

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

GENZYME CORPORATION,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC. and
SAREPTA THERAPEUTICS THREE,
LLC,

Defendants.

C.A. No. 24-882 (RGA)

CLAIM CONSTRUCTION ORDER

In accordance with the Court’s Oral Order (D.I. 159), the Court’s rulings made at the Markman Hearing held on April 22, 2026, the Court’s April 20, 2026 Order (D.I. 157), and the parties’ agreed constructions as reflected in the Amended Joint Claim Construction Chart (D.I. 131), the terms of U.S. Patent Nos. 7,704,721 (“’721 patent”), 9,051,542 (“’542 patent”), 12,013,326 (“’326 patent”), 12,031,894 (“’894 patent”), 12,123,880 (“’880 patent”), 12,298,313 (“’313 patent”), and 11,698,377 (“’377 patent”) are construed as set forth below:

TERM	PATENT CLAIMS	CONSTRUCTION
“the pH of the composition is between 7.5 and 8.0”	’542 patent: claims 3, 5, 6	Plain and ordinary meaning (<i>i.e.</i> , “the pH of the composition is between 7.5 and 8.0 when prepared”)
“without significant aggregation”	’542 patent: claim 5	<p>“the purified, recombinant AAV vector particles have an average particle radius (Rh) of less than about 20 nm as measured by dynamic light scattering.”</p> <p>The purified, recombinant vector particles must satisfy the recited metric and threshold after storage.</p>
“without significant aggregation”	’542 patent: claim 6	“recovery of the purified, recombinant virus particles is at

TERM	PATENT CLAIMS	CONSTRUCTION
		<p>least about 90% following filtration of the composition of said AAV vector particles through a 0.22 μm filter.”</p> <p>The purified, recombinant vector particles must satisfy the recited metric and threshold after storage.</p>
“dynamic light scattering”	<p>’542 patent: claim 5</p> <p>’721 patent: claim 6</p>	“a technique in physics that can be used to determine a size distribution profile of small particles in suspension or polymers in solution”
“filtration . . . through a 0.22 μm filter”	<p>’542 patent: claim 6</p> <p>’721 patent: claim 7</p>	“passing a liquid through a 0.22 μm filter to remove materials”
“ionic strength”	<p>’542 patent: claims 3, 5, 6</p> <p>’721 patent: claims 1, 6, 7</p>	<p>“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: $\mu = \frac{1}{2} \sum c_i z_i^2$)”</p>
“multivalent ion”	<p>’542 patent: claims 3, 5, 6</p> <p>’721 patent: claims 1, 6, 7</p>	“an ionic species having a charge valency greater than one (whether positive or negative)”
<p>“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”</p>	<p>’542 patent: claims 3, 5, 6</p> <p>’721 patent: claims 1, 6, 7</p>	“recombinant AAV virion or virus particles”
“purified”	<p>’542 patent: claims 3, 5, 6</p> <p>’721 patent: claims 1, 6, 7</p>	“having been subjected to a purification procedure”
“storage” / “stored”	’542 patent: claims 3, 5, 6	“maintenance in a frozen or nonfrozen state”
“the pH of the purified preparation of rAAV virions is between 7.5 and 8.0”	’721 patent: claims 1, 6, 7	<p>Plain and ordinary meaning (<i>i.e.</i>, “the pH of the purified preparation of rAAV virions is between 7.5 and 8.0 when</p>

TERM	PATENT CLAIMS	CONSTRUCTION
		prepared”)
“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”	’326 patent: claims 1-3, 7-9, 12-16	Preamble is limiting.
“A method of determining the molar concentrations of each species of individual viral particles in a heterogeneous mixture of viral particles comprising recombinant adeno-associated viral (rAAV) vectors encapsidated into viral capsids”	’326 patent: claims 20-22, 25-27, 30	Preamble is limiting.
“A method of quantifying one or more species of individual variant viral particles comprising fragmented recombinant adeno-associated viral (rAAV) genomes in a heterogeneous mixture of viral particles”	’894 patent: claims 1-5, 10-23, 30	Preamble is limiting.
“A method to determine the serotype of an adeno-associated virus (AAV) particle”	’377 patent: claims 1, 3-8, 11	Preamble is limiting.
“A method to determine the serotype of a viral particle”	’377 patent: claims 2, 13-17, 20	Preamble is limiting.
“A method of analyzing a preparation of AAV particles”	’880 patent: claims 1-5, 7, 21	Preamble is limiting.
“A method of determining post-translational modifications of viral proteins (VPs) in a preparation of viral particles”	’880 patent: claims 10-15	Preamble is limiting.
“variants” / “variant”	’880 patent: claims 2, 21 ’313 patent: claims 12, 23	Plain and ordinary meaning (i.e., “AAV mutant capsid protein[s]”)

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

IT IS SO ORDERED this 27th day of April 2026

/s/ Richard G. Andrews

Honorable Richard G. Andrews
United States District Court Judge