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 SUR-REPLY IN SUPPORT OF ITS OPPOSITION TO PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL

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EX1005	Declaration of Dr. Mark A. Kay ("Kay Decl.")
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EX1007	Auricchio *et al*., "Isolation of Highly Infectious And Pure Adeno-Associated Virus Type 2 Vectors with a Single-Step Gravity-Flow Column," *Human Gene Therapy* (2001): 71-76 ("Auricchio")
EX1008	WO 03/097797 A1 (PCT/US03/15061), "Methods of Adenovirus Purification," International Publication Date Nov. 27, 2003 ("Konz")
EX1009	Potter *et al*., "Streamlined Large-Scale Production of Recombinant Adeno-Associated Virus (rAAV) Vectors," *Methods in Enzymology*, Vol. 346, 2002, 413-430 ("Potter")
EX1010	U.S. Patent No. 9,051,542 ("the '542 patent")
EX1011	*Genzyme Corp. v. Sarepta Therapeutics, Inc. et al*., Second Amended Complaint, C.A. No. 24-cv-00882-RGA (D. Del.), D.I. 81
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EX1019	Patent Owner's Statutory Disclaimer ("Disclaimer")
EX1020	WO 01/66137 A1 (PCT/US01/07194), "Adenovirus Formulations," International Publication Date Sept. 13, 2001 ("Evans")
EX1021	Verma and Somia, "Gene therapy – promises, problems and prospects," *Nature*, Vol. 389, 1997 ("Verma")
EX1022	Clark *et al*., "Highly Purified Recombinant Adeno-Associated Virus Vectors Are Biologically Active and Free of Detectable Helper and Wild-Type Viruses," *Human Gene Therapy*, 10:1031-1039 (1999) ("Clark")

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EX1023	Hermens *et al*., "Purification of Recombinant Adeno-Associated Virus by Iodixanol Gradient Ultracentrifugation Allows Rapid and Reproducible Preparation of Vector Stocks for Gene Transfer in the Nervous System," *Human Gene Therapy* 10:1885-1891 (1999) ("Hermens")
EX1024	Girod *et al*., "The VP1 capsid protein of adeno-associated virus type 2 is carrying a phospholipase A2 domain required for virus infectivity," *Journal of General Virology* 83.5 (2002): 973-978 ("Girod")
EX1025	Salvetti *et al*., "Factors Influencing Recombinant Adeno-Associated Virus Production," *Human Gene Therapy*, 9:695-706 (1998) ("Salvetti")
EX1026	Hauswirth *et al*., "Production and Purification of Recombinant Adeno-Associated Virus," *Methods in Enzymology*, Vol. 316, 2000, pp. 743-61 ("Hauswirth")
EX1027	Grimm and Kay, "From Virus Evolution to Vector Revolution: Use of Naturally Occurring Serotypes of Adeno-Associated Virus (AAV) as Novel Vectors for Human Gene Therapy," *Current Gene Therapy*, 2003, 3, 281-304 ("Grimm and Kay")
EX1028	Xie *et al*., "Large-scale production, purification, and crystallization of wild-type adeno-associated virus-2," *J. Virol. Methods*, 122 (2004) 17-27 ("Xie")
EX1029	Tamayose *et al*., "A New Strategy for Large-Scale Preparation of High-Titer Recombinant Adeno-Associated Virus Vectors by Using Packaging Cell Lines and Sulfonated Cellulose Column Chromatography," *Human Gene Therapy*, 7:507-513 (1996) ("Tamayose")
EX1030	Floyd and Sharp, "Aggregation of Poliovirus and Reovirus by Dilution in Water," *Applied and Environmental Microbiology*, pp. 159-167 (1977) ("Floyd I")

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EX1033	Kegel and van der Schoot, "Competing Hydrophobic and Screened-Coulomb Interactions in Hepatitis B Virus Capsid Assembly," *Biophysical Journal* (2004), 3905-3913 ("Kegel")
EX1034	Davidoff *et al*., "Purification of recombinant adeno-associated virus type 8 vectors by ion exchange chromatography generates clinical grade vector stock," *Journal of Virological Methods* (2004): 209-215 ("Davidoff")
EX1035	Dika *et al*., "Impact of internal RNA on aggregation and electrokinetics of viruses: comparison between MS2 phage and corresponding virus-like particles," *Applied and Environmental Microbiology* (2011): 4939-4948 ("Dika")
EX1036	De Sá Magalhães *et al*., "Quality assessment of virus-like particle: A new transmission electron microscopy approach," *Frontiers in Molecular Biosciences* (2022): 975054, ("De Sá Magalhães")
EX1037	Janc *et al*., "In-Depth Comparison of Adeno-Associated Virus Containing Fractions After CsCl Ultracentrifugation Gradient Separation," *Viruses* (2024): 1235 ("Janc")
EX1038	Dobnik *et al*., "Accurate Quantification and Characterization of Adeno-Associated Viral Vectors," *Frontiers in Microbiology* (2019): 1570 ("Dobnik")

