.” Paper 2, 9. This portion of the Petition properly cites specific portions of Professor Kay’s declaration and specific supporting scientific publications.

Patent Owner's mischaracterizations of the Petition and its reliance on Professor Kay's declaration should be rejected.

3. The Petition Presents Ample Evidence That Auricchio Disclosed the Claimed Ionic Strength

Patent Owner's attempts to rely on conclusory attorney argument, without any supporting expert testimony, to dispute the scientific merits of Professor Kay's opinions regarding Auricchio in the context of a request for discretionary denial should be rejected. In any event, Patent Owner's attorney arguments are incorrect.

Patent Owner mischaracterizes Auricchio's disclosures. As the Petition and Professor Kay explained, Auricchio repeatedly touts the "high salt" elution step as an important feature of its single step column purification (SSCP) method. Paper 2, 2-3, 21-22; EX1005 ¶¶168-70, 183-84. In fact, Auricchio expressly describes the high salt elution step as the last step of the method. *Id.* A POSA would have understood that this high salt elution step contributed to the stability of the preparation and high infectious titer. *Id.* Professor Kay explained, "Whether or not the concentrated rAAV2 preparation was subsequently subjected to an additional buffer exchange for the purpose of reducing the salt concentration or otherwise, the core steps of the method did not require any such additional buffer exchange." Paper 2, 21-22; EX1005 ¶184.

Notably, none of the challenged claims of the '721 patent require *storing* the

purified rAAV preparation in the high ionic strength buffer recited in the claims. EX1001, 14:9-29, 33-40, 49-51. As the Petition and Professor Kay set out, Auricchio's method meets the limitations of the claims in that it involves producing a purified preparation of rAAV virions in a high salt buffer. Paper 2, 38-39; EX1005, ¶¶306-15. The fact that the preparation was subsequently transferred to another buffer for further characterization is irrelevant, especially given the emphasis in Auricchio on elution in high salt. Paper 2, 21-22; EX1005 ¶184. Auricchio's SSCP method, culminating in elution in a high salt buffer, produced a stable, high infectious titer preparation. Paper 2, 31-34; ¶¶274-85.

Patent Owner's arguments, which are incorrect, unsupported, and inappropriate for a discretionary denial request, should be rejected.

4. Patent Owner Again Materially Mischaracterizes Potter's Disclosures

Patent Owner again attempts to rely solely on attorney argument, without any supporting expert testimony, to advance yet another material mischaracterization of Potter's disclosures. To the extent Patent Owner's argument can be understood, Patent Owner seems to assert that Petitioner and Professor Kay rely on different rAAV solutions disclosed in Potter for ionic strength and for physical viral titer. Paper 8, 17-18. This conclusory attorney argument is incorrect, contradicted by the disclosures of Potter, and unsupported by expert testimony. Rather than respond to

the misrepresentation of Potter's disclosures regarding physical viral titer in the Novartis IPR proceedings, Patent Owner advances a different approach to mischaracterize Potter.

As set out in the Petition and Professor Kay's declaration, Potter discloses a protocol for producing a reference standard rAAV formulation for preclinical use. Paper 2, 27-28; EX1005, ¶224. After disclosing a multi-step purification and concentration method, Potter elutes the final stock with a 0.5 M NaCl solution, and then characterizes the resulting concentrated stock solution in various different ways, including through physical viral titer. Paper 2, 28-30; EX1005, ¶¶233-37. As the Petition and Professor Kay set out, the physical viral titer falls squarely within the claimed range. Paper 2, 15, 58-60; EX1005, ¶¶165, 264, 393-99.

Patent Owner's arguments should be dismissed out of hand.

D. 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).

Fintiv Factor 1 should be viewed in light of recent opinions finding that the complexity of the 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*

Inter Partes Review 2025-01195 of U.S. Patent No. 7,704,721 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, after asserting the two patents (the '542 and '721) that Petitioner has challenged in IPR2025-01194 and IPR2025-00195, Patent Owner recently asserted five additional patents from two more patent families, spanning a diverse range of subject matter. EX1011; EX1085; EX1086. 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 analytical ultracentrifugation methods. EX1011, ¶¶25-38. The complexity that these diverse patent families and technologies presents to the District Court weighs against discretionary denial.

Fintiv Factor 2 weighs against discretionary denial in that the trial date is currently scheduled for June 14, 2027, more than sixth months after the date for a Final Written Decision, January 8, 2027, should IPR be instituted here. EX1084, 3.

Fintiv Factor 3 weighs against discretionary denial. The case is in its early stages. Fact discovery is proceeding, and the parties have not finished exchanging preliminary disclosures under the Delaware local rules. EX1084, 2-3. The claim construction hearing is currently scheduled for April 8, 2026. EX1084, 3.

Fintiv Factor 4 weighs against discretionary denial. As discussed above, the Petition challenges four claims (2, 3, 4, and 11) that are not at issue in the District Court proceeding. EX1087, 2; Paper 1, 8. In addition, Petitioner has filed a *Sotera* stipulation here, ensuring that there will be no duplication in the two proceedings. Paper 6.

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

Fintiv Factor 6 weighs heavily 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. The Petition relies on multiple prior art references, in different combinations, none of which was before the Patent Office during prosecution, and only one of which (Potter) was before the Board as a background reference in prior IPR proceedings brought by an unrelated party, Novartis. Moreover, it is this prior art reference that Patent Owner materially mischaracterized during those proceedings. Notably, Patent Owner declines to address its prior mischaracterizations in its discretionary denial request, but defers any such discussion to its POPR.

And despite Patent Owner's efforts to distort the reliance of Petitioner and its expert, Professor Kay, on a second reference, Konz, that reference was never before the Board during the Novartis proceedings, nor are the arguments Petitioner

advances here regarding Konz the same as those advanced by Novartis regarding a different reference, Evans, which is incorporated by reference into Konz.

Moreover, Novartis in a prior district court litigation, brought counterclaims alleging inequitable conduct by Patent Owner during prosecution of the '721 patent. The court permitted Novartis to amend its answer to add these counterclaims over Patent Owner's objections that such an amendment would be futile. For these reasons, *Fintiv* Factor 6 weighs heavily against discretionary denial.

III. CONCLUSION

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

October 8, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §42.6, I hereby certify that on October 8, 2025, the foregoing document, Petitioner's Opposition to Patent Owner's Request for Discretionary Denial, and Exhibits 1079-87 were served via email on the following counsel of record:

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