

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

GENZYME CORPORATION,
Patent Owner.

Case No. IPR2023-01044
Patent No. 10,429,288

PETITIONERS' UPDATED EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63(e), Petitioners Novartis Gene Therapies, Inc. and Novartis Pharmaceuticals Corporation (collectively, “Novartis”) hereby submit a current listing of Petitioners’ exhibits. Exhibit 1029 is being filed today.

Exhibit	Description	Served Not Filed
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, <i>Monitoring the homogeneity of adenovirus preparations (a gene therapy delivery system) using analytical ultracentrifugation</i> , Analytical Biochemistry 362:16-37 (2007)	
1005	James L. Cole et al., <i>Analytical Ultracentrifugation: Sedimentation Velocity and Sedimentation Equilibrium</i> , Methods in Cell Biology 84:143-79 (2008)	
1006	James L. Cole & Jeffrey C. Hansen, <i>Analytical Ultracentrifugation as a Contemporary Biomolecular Research Tool</i> , J. of Biomolecular Techniques 10(4):163-76 (1999)	
1007	Peter Schuck, <i>Size-Distribution Analysis of Macromolecules by Sedimentation Velocity Ultracentrifugation and Lamm Equation Modeling</i> , Biophysical J. 78(3):1606-19 (2000)	
1008	Kai Gao 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 1(9):1-8 (2014)	

Exhibit	Description	Served Not Filed
1009	Mainul Hoque et al., <i>Chimeric Virus-like Particle Formation of Adeno-Associated Virus</i> , 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, <i>Characterizing Biopharmaceuticals using Analytical Ultracentrifugation</i> , 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)	
1013	Greg Ralston, <i>Introduction to Analytical Ultracentrifugation</i> (Beckman Coulter Life Sciences)	
1014	Silke Steinbach et al., <i>Assembly of adeno-associated virus type 2 capsids in vitro</i> , J. of Gen. Virology 78:1453-62 (1997)	
1015	U.S. Patent Application Publication No. US 2009/0017542 A1	
1016	Huaying Zhao et al., <i>Overview of Current Methods in Sedimentation Velocity and Sedimentation Equilibrium Analytical Ultracentrifugation</i> , Current Protocols in Protein Science Supplement 71:20.12.1-20.12.49 (2013)	
1017	Douglas M. McCarty, <i>Self-complementary AAV Vectors; Advances and Applications</i> , Molecular Therapy 16(10): 1648-56 (2008)	

Exhibit	Description	Served Not Filed
1018	Timothy R. Dafforn, <i>So how do you know you have a macromolecular complex?</i> , Acta Crystallographica D63:17-25 (2007)	
1019	Jim Gombold et al., <i>Lot Release and Characterization Testing of Live-Virus-Based Vaccines and Gene Therapy Products, Part 2</i> , 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	
1021	James L. Cole et al., <i>Analytical Ultracentrifugation: Sedimentation Velocity and Sedimentation Equilibrium</i> , Methods in Cell Biology 84:143-79 (2008) (Supplement to Ex. 1005)	X
1022	Peter Schuck, <i>Size-Distribution Analysis of Macromolecules by Sedimentation Velocity Ultracentrifugation and Lamm Equation Modeling</i> , Biophysical J. 78(3):1606-19 (2000) (Supplement to Ex. 1007)	X
1023	Kai Gao 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 1(9):1-8 (2014) (Supplement to Ex. 1008)	X
1024	Mainul Hoque et al., <i>Chimeric Virus-like Particle Formation of Adeno-Associated Virus</i> , Biochemical & Biophysical Research Communications 266:371-76 (1999) (Supplement to Ex. 1009)	X

Exhibit	Description	Served Not Filed
1025	Huaying Zhao et al., <i>Overview of Current Methods in Sedimentation Velocity and Sedimentation Equilibrium Analytical Ultracentrifugation</i> , Current Protocols in Protein Science Supplement 71:20.12.1-20.12.49 (2013) (Supplement to Ex. 1016)	X
1026	Douglas M. McCarty, <i>Self-complementary AAV Vectors; Advances and Applications</i> , Molecular Therapy 16(10): 1648-56 (2008) (Supplement to Ex. 1017)	X
1027	Timothy R. Dafforn, <i>So how do you know you have a macromolecular complex?</i> , Acta Crystallographica D63:17-25 (2007) (Supplement to Ex. 1018)	X
1028	Jim Gombold et al., <i>Lot Release and Characterization Testing of Live-Virus-Based Vaccines and Gene Therapy Products, Part 2</i> , 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 (Supplement to Ex. 1019)	X
1029	Confidential Settlement and License Agreement (FILED UNDER SEAL)	

Respectfully submitted,

Dated: February 26, 2024

By: /John D. Livingstone/
John D. Livingstone, Lead Counsel
Registration No. 59,613

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing **Petitioners' Updated Exhibit List** and **Exhibit 1029** were served electronically via email on February 26, 2024, in their entirety on the following:

Amanda K. Antons
Dechert LLP
33 W. Wacker Dr.
Suite 3400
Chicago, IL 60601
amanda.antons@dechert.com

Katherine A. Helm
Blaine Hackman
Dechert LLP
Three Bryant Park
1095 Avenue of the Americas
New York, NY 10036-6797
Khelm@dechert.com
blaine.hackman@dechert.com

Zolgensma-Dechert-AllIPRs@dechert.com

Patent Owner has consented to electronic service by email.

Dated: February 26, 2024

/William Esper/

William Esper
Case Manager and PTAB Coordinator
Finnegan, Henderson, Farabow,
Garrett & Dunner, LLP