IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENZYME CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 24-882 (RGA)
	)	
SAREPTA THERAPEUTICS, INC., and SAREPTA THERAPEUTICS THREE, LLC.	)	JURY TRIAL DEMANDED
	)	
Defendants.	)	
	)	

JOINT CLAIM CONSTRUCTION CHART

Pursuant to the Joint Scheduling Order (D.I. 31), Plaintiff Genzyme Corporation ("Plaintiff" or "Genzyme") and Defendants Sarepta Therapeutics, Inc. and Sarepta Therapeutics Three, LLC (collectively, "Defendants" or "Sarepta") submit this Joint Claim Construction Chart identifying the claim terms at issue for U.S. Patent Nos. 9,051,542 ("the '542 patent"), 7,704,721 ("the '721 patent"), 12,013,326 ("the '326 patent"), 12,031,894 ("the '894 patent"), 11,698,377 ("the '377 patent"), 12,123,880 ("the '880 patent"), and 12,298,313 ("the '313 patent") (collectively, the "patents-in-suit"), each party's proposed constructions, and each party's citations to the intrinsic evidence in support of the proposed constructions of the claim terms of the patents-in-suit.

A copy of the '542 patent (Exhibit A), '721 patent (Exhibit B), '326 patent (Exhibit C), '894 patent (Exhibit D), '377 patent (Exhibit E), '880 patent (Exhibit F), and '313 patent (Exhibit G); portions of the file histories for the '542 patent (Exhibit H), '721 patent (Exhibit I), '377 patent (Exhibit J), '880 patent (Exhibit K), and '313 patent (Exhibit L); and exhibits M-AC (described in detail below) relied upon by the Parties are attached hereto.

I. Construction of Claim Terms on which the Parties Agree

The parties have agreed to the following constructions for the claim terms of the patents-in-suit.

A. U.S. Patent Nos. 9,051,542 and 7,704,721

Patent: Claim(s)	Claim Term	Joint Proposed Construction
’542: claim 5 ’721: claim 6	“dynamic light scattering”	“a technique in physics that can be used to determine a size distribution profile of small particles in suspension or polymers in solution”
’542: claim 6 ’721: claim 7	“filtration . . . through a 0.22 µm filter”	“passing a liquid through a 0.22 µm filter to remove materials”
’542: claims 3, 5, 6 ’721: claims 1, 6, 7	“ionic strength”	“one half of the sum of the molar concentration of each solute species times the square of the charge on each species for all excipients present in the solution (calculated according to the equation: $\mu=\frac{1}{2}\sum c_i z_i^2$)”
’542: claims 3, 5, 6 ’721: claims 1, 6, 7	“multivalent ion”	“an ionic species having a charge valency greater than one (whether positive or negative)”
’542: claims 3, 5, 6 ’721: claims 1, 6, 7	“recombinant adeno-associated virus (AAV) vector particles” / “recombinant adeno-associated virus (rAAV) virions” / “recombinant AAV vector particles” / “AAV vector particles” / “recombinant virus particles” / “rAAV virions”	“recombinant AAV virion or virus particles”
’542: claims 3, 5, 6 ’721: claims 1, 6, 7	“purified”	“having been subjected to a purification procedure”
’542: claims 3, 5, 6	“storage” / “stored”	“maintenance in a frozen or nonfrozen state”

Patent: Claim(s)	Claim Term	Joint Proposed Construction
’721: claims 1, 6, 7	“the pH of the purified preparation of rAAV virions is between 7.5 and 8.0”	Plain and ordinary meaning (*i.e.*, “the pH of the purified preparation of rAAV virions is between 7.5 and 8.0 when prepared”)

B. U.S. Patent Nos. 12,013,326 and 12,031,894

Patent: Claim(s)	Claim Term	Joint Proposed Construction
’326: claims 1-3, 7-9, 12-16	“A method of determining the size of one or more fragmented genomes in a preparation of viral particles comprising recombinant adeno-associated viral (rAAV) vectors encapsidated into viral capsids”	Preamble is limiting.
’326: claims 20-22, 25-27, 30	“A method of determining the molar concentrations of each species of individual viral particles in a heterogenous mixture of viral particles comprising recombinant adeno-associated viral (rAAV) vectors encapsidated into viral capsids”	Preamble is limiting.
’894: claims 1-5, 10-23, 30	“A method of quantifying one or more species of individual variant viral particles comprising fragmented recombinant adeno-associated viral (rAAV) genomes in a heterogenous mixture of viral particles”	Preamble is limiting.

C. U.S. Patent Nos. 11,698,377, 12,123,880, and 12,298,313

Patent: Claim(s)	Claim Term	Joint Proposed Construction
’377: claims 1, 3-8, 11	“A method to determine the serotype of an adeno-associated virus (AAV) particle”	Preamble is limiting.
’377: claims 2, 13-17, 20	“A method to determine the serotype of a viral particle”	Preamble is limiting.
’880: claims 1-5, 7, 21	“A method of analyzing a preparation of AAV particles”	Preamble is limiting.

