

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAREPTA THERAPEUTICS, INC.,
Petitioner

v.

GENZYME CORPORATION,
Patent Owner.

Case: IPR2026-00150
Patent No. 12,031,894

**PATENT OWNER'S OBJECTIONS TO
EVIDENCE FILED WITH THE PETITION**

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner submits the following objections to evidence submitted with the Petition in the instant proceeding. These objections have been timely filed and served within ten business days of the institution of the trial in this matter.

I. Exhibit 1006

Patent Owner objects to Exhibits 1006 (WO2014/125101 A1 and certified English translation (“Le Bec”)) for the following reasons:

- As inadmissible under Fed. R. Evid. 401 and/or 403 for lack of relevance and/or as prejudicial, misleading, and/or wasting time;
- For lack of authentication under Fed. R. Evid. 901; and
- As hearsay under Fed. R. Evid. 801-802 to the extent statements therein are relied on for the truth of the matter asserted and do not fall within any exceptions.

Patent Owner likewise objects to any portion of the Petition and Dr. Berkowitz’s Declaration (Ex. 1004) purporting to rely on Exhibit 1006.

II. Exhibits 1007-1013, 1023-1038, and 1040-1041

Patent Owner objects to the following exhibits:

Exhibit Number	Description
EX1007	de la Maza and Carter, “DNA Structure of Incomplete Adeno-Associated-Virus Particles” in REPLICATION OF MAMMALIAN PARVOVIRUSES (Ward, D., and Tattersall, P., eds.), Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, 193-204 (1978) (“de la Maza”)
EX1008	de la Maza and Carter, “Molecular Structure of Adeno-Associated Virus Variant DNA” <i>J. Biol. Chem.</i> 255:3194-3203 (1980) (“de la Maza (April 1980)”)
EX1009	Cole <i>et al.</i> , “Analytical Ultracentrifugation: Sedimentation Velocity and Sedimentation Equilibrium” in METHODS IN CELL BIOLOGY, VOL. 84, 143-179 (2008) (“Cole”)
EX1010	Sommer <i>et al.</i> , “Quantification of Adeno-Associated Virus Particles and Empty Capsids by Optical Density Measurement” <i>Molecular Therapy</i> 7:122-28 (2003) (“Sommer”)
EX1011	Carter <i>et al.</i> , “Adeno-Associated Virus Autointerference” <i>Virology</i> 92:449-462 (1979) (“Carter”)
EX1012	Myers and Carter, “Assembly of Adeno-Associated Virus” <i>Virology</i> 102:71-82 (1980) (“Myers”)
EX1013	de la Maza and Carter, “Heavy and Light Particles of Adeno-Associated Virus” <i>J. Virol.</i> 33:1129-1137 (1980) (“de la Maza (March 1980)”)
EX1023	Berkowitz and Philo, “Monitoring the homogeneity of adenovirus preparations (a gene therapy delivery system) using analytical ultracentrifugation” <i>Anal. Biochem.</i> 362:1637 (2007) (“Berkowitz”)

Exhibit Number	Description
EX1024	Berkowitz and Philo, “Characterizing Biopharmaceuticals using Analytical Ultracentrifugation” in BIOPHYSICAL CHARACTERIZATION OF PROTEINS IN DEVELOPING BIOPHARMACEUTICALS (Houde, D., and Berkowitz, S., eds.), Elsevier, 211-260 (2015)
EX1025	Cole and Hansen, “Analytical Ultracentrifugation as a Contemporary Biomolecular Research Tool” <i>J. Biomolecular Techniques</i> 10:163-176 (1999) (“Cole (1999)”)
EX1026	Gao <i>et al.</i> , “Empty virions in AAV8 vector preparations reduce transduction efficiency and may cause total viral particle dose-limiting side effects” <i>Molecular Therapy – Methods & Clinical Development</i> 9:1-8 (2014) (“Gao”)
EX1027	Gombold <i>et al.</i> , “Lot Release and Characterization Testing of Live-Virus-Based Vaccines and Gene Therapy Products, Part 2” <i>BioProcess International</i> 4:56-65 (2006) (“Gombold”)
EX1028	Hoque <i>et al.</i> , “Chimeric Virus-like Particle Formation of Adeno-Associated Virus” <i>Biochemical and Biophysical Research Communications</i> 266:371–376 (1999) (“Hoque”)
EX1029	European Medicines Agency, Committee for Medicinal Products for Human Use, Glybera Assessment Report (July 19, 2012)
EX1030	Ward and Tattersall, Preface, in REPLICATION OF MAMMALIAN PARVOVIRUSES (Ward, D., and Tattersall, P., eds.), Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, ix-x (1978) (“Ward”)

