UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

GENZYME CORPORATION,
Patent Owner.

Case No. IPR2023-01045
Patent No. 10,429,288

PETITIONER'S EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63(e), Petitioner Novartis Gene Therapies, Inc. and Novartis Pharmaceuticals Corporation (collectively "Petitioner") hereby submit a current listing of Petitioner's exhibits. Exhibits 1001-1020 are being filed today.

Exhibit	Description
1001	U.S. Patent No. 10,429,288 ("the '288 patent")
1002	File History of the '288 patent
1003	WO2014/125101 A1 and certified English translation ("Le Bec")
1004	Steven A. Berkowitz & John S. Philo, *Monitoring the homogeneity of adenovirus preparations (a gene therapy delivery system) using analytical ultracentrifugation*, Analytical Biochemistry 362:16-37 (2007)
1005	James L. Cole et al., *Analytical Ultracentrifugation: Sedimentation Velocity and Sedimentation Equilibrium*, Methods in Cell Biology 84:143-79 (2008)
1006	James L. Cole & Jeffrey C. Hansen, *Analytical Ultracentrifugation as a Contemporary Biomolecular Research Tool*, J. of Biomolecular Techniques 10(4):163-76 (1999)
1007	Peter Schuck, *Size-Distribution Analysis of Macromolecules by Sedimentation Velocity Ultracentrifugation and Lamm Equation Modeling*, Biophysical J. 78(3):1606-19 (2000)
1008	Kai Gao et al., *Empty virions in AAV8 vector preparations reduce transduction efficiency and may cause total viral particle dose-limiting side effects*, Molecular Therapy – Methods & Clinical Development 1(9):1-8 (2014)
1009	Mainul Hoque et al., *Chimeric Virus-like Particle Formation of Adeno-Associated Virus*, Biochemical & Biophysical Research Communications 266:371-76 (1999)
1010	European Medicines Agency, Committee for Medicinal Products for Human Use, Glybera Assessment Report (July 19, 2012)
1011	Steven A. Berkowitz & John S. Philo, *Characterizing Biopharmaceuticals using Analytical Ultracentrifugation*, *in* Biophysical Characterization of Proteins in Developing Biopharmaceuticals 211-60 (2015)
1012	European Patent Office, Third Party Observation for application Number EP20160703205 (July 30, 2020)

Exhibit	Description
1013	Greg Ralston, *Introduction to Analytical Ultracentrifugation* (Beckman Coulter Life Sciences)
1014	Silke Steinbach et al., *Assembly of adeno-associated virus type 2 capsids* in vitro, J. of Gen. Virology 78:1453-62 (1997)
1015	U.S. Patent Application Publication No. US 2009/0017542 A1
1016	Huaying Zhao et al., *Overview of Current Methods in Sedimentation Velocity and Sedimentation Equilibrium Analytical Ultracentrifugation*, Current Protocols in Protein Science Supplement 71:20.12.1-20.12.49 (2013)
1017	Douglas M. McCarty, *Self-complementary AAV Vectors; Advances and Applications*, Molecular Therapy 16(10): 1648-56 (2008)
1018	Timothy R. Dafforn, *So how do you know you have a macromolecular complex?*, Acta Crystallographica D63:17-25 (2007)
1019	Jim Gombold et al., *Lot Release and Characterization Testing of Live-Virus-Based Vaccines and Gene Therapy Products, Part 2*, BioProcess Int'l 4(5): 56-65 (2006), *reprinted in* https://www.casss.org/docs/default-source/cmc-strategy-forum-north-america/cmc-north-america-summary-papers/cmc-summary-paper-cmc-strategy-forum-north-america-winter-2005---2---part-2.pdf?sfvrsn=ffe73be0_3
1020	Declaration of Dr. Steven Berkowitz

Respectfully submitted,

Date: June 30, 2023

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

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), the undersigned certifies that on June 30, 2023, a copy of the foregoing **Petitioner's Exhibit List** and **Exhibits 1001-1020** were served by FedEx Priority Overnight on the correspondence address of record indicated in the Patent Office's Patent Center website for U.S. Patent No. 10,429,288:

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A courtesy copy of the foregoing was also served by FedEx Priority Overnight upon the following counsel of record for the Patent Owner in litigation pending before the United States District Court for the District of Delaware Case No. 1:23-cv-00554:

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Date: June 30, 2023

By: /William Esper/
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