Patent: Claim(s)	Claim Term	Joint Proposed Construction
’880: claims 10-15	“A method of determining post-translational modifications of viral proteins (VPs) in a preparation of viral particles”	Preamble is limiting.
’313: claims 1-6	“A method of detecting post-translational modifications of one or more viral proteins (VPs) in a preparation of adeno-associated virus (AAV) particles”	Preamble is limiting.
’313: claims 11-19	“A method of determining the heterogeneity of viral particles in a preparation of adeno-associated virus (AAV) particles in a preparation of adeno-associated virus (AAV) particles comprising VP1, VP2 and VP3 capsid proteins”	Preamble is limiting.
’313: claims 20-27	“A method of preparing a pharmaceutical composition of adeno-associated virus (AAV) particles”	Preamble is limiting.
’313: claims 3, 17	“N-terminal acetylation”	“a process whereby an acetyl group is covalently added to the amino group of the N-terminal amino acid of a protein”

II. Each Party's Proposed Construction[1,2] of Each Disputed Term of the Patents-in-Suit

The parties dispute the construction of the following claim terms of the patents-in-suit.

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[1] Genzyme provides these proposed claim terms, proposed constructions, and supporting intrinsic evidence based on its current knowledge, understanding, and belief as to the relevant facts and circumstances. Genzyme reserves the right to propose additional and/or amended proposed constructions and intrinsic evidence based on the claim terms and proposed constructions provided by Sarepta, any subsequent communications between the parties, and any relevant discovery not yet provided by Sarepta. In addition, as Plaintiff's investigation is ongoing, Sarepta has failed to comply with its obligations to produce its core technical documents with respect to all asserted patents in accordance with the Scheduling Order, Local Rules, and/or the Delaware Default Standard for Discovery, and Sarepta has failed to serve any noninfringement contentions, further discovery and investigation may require Plaintiff to supplement and/or modify the claim terms and/or proposed constructions identified above. Genzyme has served preliminary infringement claim charts that satisfy the Local Rules or the Delaware Default Standard for Discovery for each asserted patent. Further, Genzyme reserves the right to rely upon all intrinsic evidence identified by Sarepta to support its positions as to the construction of terms proposed by either party, and any intrinsic evidence contradicting or otherwise rebutting any evidence on which Sarepta relies, to support their positions as to the construction of any disputed claim term. Additionally, Plaintiff reserves the right to submit expert declarations/testimony or other extrinsic evidence consistent with the intrinsic evidence in support of Plaintiff's proposed constructions or to rebut Sarepta's arguments and/or any expert declarations or testimony submitted by Sarepta.

[2] Defendants provide these claim terms, proposed constructions, and supporting intrinsic evidence based on their current knowledge, understanding, and belief as to the relevant facts and circumstances. Defendants reserve the right to submit additional and/or amended claim terms, proposed constructions, and/or intrinsic evidence based on the claim terms and proposed constructions provided by Plaintiff, any subsequent communications between the parties, and any relevant discovery that Plaintiff has not yet produced. In addition, as Defendants' investigation is ongoing and Plaintiff has failed to serve preliminary infringement claim charts that satisfy the Local Rules or the Delaware Default Standard for Discovery, further discovery and investigation may require Defendants to supplement and/or modify the claim terms and/or proposed constructions identified above. Defendants have fully complied with all of their disclosure requirements under the Scheduling Order, Local Rules, and the Delaware Default Standard for Discovery. Further, Defendants reserve the right to rely on any intrinsic evidence identified by Plaintiff, and any intrinsic evidence contradicting or otherwise rebutting any evidence on which Plaintiff relies, to support their positions as to the construction of any disputed claim term. Additionally, Defendants reserve the right to submit expert declarations/testimony or other extrinsic evidence consistent with the intrinsic evidence in support of Defendants' proposed constructions or to rebut Plaintiff's arguments and/or any expert declarations or testimony submitted by Plaintiff.

A. U.S. Patent Nos. 9,051,542 and 7,704,721

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
"preventing aggregation" '721: claims 1, 6, 7	Preamble is not limiting. Not indefinite. No construction required.	In support of its proposal, Plaintiff may rely on at least the following: The '721 patent (Ex. B), including at 1:11-16, 1:38-2:5, 2:6-26, 2:27-2:45, 2:46-3:5, 3:14-3:19, 3:33-37, 3:43-52, 3:53-64, 4:10-35, 4:39-44, 4:50-5:1, 6:4-7:24, 7:25-28, 7:65-9:4, 9:5-10:27, 10:28-42, Table 2, Table 3, Figs. 1A-1B, Fig. 2, claims 1, 6, 7, Examples 1-4. The '721 patent file history (Ex. I), including at GENZ-SAREPTA-00000806-817, GENZ-SAREPTA-00000861-870, GENZ-SAREPTA-00000877-985, GENZ-SAREPTA-00000927-	Preamble is limiting. This term is indefinite.	U.S. Patent No. 7,704,721, its claim language and prosecution history, including references and/or declarations cited or submitted therein, as well as for related family patents. *See, e.g.*, Ex. B, the specification of U.S. Patent No. 7,704,721 (GENZ-SAREPTA-00000017-0031), including Abstract; col. 1, lines 14-15; col. 1, lines 38-40; col. 3, lines 3-5; col. 3, lines 14-17; col. 4, lines 41-44; col. 6, lines 10-40; col. 7, lines 2-7; col. 8, lines 27-50; col. 9, lines 14-19; col. 9, lines 25-27; col. 9, lines 44-55. *See also, e.g.*, Ex. I, the prosecution history of the '721 patent,	Plaintiff believes Defendants' §112 positions are best left for expert discovery and are not amenable to resolution at claim construction. Defendants believe that claim construction is the appropriate time under the Scheduling Order for the Court to consider these issues and that construction