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EX1039	Stagg, *et al*. "Cryo-Electron Microscopy of Adeno-Associated Virus," *Chemical Reviews* 122.17 (2022): 14018-14054 ("Stagg")
EX1040	Hoggan *et al.*, "Studies of small DNA viruses found in various adenovirus preparations: physical, biological, and immunological characteristics," *Proceedings of the National Academy of Sciences* 55.6 (1966): 1467-1474 ("Hoggan")
EX1041	Johnson and Bodily, "Effect of environmental pH on adenovirus-associated virus," *Proceedings of the Society for Experimental Biology and Medicine*, 150.3 (1975): 585-590 ("Johnson")
EX1042	Zolotukhin *et al*., "Recombinant adeno-associated virus purification using novel methods improves infectious titer and yield," *Gene Therapy* (1999): 973-985 ("Zolotukhin")
EX1043	Huang *et al*., "Aggregation of AAV Vectors, its Impact on Liver-directed Gene Transfer and Development of Vector Formulations to Prevent and Dissolve Aggregation and Enhance Gene Transfer Efficiency," *Molecular Therapy*, Vol. 1, No. 5, May 2000, S286 ("Huang")
EX1044	Qu *et al*., "Evidence That Ionic Interactions Are Involved in Concentration-Induced Aggregation of Recombinant Adeno-Associated Virus," *Molecular Therapy*, Vol. 7, No. 5, May 2003, S348 ("Qu")
EX1045	Wright *et al*., "Recombinant adeno-associated virus: Formulation challenges and strategies for a gene therapy vector," *Current Opinion in Drug Discovery & Development* 2003: 174-178 ("Wright 2003")
EX1046	Wright *et al*., "Formulation Development for AAV2 Vectors: Identification of Excipients That Inhibit Vector Aggregation," *Molecular Therapy*, Vol. 9, Supp. 1, May 2004, S163 ("Wright 2004")

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EX1047	Wright *et al*., "Identification of Factors that Contribute to Recombinant AAV2 Particle Aggregation and Methods to Prevent Its Occurrence during Vector Purification and Formulation," *Molecular Therapy*, 2005, pp. 171-78 ("Wright 2005")
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EX1050	Venkatakrishnan *et al*., "Structure and Dynamics of Adeno-Associated Virus Serotype 1 VP1-Unique N-Terminal Domain and Its Role in Capsid Trafficking," *Journal of Virology* 87.9 (2013): 4974-4984 ("Venkatakrishnan")
EX1051	Tibbetts and Giam, "In Vitro Association of Empty Adenovirus Capsids with Double-Stranded DNA," *Journal of Virology* 32.3 (1979): 995-1005 ("Tibbetts")
EX1052	Huyghe *et al*., "Purification of a Type 5 Recombinant Adenovirus Encoding Human P53 by Column Chromatography," *Human Gene Therapy* 6.11 (1995): 1403-1416 ("Huyghe")
EX1053	Roth and Jeltsch, "Biotin-Avidin Microplate Assay for the Quantitative Analysis of Enzymatic Methylation of DNA by DNA Methyltransferases," *Biol. Chem*., Vol. 381, pp. 269-272, March 2000 ("Roth")
EX1054	O'Riordan *et al*., "Scaleable chromatographic purification process for recombinant adeno-associated virus (rAAV)," *The Journal of Gene Medicine*, 2.6 (2000): 444-454 ("O'Riordan")

