

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVARTIS GENE THERAPIES, INC. & NOVARTIS PHARMACEUTICALS
CORPORATION,
Petitioner,

v.

GENZYME CORPORATION,
Patent Owner.

Case No. IPR2023-00608
Patent No. 9,051,542

**PETITIONER'S REPLY TO PATENT OWNER'S
PRELIMINARY RESPONSE**

PETITIONER’S UPDATED EXHIBIT LIST

Exhibit	Description
Ex. 1001	U.S. Patent No. 9,051,542 B2 to Wright, et al.
Ex. 1002	File History of U.S. Patent No. 9,051,542 B2 to Wright, et al.
Ex. 1003	International Patent Pub. No. WO 01/66137 A1 to Evans and Volkin.
Ex. 1004	International Patent Pub. No. WO 99/41416 to Frei, et al.
Ex. 1005	Huang J, Gao, 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,” <i>Mol Ther.</i> 1:S286 (2000).
Ex. 1006	Mingozi, et al., “Improved Hepatic Gene Transfer by Using an Adeno-Associated Virus Serotype 5 Vector,” <i>J Virol.</i> 76:10497-502 (2002).
Ex. 1007	Wright et al., “Recombinant Adeno-Associated Virus: Formulation Challenges and Strategies for a Gene Therapy Vector,” <i>Curr. Opin. Drug Disc. Dev.</i> 6(2): 174-178 (2003).
Ex. 1008	Gatlin, L., Chapter 17, “Formulation and Administration Techniques to Minimize Injection Pain and Tissue Damage Associated with Parental Products,” in <i>Injectable Drug Development: Techniques to Reduce Pain and Irritation</i> , (eds. P. Gupta and G. Brazeau), pp. 401-421 (1999).
Ex. 1009	International Patent Pub. No. WO 03/039459 A2 to Liu, et al.
Ex. 1010	International Patent Pub. No. WO 03/046142 A2 to Lochrie and Colosi.
Ex. 1011	Potter M., et, al. Chapter 24, Streamlined Large-Scale Production of Recombinant Adeno-Associated Virus (rAAV) Vectors” in <i>Methods in Enzymol.</i> , 346:413 (2002)

Exhibit	Description
Ex. 1012	Clark, K., Recent advances in recombinant adeno-associated virus vector production, <i>Kidney Int'l</i> , Vol. 61, Symposium 1, pp. S9–S15 (2002).
Ex. 1013	Croyle, et al., “Development of Formulations That Enhance Physical Stability of Viral Vectors for Gene Therapy,” <i>Gene Ther.</i> , 8:1281-1290 (2001).
Ex. 1014	<i>Cambridge English dictionary</i> . Retrieved from https://dictionary.cambridge.org/us/doctionary/english/about .
Ex. 1015	U.S. Patent No. 6,261,823 B1 to Tang et al.
Ex. 1016	Freireich, E., et al., “Quantitative Comparison of Toxicity of Anticancer Agents in Mouse, Rat, Hamster, Dog, Monkey, and Man,” <i>Cancer Chemoth Rep.</i> 50(4): 219-244 (1966).
Ex. 1017	U.S. Food and Drug Administration, “ <i>Guidance for Industry, Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers</i> ” (July 2005).
Ex. 1018	Carpenter, J. F. & Manning, M.C. (Eds.), <i>Rational Design of Stable Protein Formulations: Theory and Practice</i> , Vol. 13 (2002).
Ex. 1019	F. B. Johnson and A. S. Bodily, <i>Effects of Environmental pH on Adenovirus-Associated Virus (39085)</i> , Procs. of the Soc. for Experimental Biology and Med., pp. 585-90 (1975).
Ex. 1020	<i>Remington: The Science and Practice of Pharmacy</i> , Nineteenth Ed., Vol. I, Chapters 17, 18, 23, and 36 (1995).
Ex. 1021	<i>Remington: The Science and Practice of Pharmacy</i> , Nineteenth Ed., Vol. II, Chapter 87(1995).
Ex. 1022	Ainley Wade and Paul J Weller (Eds.), <i>Handbook of Pharmaceutical Excipients</i> . The Pharmaceutical Press: London, 1994 (pp. 454-458).

Exhibit	Description
Ex. 1023	Joint Claim Construction Brief, Case Number, C.A. No. 21-1736-RGA (U.S. Dist. Ct. Del.), served by Aventis Inc., and Genzyme Corporation on January 20, 2023.
Ex. 1024	Appendix 2A to Laboratory Stock Solutions and Equipment, Common Buffers and Stock Solutions, <i>Current Protocols in Nucleic Acid Chemistry</i> , pp. A.2A.1-A.2A.12 (2000).
Ex. 1025	Declaration of Dr. Mansoor M. Amiji, Ph.D.
Ex. 1026	U.S. Patent No. 6,146,874 to Zolotukhin et al.
Ex. 1027	U.S. Patent Application Publication No. 2004/0166122 A1 to Evans, et al.
Ex. 1028	U.S. Patent Application Publication No. 2002/0041884 A1 to Evans, et al.
Ex. 1029	File History of U.S. Patent No. 7,704,721 B2 to Wright, et al.
Ex. 1030	Litigation Stipulation

I. Discretionary Denial is Not Appropriate in View of Petitioner's Stipulation

In Director Vidal's June 21, 2022 Guidance on Discretionary Denials, she stated that "the PTAB will not discretionarily deny institution of an IPR or PGR in view of parallel district court litigation where a petitioner stipulates not to pursue in a parallel district court proceeding the same grounds as in the petition or any grounds that could have reasonably been raised in the petition." Director's Interim Guidance at 7.¹ In the interest of efficiency, Petitioner has filed a *Sotera* stipulation (Ex. 1030) in the related litigation in order to moot the *Fintiv* issues raised by Patent Owner (*see* POPR at 61-67). *See id.*

Respectfully Submitted

Date: July 12, 2023

By: /John D. Livingstone /
John D. Livingstone
Reg. No. 59,613

*Lead Counsel for Petitioner Novartis Gene
Therapies, Inc., and Novartis
Pharmaceuticals Corporation*

¹ Available at:

https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf.

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that on July 12, 2023, a copy of the foregoing **PETITIONER’S REPLY TO PATENT OWNER’S PRELIMINARY RESPONSE and NOVARTIS EXHIBIT 1031** were served on Patent Owner via email (by consent) to:

Zolgensma-Dechert-AllIPRs@dechert.com

Dated: July 12, 2023

By: /Lauren K. Young/
Lauren K. Young
Litigation Legal Assistant
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.