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
		940, GENZ-SAREPTA-00000947-956, GENZ-SAREPTA-00001057-1072, GENZ-SAREPTA-00001089-1098, GENZ-SAREPTA-00001114-115. *See also*, *e.g.*, the following references cited on the face of the '721 patent: Ex. V, *Strategies to Suppress Aggregation of Recombinant Keratinocyte Growth Factor during Liquid Formulation Development*, Chen et al. (1994) J. of Pharmaceutical Sciences 83(12):1657-1661); Ex. M, *Aggregation of AAV Vectors, its Impact on Liver-directed Gene Transfer and Development of Vector Formulations to*		including for example, May 18, 2006 Office Action (GENZ-SAREPTA-00000805-0817); September 18, 2006 Amendment Under 37 CFR 1.111 (GENZ-SAREPTA-00000860-0870), pgs. 2, 5-10; December 7, 2006 Office Action (GENZ-SAREPTA-00000876-0895); February 19, 2008 Office Action (GENZ-SAREPTA-00000926-0940); August 19, 2008 Amendment Under 37 CFR 1.111 (GENZ-SAREPTA-00000947-0956), pgs. 2, 5-9; November 18, 2008 Office Action (GENZ-SAREPTA-00001057-1072); December 8, 2009 Submission Under 37 CFR 1.114 (GENZ-SAREPTA-00001089-1098), pgs. 5-8; December 18, 2009 Notice of	is needed to determine claim definiteness and scope.

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
		Prevent and Dissolve Aggregation and Enhance Gene Transfer Efficiency, Huang et al. (2000) Molecular Therapy 1(4); S286; Ex. N, *Stabilizers against heat-induced aggregation of RPR 114849, an acidic fibroblast growth factor (aFGF)*, Won et al. (1998) Int'l J. of Pharmaceutics 167:25-36; Ex. O, *Recombinant adeno-associated virus: Formulation challenges and strategies for a gene therapy vector*, Wright et al. (2003) Current Opinion in Drug Discovery & Development 6(2); 174-178; Ex. P, *Instability, stabilization and formulation of liquid protein pharmaceuticals*, Wang et al. (1999) Int'l J. of Pharmaceutics		Allowance, Interview Summary, Examiner's Amendment (GENZ-SAREPTA-00001106-1115). *See also, e.g.*, Ex. H, the prosecution history of U.S. Patent No. 9,051,542, including for example, May 21, 2014 Office Action (GENZ-SAREPTA-00000254-0267); November 18, 2014 Amendment under 37 CFR 1.111 (GENZ-SAREPTA-00000278-0287). *See also, e.g,*, Ex. AA, Patent Owner's Preliminary Response in IPR2025-01195 (Paper 11), at 2-12, 15-16, 19-29, 32-33, 39, 45-49, 51-56, 62-64, 66-67; Declaration of Dr. Martyn C. Davies in IPR2025-01195 (Ex. 2023), at pgs. 18-32, 33-39, 41-42, 44-	

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
		185:129-188; Ex. Q, *Identification of Factors that Contribute to Recombinant AAV2 Particle Aggregation and Methods to Prevent Its Occurrence during Vector Purification and Formulation*, Wright et al. (2005) Molecular Therapy 12(1);171-178. Genzyme reserves the right to rely upon intrinsic evidence cited by Sarepta, or additional intrinsic evidence based on how Sarepta argues indefiniteness in its briefing.		45, 56-57, 58-64, 65-68, 73-76, 80-81. Evidence cited by Genzyme.	
"without significant aggregation" '542: claim 3	Not indefinite. Plain and ordinary meaning (*i.e.*, "without a material amount of aggregation")	In support of its proposal, Plaintiff may rely on at least the following: The '542 patent (Ex. A), including at 1:40-2:8, 2:9-14, 2:15-28, 2:29-47, 2:48-3:7,	Indefinite	U.S. Patent No. 9,051,542, its claim language and prosecution history, including references and/or declarations cited or submitted therein, as well as for	Plaintiff believes this term does not need construction, but if it does, the plain and ordinary

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
		3:46-67, 4:14-38, 4:42-47, 6:6-7:25, 7:66-9:4, 9:5-10:28, 10:29-43, Table 2, Table 3, Figs. 1A-1B, Fig. 2, claims 1, 3, 5, 6, Examples 1-4. The '542 patent file history (Ex. H), including at GENZ-SAREPTA_00000380-383. *See also, e.g.*, the following references cited on the face of the '542 patent: Ex. P, *Instability, stabilization and formulation of liquid protein pharmaceuticals*, Wang et al. (1999) Int'l J. of Pharmaceutics 185:129-188; Ex. Q, *Identification of Factors that Contribute to Recombinant AAV2 Particle Aggregation and Methods to Prevent Its Occurrence during*		related family patents. *See, e.g.*, Ex. A, the specification of U.S. Patent No. 9,051,542 (GENZ-SAREPTA-00000001-0016), including, col. 1, lines 46-49; col. 1, lines 51-55; col. 3, lines 16-21; col. 3, lines 46-63; col. 4, lines 61-67; col. 6, lines 45-50; col. 6, line 63 – col. 7, line 8; col. 7, lines 18-25; col. 7, lines 49-64; col. 7, line 66 – col. 8, line 5; col. 8, lines 41-56; col. 9, lines 5-55; col. 10, lines 21-39; col. 10, lines 44-50; Tables 2-3; Figures 1A, 1B, & 2. *See also, e.g.*, Ex. H, the prosecution history of the '542 patent, including, for example: 2014-02-18 Amendment Under 37 CFR 1.111, (GENZ-SAREPTA-00000241-0247), pg. 6; 2014-11-	meaning is appropriate. Plaintiff believes Defendants' §112 positions are best left for expert discovery and are not amenable to resolution at claim construction. Defendants believe that claim construction is the appropriate time under the Scheduling Order for the Court to consider these issues and that construction