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EX1055	Kreilgaard *et al*. "Effect of Tween 20 on Freeze-Thawing-And Agitation-Induced Aggregation of Recombinant Human Factor XIII," *Journal of Pharmaceutical Sciences* (1998): 1593-1603 ("Kreilgaard")
EX1056	Croyle *et al*., "Development of Novel Formulations That Enhance Adenoviral-Mediated Gene Expression in the Lung *in Vitro* and *in Vivo*," *Molecular Therapy* (2001): 22-28 ("Croyle")
EX1057	Wu *et al*., "A novel method for purification of recombinant adeno-associated virus vectors on a large scale," *Chinese Science Bulletin*, Vol. 46, 2001, 485-89 ("Wu")
EX1058	Kessler *et al*., "Gene delivery to skeletal muscle results in sustained expression and systemic delivery of a therapeutic protein," *Proceedings of the National Academy of Sciences* (1996): 14082-14087 ("Kessler")
EX1059	U.S. Patent Application Publication No. 2004/0209245 ("the '245 Publication")
EX1060	IPR2023-00608, Petition for Inter Partes Review of U.S. Patent No. 9,051,542, Declaration of Martyn C. Davies ("608 Davies Decl.")
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EX1064	Sommer *et al*., "Quantification of Adeno-Associated Virus Particles and Empty Capsids by Optical Density Measurement," *Molecular Therapy* (2003): 122-128 ("Sommer")
EX1065	Yeung and Tufaro, "Virus Vectors for Gene Therapy of the Nervous System," in Protocols for Neural Cell Culture, 3d edition, Fedoroff and Richardson, eds., 2001, pp. 229-44 ("Yeung")
EX1066	Grimm *et al*. "Novel Tools for Production and Purification of Recombinant Adenoassociated Virus Vectors," *Human Gene Therapy* 9 (18) (1998): 2745-2760 ("Grimm")
EX1067	Grieger et al., "Production and characterization of adeno-associated viral vectors," *Nature Protocols* (2006), 1412-1428 ("Grieger")
EX1068	Schwartz, "Diafiltration for Desalting or Buffer Exchange," *BioProcess International*, May 2003, pp. 43-49 ("Schwartz")
EX1069	Hatano *et al*. "Immunogenic and Antigenic Properties of a Heptavalent High-Molecular-Weight O-Polysaccharide Vaccine Derived From Pseudomonas aeruginosa." *Infection and Immunity* (1994): 3608-3616 ("Hatano")
EX1070	Monahan *et al*., "Direct intramuscular injection with recombinant AAV vectors results in sustained expression in a dog model of hemophilia," *Gene Therapy* (1998): 40-49 ("Monahan")
EX1071	Oster, "The isoelectric points of some strains of tobacco mosaic virus," *J. Biol. Chem.* 190 (1951): 55-59 ("Oster")

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EX1072	Konz *et al*., "Development of a Purification Process for Adenovirus: Controlling Vrius Aggregation to Improve the Clearance of Host Cell DNA," *Biotechnol. Prog*. 2005, 21, 466-472 ("Konz 2005")
EX1073	*Phosphate-buffered saline,* COLD SPRING HARBOR LABORATORY PRESS (2006), https://cshprotocols.cshlp.org/content/2006/1/pdb.rec8247
EX1074	Po and Senozan, "The Henderson-Hasselbalch Equation: Its History and Limitations," *Journal of Chemical Education* 78.11 (2001): 1499 ("Po")
EX1075	Green, "The Preparation of Acetate and Phosphate Buffer Solutions of Known pH and Ionic Strength," *Journal of the American Chemical Society* 55.6 (1933): 2331-2336 ("Green")
EX1076	T.W. Graham Solomons, ORGANIC CHEMISTRY (5th ed. 1992) ("Solomons")
EX1077	CURRENT PROTOCOLS IN NUCLEIC ACID CHEMISTRY (2000) A.2A.1-A.2A.12 (2000) ("Current Protocols")
EX1078	Bates and Acree, "pH Values of Certain Phosphate-Chloride Mixtures and the Second Dissociation Constant of Phosphoric Acid From 0° to 60° C," *J. Res. Natl. Bur. Stand*. 30.2 (1943): 129-155 ("Bates")
EX1079	*Genzyme Corp. et al. v. Novartis Gene Therapies, Inc., et al*., 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

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EX1080	*Genzyme Corp. et al. v. Novartis Gene Therapies, Inc., et al*., 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	*Genzyme Corp. et al. v. Novartis Gene Therapies, Inc., et al*., 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
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EX1085	*Genzyme Corp. v. Sarepta Therapeutics, Inc. et al*., 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	*Genzyme Corp. v. Sarepta Therapeutics, Inc. et al*., 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)