Exhibit Number	Description
EX1031	Schuck, “Size-Distribution Analysis of Macromolecules by Sedimentation Velocity Ultracentrifugation and Lamm Equation Modeling” <i>Biophysical Journal</i> 78:1606-1619 (2000) (Schuck”)
EX1032	Schuck <i>et al.</i> , “Size-Distribution Analysis of Proteins by Analytical Ultracentrifugation: Strategies and Application to Model Systems” <i>Biophysical Journal</i> 82:1096-1111 (2002) (Schuck (2002))”)
EX1033	Carter, “Adeno-associated virus and the development of adeno-associated virus vectors: a historical perspective” <i>Molecular Therapy</i> 10:981-89 (2004) (“Carter (2004)”).
EX1034	Carter, “My Pathway to Adeno-Associated Virus and Adeno-Associated Virus Gene Therapy: A Personal Perspective” <i>Human Gene Therapy</i> 31:494-98 (2020) (“Carter (2020)”)
EX1035	Tratschin <i>et al.</i> , “A human parvovirus, adeno-associated virus as a eukaryotic vector: transient expression and encapsidation of the prokaryotic gene for chloramphenicol acetyl transferase” <i>Molecular Cell Biology</i> 4:2072–81 (1984) (“Tratschin”)
EX1036	Hermonat and Muzyczka, “Use of adeno-associated virus as a mammalian DNA cloning vector: transduction of neomycin resistance into mammalian tissue culture cells” <i>Proc. Natl. Acad. Sci. USA</i> 81:6466-70 (1984) (“Hermonat”)
EX1037	Carter <i>et al.</i> , “Specific Cleavage of Adenovirus-Associated Virus DNA by Restriction Endonuclease R·EcoRI – Characterization of Cleavage Products” <i>Virology</i> 63:523-528 (1975) (“Carter (1975)”)

Exhibit Number	Description
EX1038	Carter <i>et al.</i> , “Genome Localization of Adeno-Associated Virus RNA” <i>J. Virology</i> 19:1044-1053 (1976) (“Carter (1976)”)
EX1040	Srivastava <i>et al.</i> , “A Tribute to Barrie J. Carter” <i>Human Gene Therapy</i> 31:491-493 (2020) (“Srivastava”)
EX1041	Lock <i>et al.</i> , “Analysis of particle content of recombinant adeno-associated virus serotype 8 vectors by ion-exchange chromatography” <i>Human Gene Therapy Methods</i> 23(1):56-64 (2012) (“Lock”)

- For lack of authentication under Fed. R. Evid. 901; and
- As hearsay under Fed. R. Evid. 801-802 to the extent statements therein are relied on for the truth of the matter asserted.

Patent Owner likewise objects to any portion of the Petition and Dr. Berkowitz’s Declaration (Ex. 1004) purporting to rely on any of the Exhibits identified herein.

III. Exhibit 1039

Patent Owner objects to Exhibit 1039 (European Patent Office, Communication of the European Patent Office and Annex, Application No. 16 703 205.1, dated July 19, 2023) for the following reasons:

- As inadmissible under Fed. R. Evid. 401 and/or 403 for lack of relevance and/or as prejudicial, misleading, and/or wasting time.

- For lack of authentication under Fed. R. Evid. 901; and
- As hearsay under Fed. R. Evid. 801-802 to the extent statements therein are relied on for the truth of the matter asserted that does not fall within any exceptions.

Patent Owner likewise objects to any portion of the Petition and Dr. Berkowitz's Declaration (Ex. 1004) purporting to rely on Exhibit 1039.

IV. Exhibit 1004

Patent Owner objects to Exhibit 1004 (Berkowitz Declaration) as inadmissible under at least Fed. R. Evid. 702 because Dr. Berkowitz's opinions are conclusory; do not sufficiently disclose underlying facts or data in support; are unreliable; and lack the requisite scientific, technical, or other specialized knowledge sufficient to help the trier of fact understand the evidence or determine a fact in issue. Dr. Berkowitz lacks sufficient skill in the art, making his testimony unreliable and unhelpful to understanding the evidence and determining facts in issue. Additionally, under Fed. R. Evid. 401(test for relevance), Fed. R. Evid. 402 (relevance), and Fed. R. Evid. 403 (probative value outweighed by prejudice, confusing of issues, wasting time), his opinions are irrelevant, confusing, and of minimal probative value.

In particular, Dr. Berkowitz testimony at paragraphs 139 and 191-193 relating to "direct linear relationship between the sedimentation coefficient and the

size of the DNA packaged in an AAV particle” and “best fit” analysis fails to apply scientifically accepted linear regression analysis. Dr. Berkowitz’s opinions alleging the obviousness of the linear relationship between genome size and sedimentation coefficient based, in part, on this flawed analysis of Le Bec (Ex. 1006) are therefore unreliable, irrelevant, and/or prejudicial against Patent Owner.

Respectfully submitted,

Dated: May 20, 2026

/ Blaine M. Hackman /
Blaine M. Hackman, Reg. No. 67,479
Dechert LLP
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, IPR2026-00150

I caused to be served a copy of:

**PATENT OWNER'S OBJECTIONS TO
EVIDENCE FILED WITH THE PETITION**

upon:

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Date: May 20, 2026

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