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
		Vector Purification and Formulation, Wright et al. (2005) Molecular Therapy 12(1);171-178; Ex. R, *A Short-Term Field Use and Shipping Stability Study of a Wild Type Ad5 Adenoviral Reference Material*, Adadevoh, K. et al. (2002) BioProcessing 1(3):62-69. Genzyme reserves the right to rely upon intrinsic evidence cited by Sarepta, or additional intrinsic evidence based on how Sarepta argues indefiniteness in its briefing.[3]		18 Amendment Under 37 CFR 1.111, (GENZ-SAREPTA-00000278-0287), pg. 8; 2014-12-23 Facsimile Transmission, (GENZ-SAREPTA-00000367-0370), pgs. 2-3; 2015-02-03 Applicant-Initiated Interview Summary, (GENZ-SAREPTA-00000378-0379), pg. 1. *See also, e.g.*, Ex. W, the prosecution history of U.S. Provisional Application No. 60/575,997, including for example 2004-06-01 As-Filed Application. *See also, e.g,*, Ex. X, Patent Owner's Preliminary Response in IPR2023-00608 (Paper 14), at pgs. 58-59; Declaration of Dr. Martyn C. Davies in	is needed to determine claim definiteness and scope.

[3] Genzyme objects to Sarepta's inclusion of extrinsic evidence in its intrinsic evidence citations.

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
				IPR2023-00608 (Ex. 2004), at ¶¶ 43-52, 54-55, 117, 125-127, 129-133, 150-157. *See also, e.g,,* Ex. Y, Patent Owner's Preliminary Response in IPR2023-00609 (Paper 16), at pgs. 14, 28, 32, 34, 36, 43; Declaration of Dr. Martyn C. Davies in IPR2023-00609 (Ex. 2004), at ¶¶ 42-50, 52-53, 65-66, 98, 102, 104-106, 108-112, 125. *See also, e.g,,* Ex. Z, Patent Owner's Preliminary Response in IPR2025-01194 (Paper 11), at pgs. 7, 10, 23, 38-40, 52, 54-55, 61-63, 66-67; Declaration of Dr. Martyn C. Davies in IPR2025-01194 (Ex. 2023), at ¶¶ 46-61, 63-64, 69, 78-79, 83, 115-118, 143, 151, 157, 174-182, 190.	

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
				Evidence cited by Genzyme.[4]	
"without significant aggregation" '542: claim 5	"the purified, recombinant AAV vector particles have an average particle radius (Rh) of less than about 20 nm as measured by dynamic light scattering." The purified, recombinant vector particles must satisfy the recited metric and threshold after storage.	In support of its proposal, Plaintiff may rely on at least the following: The '542 patent (Ex. A), including at 1:17-19, 1:40-2:8, 2:9-14, 2:15-28, 2:29-47, 2:48-3:7, 3:10-15, 3:46-63, 4:14-38, 4:42-47, 6:6-7:25, 7:66-9:4, 9:5-10:28, 10:29-43, Table 2, Table 3, Figs. 1A-1B, Fig. 2, claims 1, 5, Examples 1-4. Genzyme reserves the right to rely upon intrinsic evidence cited	"the purified, recombinant AAV vector particles have an average particle radius (Rh) of less than about 20 nm as measured by dynamic light scattering." The recited metric and threshold for determining aggregation in claim 5 is a post-storage not pre-storage metric and threshold.	U.S. Patent No. 9,051,542, its claim language and prosecution history, including references and/or declarations cited or submitted therein, as well as for related family patents. *See, e.g.*, Ex. A., the specification of U.S. Patent No. 9,051,542 (GENZ-SAREPTA-00000001-0016), including, col. 1, lines 46-49; col. 1, lines 51-55; col. 3, lines 16-21; col. 3, lines 46-63; col. 4, lines 61-67; col. 6, lines 45-50; col. 6, line	Plaintiff believes there is no relevant question for construction, as the parties' constructions agree that the recited metric must be satisfied after storage except Defendants insist on using the phrase "post-storage not pre-storage," which may

[4] Defendants intend to rely on the claim construction papers related to the term "significant aggregation" in *Genzyme Corporation et al. v. Novartis Gene Therapies, Inc. et al.*, 21-cv-1736 (D. Del.), including the Memorandum Opinion, D.I. 263 at 18-26 (Aug. 18, 2023); the Claim Construction Order, D.I. 268 at 7 (Aug. 30, 2023); the Joint Claim Construction Brief, D.I. 105 (public) at 72-86 (Jan. 20, 2023); and the Markman hearing transcript, D.I. 177 at 103-116 (May 7, 2023). Defendants also intend to rely on the summary judgement papers related to the term "significant aggregation" in *Genzyme Corporation et al. v. Novartis Gene Therapies, Inc. et al.*, 21-cv-1736 (D. Del.), including D.I. 312 at 32-36, 38-43 (Dec. 1, 2023); D.I. 344 at 13-17, 19-20 (Dec. 22, 2023); D.I. 346 at 28-36 (Dec. 22, 2023); D.I. 315 at 26-32 (Dec. 1, 2023); D.I. 342 at 19-24 (Dec. 22, 2023); and D.I. 348 at 15-19 (Dec. 22, 2023).