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EX1087	*Genzyme Corp. v. Sarepta Therapeutics, Inc. et al*., 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

Sarepta's arguments are directly responsive to Genzyme's contentions regarding alleged "settled expectations" – the principal argument in Genzyme's request for discretionary denial. Genzyme should not benefit from "settled expectations" that are based on its unfair dealings with the Patent Office and prior misrepresentations to the Board. The unique circumstances here do not "vastly expand" the scope of discretionary denial disputes. Instead, Genzyme's pattern of unfair dealings weighs heavily against its request for discretionary denial, in accordance with Board precedent. Maintaining the integrity of the patent examination and IPR processes is among the best uses of Board resources. Thus, Genzyme's discretionary denial request should be denied.

I. Consideration of Genzyme's Unfair Dealings as One Factor in the Discretionary Denial Process Is Squarely in Line with Board Precedent

Sarepta appropriately relies on Board precedent for its argument that Genzyme's unfair dealings should be considered as one factor that weighs heavily against discretionary denial. In *Tessell*, the Board stated 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, p. 2 (PTAB June 12, 2025) (emphasis added). This statement is not restricted to the particular facts of *Tessell*, nor is it restricted to unfair dealings by *petitioners*, notwithstanding Genzyme's spurious arguments to the

contrary. Sarepta has set out in detail Genzyme's misrepresentations, centered around a specific piece of prior art, during the Novartis IPR proceedings challenging the related '542 patent. Sarepta has further pointed to Novartis's specific inequitable conduct allegations that the District Court permitted Novartis to add to its pleadings over Genzyme's objections in a prior litigation involving the related '542 patent.

Moreover, in *Tessell*, the Board stated that "the determination to exercise discretion to deny institution is based on a holistic assessment of all of the evidence and arguments presented." *Tessell*, Paper 14, p. 3. Sarepta has argued that such a holistic assessment, including consideration of Genzyme's unfair dealings as a particularly significant factor among multiple other factors, warrants denial of Genzyme's discretionary denial request. Sarepta's arguments fall squarely within Board precedent, and do not require any extension of *Tessell*.

II. Genzyme Has Repeatedly Failed to Offer Any Substantive Response Regarding Its Misrepresentations of Potter During the Novartis IPRs

As Sarepta set out in detail in its Petition, Genzyme and its expert did not "accurately" respond to Novartis's arguments regarding the disclosures of Potter during the Novartis IPR proceedings. Instead, they misrepresented to the Board that Potter discloses vector genome concentrations that are "orders of magnitude" lower than those of the claimed compositions – when the plain disclosure in Potter confirms that they are not. This misrepresentation is not an insignificant

misstatement regarding a "different section" of a "minor reference." It is a mischaracterization that Genzyme advanced and relied on to distinguish Potter from the challenged claims and overcome Novartis's arguments. Moreover, there is no "substantive dispute" on the technical merits, as Genzyme contends. The disclosure in Potter is clear on its face. Yet, even now, Genzyme offers no explanation for its blatant mischaracterization. This omission in Genzyme's reply speaks volumes.

III. Inequitable Conduct Issues Weigh Against Discretionary Denial

Sarepta has neither argued that inequitable conduct is relevant to the merits of the Petition nor sought to adjudicate inequitable conduct before the Board. Instead, Sarepta's arguments respond directly to Genzyme's efforts to rely on settled expectations to defeat Sarepta's Petition. The fact that the District Court in the earlier Novartis litigation allowed Novartis to amend its pleadings to add inequitable conduct allegations, over Genzyme's objections, helps to demonstrate a pattern of unfair dealings by Genzyme that weighs heavily against discretionary denial. Moreover, it is Genzyme, not Sarepta, that seeks to expand Board precedent. Without citing any supporting case, Genzyme argues that the existence of inequitable conduct proceedings somehow weighs *in favor of* discretionary denial. This argument, which ignores Genzyme's improper efforts to benefit from its earlier misstatements during prosecution by relying on settled expectations, is contrary to *Tessell* and should be flatly rejected.

Respectfully submitted,

October 22, 2025

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §42.6, I hereby certify that on October 22, 2025, the foregoing document, Petitioner's Sur-Reply in Support of Its Opposition to Patent Owner's Request for Discretionary Denial was served via email on the following counsel of record:

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