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
		by Sarepta.[5]		63 – col. 7, line 8; col. 7, lines 18-25; col. 7, lines 49-64; col. 7, line 66 – col. 8, line 5; col. 8, lines 41-56; col. 9, lines 5-55; col. 10, lines 21-39; col. 10, lines 44-50; Tables 2-3; Figures 1A, 1B, & 2. *See also, e.g.*, Ex. H, the prosecution history of the '542 patent, including, for example: 2014-02-18 Amendment Under 37 CFR 1.111, (GENZ-SAREPTA-00000241-0247), pg. 6; 2014-11-18 Amendment Under 37 CFR 1.111, (GENZ-SAREPTA-00000278-0287), pg. 8; 2014-12-23 Facsimile Transmission, (GENZ-SAREPTA-00000367-0370), pgs. 2-3; 2015-02-03 Applicant-Initiated Interview	cause jury confusion. The difference does not bear on infringement or validity and is best addressed, if necessary, at the jury instruction stage. Defendants believe construction is needed to define the scope of the claims for potential invalidity and infringement. Defendants' proposed construction makes clear

[5] Genzyme objects to Sarepta's inclusion of extrinsic evidence in its intrinsic evidence citations.

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
				Summary, (GENZ-SAREPTA-00000378-0379), pg. 1. *See also, e.g.*, Ex. W, the prosecution history of U.S. Provisional Application No. 60/575,997, including for example 2004-06-01 As-Filed Application. *See also, e.g,*, Ex. X, Patent Owner's Preliminary Response in IPR2023-00608 (Paper 14), at pgs. 58-59; Declaration of Dr. Martyn C. Davies in IPR2023-00608 (Ex. 2004), at ¶¶ 43-52, 54-55, 117, 125-127, 129-133, 150-157. *See also, e.g,*, Ex. Y, Patent Owner's Preliminary Response in IPR2023-00609 (Paper 16), at pgs. 14, 28, 32, 34, 36, 43; Declaration of Dr.	when this term must be met, consistent with the Court's construction in *Genzyme Corporation et al. v. Novartis Gene Therapies, Inc. et al.*, 21-cv-1736 (D. Del.). Contrary to Plaintiff's contention, Defendants' proposed construction is not likely to cause jury confusion, but instead, makes plain that the recited metric and threshold

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
				Martyn C. Davies in IPR2023-00609 (Ex. 2004), at ¶¶ 42-50, 52-53, 65-66, 98, 102, 104-106, 108-112, 125. *See also, e.g,,* Ex. Z, Patent Owner's Preliminary Response in IPR2025-01194 (Paper 11), at pgs. 7, 10, 23, 38-40, 52, 54-55, 61-63, 66-67; Declaration of Dr. Martyn C. Davies in IPR2025-01194 (Ex. 2023), at ¶¶ 46-61, 63-64, 69, 78-79, 83, 115-118, 143, 151, 157, 174-182, 190. Evidence cited by Genzyme.[6]	are measured post-storage not pre-storage – unlike Plaintiff's proposed construction, which is ambiguous as to when the measurement must be made.

[6] Defendants intend to rely on the claim construction papers related to the term "significant aggregation" in *Genzyme Corporation et al. v. Novartis Gene Therapies, Inc. et al.*, 21-cv-1736 (D. Del.), including the Memorandum Opinion, D.I. 263 at 18-26 (Aug. 18, 2023); the Claim Construction Order, D.I. 268 at 7 (Aug. 30, 2023); the Joint Claim Construction Brief, D.I. 105 (public) at 72-86 (Jan. 20, 2023); and the Markman hearing transcript, D.I. 177 at 103-116 (May 7, 2023). Defendants also intend to rely on the summary judgement papers related to the term "significant aggregation" in *Genzyme Corporation et al. v. Novartis Gene Therapies, Inc. et al.*, 21-cv-1736 (D. Del.), including D.I. 312 at 32-36, 38-43 (Dec. 1, 2023); D.I. 344 at 13-17, 19-20 (Dec. 22, 2023); D.I. 346 at 28-36 (Dec. 22, 2023); D.I. 315 at 26-32 (Dec. 1, 2023); D.I. 342 at 19-24 (Dec. 22, 2023); and D.I. 348 at 15-19 (Dec. 22, 2023).

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
"without significant aggregation" '542: claim 6	"recovery of the purified, recombinant virus particles is at least about 90% following filtration of the composition of said AAV vector particles through a 0.22 μm filter." The purified, recombinant vector particles must satisfy the recited metric and threshold after storage.	In support of its proposal, Plaintiff may rely on at least the following: The '542 patent (Ex. A), including at 1:17-19, 1:40-2:8, 2:9-14, 2:15-28, 2:29-47, 2:48-3:7, 3:10-15, 3:46-67, 7:66-9:4, 9:5-10:28, 10:29-43, Table 2, Table 3, claims 1, 6, Examples 1-4. Genzyme reserves the right to rely upon intrinsic evidence cited by Sarepta.[7]	"recovery of the purified, recombinant virus particles is at least about 90% following filtration of the composition of said AAV vector particles through a 0.22 μm filter." The recited metric and threshold for determining aggregation in claim 6 is a post-storage not pre-storage metric and threshold.	U.S. Patent No. 9,051,542, its claim language and prosecution history, including references and/or declarations cited or submitted therein, as well as for related family patents. *See, e.g.*, Ex. A, the specification of U.S. Patent No. 9,051,542 (GENZ-SAREPTA-00000001-0016), including, col. 1, lines 46-49; col. 1, lines 51-55; col. 3, lines 16-21; col. 3, lines 46-63; col. 4, lines 61-67; col. 6, lines 45-50; col. 6, line 63 – col. 7, line 8; col. 7, lines 18-25; col. 7, lines 49-64; col. 7, line 66 – col. 8, line 5; col. 8, lines 41-56; col. 9, lines 5-55; col. 10, lines 21-39; col. 10, lines 44-50; Tables 2-3;	Plaintiff believes there is no relevant question for construction, as the parties' constructions agree that the recited metric must be satisfied after storage except Defendants insist on using the phrase "post-storage not pre-storage," which may cause jury confusion. The difference does not bear on infringement or validity

[7] Genzyme objects to Sarepta's inclusion of extrinsic evidence in its intrinsic evidence citations.

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
				Figures 1A, 1B, & 2. *See also, e.g.*, Ex. H, the prosecution history of the '542 patent, including, for example: 2014-02-18 Amendment Under 37 CFR 1.111, (GENZ-SAREPTA-00000241-0247), pg. 6; 2014-11-18 Amendment Under 37 CFR 1.111, (GENZ-SAREPTA-00000278-0287), pg. 8; 2014-12-23 Facsimile Transmission, (GENZ-SAREPTA-00000367-0370), pgs. 2-3; 2015-02-03 Applicant-Initiated Interview Summary, (GENZ-SAREPTA-00000378-0379), pg. 1. *See also, e.g.*, Ex. W, the prosecution history of U.S. Provisional Application No. 60/575,997, including for example 2004-06-01 As-Filed	and is best addressed, if necessary, at the jury instruction stage. Defendants believe construction is needed to define the scope of the claims for potential invalidity and infringement. Defendants' proposed construction makes clear when this term must be met, consistent with the Court's construction in *Genzyme Corporation et al. v.*

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
				Application. *See also, e.g,,* Ex. X, Patent Owner's Preliminary Response in IPR2023-00608 (Paper 14), at pgs. 58-59; Declaration of Dr. Martyn C. Davies in IPR2023-00608 (Ex. 2004), at ¶¶ 43-52, 54-55, 117, 125-127, 129-133, 150-157. *See also, e.g,,* Ex. Y, Patent Owner's Preliminary Response in IPR2023-00609 (Paper 16), at pgs. 14, 28, 32, 34, 36, 43; Declaration of Dr. Martyn C. Davies in IPR2023-00609 (Ex. 2004), at ¶¶ 42-50, 52-53, 65-66, 98, 102, 104-106, 108-112, 125. *See also, e.g,,* Ex. Z, Patent Owner's Preliminary Response in IPR2025-01194 (Paper 11), at pgs. 7,	*Novartis Gene Therapies, Inc. et al.*, 21-cv-1736 (D. Del.). Contrary to Plaintiff's contention, Defendants' proposed construction is not likely to cause jury confusion, but instead, makes plain that the recited metric and threshold are measured post-storage not pre-storage – unlike Plaintiff's proposed construction, which is ambiguous as

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
				10, 23, 38-40, 52, 54-55, 61-63, 66-67; Declaration of Dr. Martyn C. Davies in IPR2025-01194 (Ex. 2023), at ¶¶ 46-61, 63-64, 69, 78-79, 83, 115-118, 143, 151, 157, 174-182, 190. Evidence cited by Genzyme.[8]	to when the measurement must be made.
"the pH of the composition is between 7.5 and 8.0" '542: claims 3, 5, 6	Plain and ordinary meaning (*i.e.*, "the pH of the composition is between 7.5 and 8.0 when prepared")	In support of its proposal, Plaintiff may rely on at least the following: The '542 patent (Ex. A), including at 1:65-2:8, 3:41-45, 4:1-10, 4:14-23, 4:24-32, 5:21-38, 6:5-60, 6:61-7:25, 7:32-38, 8:1-9:4, 9:7-	Plain and ordinary meaning (*i.e.*, "the pH of the composition is between 7.5 and 8.0 when prepared and during storage")	U.S. Patent No. 9,051,542, its claim language and prosecution history, including references and/or declarations cited or submitted therein, as well as for related family patents. *See, e.g.*, Ex. A, the	Plaintiff believes the plain and ordinary meaning provides appropriate guidance for the parties on the scope of

[8] Defendants intend to rely on the claim construction papers related to the term "significant aggregation" in *Genzyme Corporation et al. v. Novartis Gene Therapies, Inc. et al.*, 21-cv-1736 (D. Del.), including the Memorandum Opinion, D.I. 263 at 18-26 (Aug. 18, 2023); the Claim Construction Order, D.I. 268 at 7 (Aug. 30, 2023); the Joint Claim Construction Brief, D.I. 105 (public) at 72-86 (Jan. 20, 2023); and the Markman hearing transcript, D.I. 177 at 103-116 (May 7, 2023). Defendants also intend to rely on the summary judgement papers related to the term "significant aggregation" in *Genzyme Corporation et al. v. Novartis Gene Therapies, Inc. et al.*, 21-cv-1736 (D. Del.), including D.I. 312 at 32-36, 38-43 (Dec. 1, 2023); D.I. 344 at 13-17, 19-20 (Dec. 22, 2023); D.I. 346 at 28-36 (Dec. 22, 2023); D.I. 315 at 26-32 (Dec. 1, 2023); D.I. 342 at 19-24 (Dec. 22, 2023); and D.I. 348 at 15-19 (Dec. 22, 2023).

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
		18, 9:19-65, 9:66-10:15, 10:35-43, 11:65-12:8, cls. 1, 4, 5, 6, Examples 1-4. The '542 patent file history (Ex. H), including at GENZ-SAREPTA-00000067, GENZ-SAREPTA-00000242, GENZ-SAREPTA-00000244-247, GENZ-SAREPTA-00000255-267, GENZ-SAREPTA-00000280-287, GENZ-SAREPTA-00000354-364, GENZ-SAREPTA-00000365, GENZ-SAREPTA-00000368-370. The '721 patent file history (Ex. I), including at GENZ-SAREPTA-00000806-817, GENZ-SAREPTA-00000861-870, GENZ-SAREPTA-00000877-		specification of U.S. Patent No. 9,051,542 (GENZ-SAREPTA-00000001-0016), including Abstract; col. 1, lines 17-19; col. 1, lines 41-49; col. 1, lines 55-58; col. 2, lines 5-8; col. 2, lines 48-52; col. 2, lines 62-65; col. 3, lines 11-22; col. 3, lines 49-55; col. 4, lines 42-47; col. 5, lines 28-30; col. 7, lines 32-35; col. 8, lines 1-5; col. 8, lines 62-63; col. 9, lines 5-24; col. 9, line 30- col. 10, line 15; col. 10, lines 35-43; col. 13, lines 17-19; Table 3. *See also, e.g.*, Ex. H, the prosecution history of U.S. Patent No. 9,051,542, including for example, March 19, 2010 Continuation Application (GENZ-SAREPTA-00000033-0074); November 9,	the asserted claims in dispute. Defendants believe that their proposed construction reflects the plain and ordinary meaning of this term in the '542 claims and that construction is needed to define the scope of the claims for potential infringement and invalidity.

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
		985, GENZ-SAREPTA-00000927-940, GENZ-SAREPTA-00000947-956, GENZ-SAREPTA-00001057-1072, GENZ-SAREPTA-00001089-1098, GENZ-SAREPTA-00001114-115. *See also, e.g.*, the following references cited on the face of the '542 patent: Ex. R, *A Short-Term Field Use and Shipping Stability Study of a Wild Type Ad5 Adenoviral Reference Material*, Adadevoh, K. et al. (2002) BioProcessing (1(3):62-69; Ex. S, *Development of formulations that enhance physical stability of viral vectors for gene therapy*, Croyle, MA et al.		2011 Office Action (GENZ-SAREPTA-00000114-0126); May 9, 2012 Amendment under 37 CFR 1.111 (GENZ-SAREPTA-00000162-0172); July 17, 2012 Office Action (GENZ-SAREPTA-00000185-0199); January 17, 2013 Submission under 37 CFR 1.114 (GENZ-SAREPTA-00000206-0216); August 15, 2013 Office Action (GENZ-SAREPTA-00000223-0234); February 18, 2014 Amendment under 37 CFR 1.111 (GENZ-SAREPTA-00000241-0247); May 21, 2014 Office Action (GENZ-SAREPTA-00000254-0267); November 18, 2014 Amendment under 37 CFR 1.111 (GENZ-SAREPTA-00000278-0287); December 23, 2014 Proposed	

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
		(2001) Gene Therapy (8:1281-1290); Ex. T, U.S. Patent No. 4,138,287 (Andersson et al.); Ex. P, *Instability, stabilization and formulation of liquid protein pharmaceuticals*, Wang et al. (1999) Int'l J. of Pharmaceutics 185:129-188; Ex. U, *Evidence That Ionic Interactions Are Involved in Concentration-Induced Aggregation of Recombinant Adeno-Associated Virus*, Qu et al. (2003) Mol. Therapy 7(5); S348; Ex. AB, *Large-scale production, purification and crystallization of wild-type adeno-associated virus-2*, Xie, Q. et al. (2004) J. Virological Methods 122; 17-22.		Examiner's Amendment (GENZ-SAREPTA-00000367-0370); February 3, 2015 Notice of Allowability (GENZ-SAREPTA-00000380-0383). *See also, e.g.*, Ex. I, the prosecution history of U.S. Patent No. 7,704,721, including for example, May 18, 2006 Office Action (GENZ-SAREPTA-00000805-0817); September 18, 2006 Amendment Under 37 CFR 1.111 (GENZ-SAREPTA-00000860-0870); December 7, 2006 Office Action (GENZ-SAREPTA-00000876-0895); February 19, 2008 Office Action (GENZ-SAREPTA-00000926-0940); August 19, 2008 Amendment Under 37 CFR 1.111 (GENZ-	

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
		Genzyme reserves the right to rely upon intrinsic evidence cited by Sarepta.		SAREPTA-00000947-0956); November 18, 2008 Office Action (GENZ-SAREPTA-00001057-1072); December 8, 2009 Submission Under 37 CFR 1.114 (GENZ-SAREPTA-00001089-1098); December 18, 2009 Notice of Allowance, Interview Summary, Examiner's Amendment (GENZ-SAREPTA-00001106-1115). Evidence cited by Genzyme.[9]	

[9] Defendants intend to rely on the claim construction papers in *Genzyme Corporation et al. v. Novartis Gene Therapies, Inc. et al.*, 21-cv-1736 (D. Del.), including the Memorandum Opinion, D.I. 263 at 24-26 (Aug. 18, 2023); the Claim Construction Order, D.I. 268 at 7 (Aug. 30, 2023); the Joint Claim Construction Brief, D.I. 105 (public) at 74-78 (Jan. 20, 2023); the Markman hearing transcript, D.I. 177 (May 7, 2023); Supplemental Claim Construction Briefing (and exhibits), D.I. 353 (public); and Declaration of Mansoor Amiji (and exhibits) D.I. 354 (public).

B. U.S. Patent Nos. 11,698,377, 12,123,880, and 12,298,313

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
"variants" / "variant" '880: claims 2, 21 '313: claims 12, 23	Plain and ordinary meaning (*i.e.*, "AAV mutant capsid protein[s]")	In support of its proposal, Plaintiff may rely on at least the following: The '880 patent (Ex. F), including at 2:45-58, 3:14-36, 4:4-16, 5:54-57, 19:54-65, 25:44-53, 26:24-63, 27:9-54, 35:45-36:36, Figures 9-19, Examples 4-5. The '313 patent (Ex. G), including at 2:48-61, 3:17-38, 4:6-18, 5:56-59, 19:54-65, 25:44-53, 26:24-63, 27:9-54, 35:45-36:36, Figures 9-19, Examples 4-5. *See also, e.g.*, the following reference cited in the specifications of the '880 and '313 patents and incorporated	"AAV mutant capsid protein[s] in which at least one amino acid has been replaced by an amino acid with a different probability of undergoing post-translational modification than the wild-type amino acid at that position"	U.S. Patent No. 12,123,880, its claim language and prosecution history, including reference and/or declarations cited or submitted therein, as well as for related family patents. *See, e.g.*, Ex. F, the specification of U.S. Patent No. 12,123,880 (GENZ-SAREPTA-00002037-2112), including: claims 1-21; Figures 1-19; 2:45-58; 3:14-36; 4:4-16; 5:40-6:3; 12:58-14:22; 19:54-65; 25:44-53; 26:24-63; 27:9-54; 35:45-36:15; 36:16-36; 64:48-67:20; 67:22-68:45; Tables 1-11; Examples 1-5; SEQ ID Nos. 1-40. U.S. Patent No. 12,298,313, its claim	Plaintiff believes the plain and ordinary meaning provides appropriate guidance for the parties on the scope of the asserted claims in dispute. Defendants believe that their proposed construction reflects the meaning of this term as it is used in the '880 and '313 patents and that construction is needed to define the

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
		therein by reference ('880 Patent at 2:13; '313 Patent at 2:4-6): Ex. AC, U.S. Patent Publication No. 2012/0164106, cited at '880 Patent at 36:16-20; '313 Patent at 36:16-20. Genzyme reserves the right to rely upon intrinsic evidence cited by Sarepta.		language and prosecution history, including reference and/or declarations cited or submitted therein, as well as for related family patents. *See, e.g.*, Ex. G, the specification of U.S. Patent No. 12,298,313 (GENZ-SAREPTA-00002113-2187), including: claims 1-27; Figures 1-19; 2:48-61; 3:17-38; 4:6-18; 5:42-6:5; 12:58-14:22; 19:54-65; 25:44-53; 26:24-63; 27:9-54; 35:45-36:15; 36:16-36; 64:31-66:67; 67:1-68:26; Tables 1-11; Examples 1-5; SEQ ID Nos. 1-40. *See also, e.g.*, the prosecution history of the '313 and '880 patents, including, for example:	scope of the claims for potential infringement and invalidity. Defendants believe that Plaintiff's proposed construction ("AAV mutant capsid protein[s]") does not help to define the scope of the term, but instead, merely substitutes a different, not clearly defined term ("mutant") that is used in the specification but not used in the claims.

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
				U.S. Provisional Application No. 62/375,314, Ex. J at (GENZ-SAREPTA-00004721-4848) U.S. Application No. 16/325,653, Ex. J at: 10/01/18 International Search Report (GENZ-SAREPTA-00004646-4652); 10/01/18 Written Opinion of the International Searching Authority (GENZ-SAREPTA-00004699-4712); 07/23/19 Preliminary Amendment (GENZ-SAREPTA-00005250-5260); 02/21/20 Preliminary Amendment (GENZ-SAREPTA-00006727-6736); 03/18/21 Office Action (GENZ-SAREPTA-00006990-6995); 06/17/21 Response (GENZ-SAREPTA-00007007-7009); 07/09/21 Office	

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
				Action (GENZ-SAREPTA-00007010-7017); 10/20/21 Interview Summary (GENZ-SAREPTA-00007029-7030); 11/09/21 Response (GENZ-SAREPTA-00007037-7052); 10/06/21 Notice of Opposition (GENZ-SAREPTA-00007542-7580); 10/06/21 Notice of Opposition (GENZ-SAREPTA-00007581-7593); 11/17/21 Office Action (GENZ-SAREPTA-00007661-7673); 02/17/22 Amendment (GENZ-SAREPTA-00007696-7711); 02/28/22 Advisory Action (GENZ-SAREPTA-00007717-7719); 02/23/22 Interview Summary (GENZ-SAREPTA-00007720); 04/28/22 Office Action (GENZ-SAREPTA-	

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
				00007731-7742); 10/27/22 Amendment (GENZ-SAREPTA-00007757-7764); 11/08/22 Office Action (GENZ-SAREPTA-00007782-7787); 02/03/23 Amendment (GENZ-SAREPTA-00007807-7813); 02/21/23 Notice of Allowance (GENZ-SAREPTA-00007817-7824). U.S. Application No. 18/321,542, Ex. K at: 10/17/23 Preliminary Amendment (GENZ-SAREPTA-00008443-8478); 07/03/24 Notice of Allowance (GENZ-SAREPTA-00008535-8542); 04/09/25 Amendment after Allowance (GENZ-SAREPTA-00008543-8549). U.S. Application No. 19/013,863, Ex. L at: 01/08/25 Preliminary	

Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence	Reason for Need of Resolution
				Amendment (GENZ-SAREPTA-00008733-8740); 04/02/25 Notice of Allowance (GENZ-SAREPTA-00008849-8855); 04/09/25 Amendment after Allowance (GENZ-SAREPTA-00008858-8865). Evidence cited by Genzyme.	

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