

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

GENZYME CORPORATION,  
Patent Owner.

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

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**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 1003**

Patent Owner objects to Exhibits 1003 (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 that does not fall within any exceptions.

Patent Owner likewise objects to any portion of the Petition and Dr. Berkowitz’s Declaration (Ex. 1020) purporting to rely on Exhibit 1003.

**II. Exhibits 1004-1011, 1013-1014, and 1016-1019**

Patent Owner objects to Exhibit 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)); Exhibit 1005 (James L. Cole et al., *Analytical Ultracentrifugation*:

*Sedimentation Velocity and Sedimentation Equilibrium*, Methods in Cell Biology 84:143-79 (2008)); Exhibit 1006 (James L. Cole & Jeffrey C. Hansen, *Analytical Ultracentrifugation as a Contemporary Biomolecular Research Tool*, J. of Biomolecular Techniques 10(4):163-76 (1999)); Exhibit 1007 (Peter Schuck, *Size-Distribution Analysis of Macromolecules by Sedimentation Velocity Ultracentrifugation and Lamm Equation Modeling*, Biophysical J. 78(3):1606-19 (2000)); Exhibit 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)); Exhibit 1009 (Mainul Hoque et al., *Chimeric Virus-like Particle Formation of Adeno-Associated Virus*, Biochemical & Biophysical Research Communications 266:371-76 (1999)); Exhibit 1010 (European Medicines Agency, Committee for Medicinal Products for Human Use, Glybera Assessment Report (July 19, 2012)); Exhibit 1011 (Steven A. Berkowitz & John S. Philo, *Characterizing Biopharmaceuticals using Analytical Ultracentrifugation*, in Biophysical Characterization of Proteins in Developing Biopharmaceuticals 211-60 (2015)); Exhibit 1013 (Greg Ralston, *Introduction to Analytical Ultracentrifugation* (Beckman Coulter Life Sciences)); Exhibit 1014 (Silke Steinbach et al., *Assembly of adeno-associated virus type 2 capsids in vitro*, J. of Gen. Virology 78:1453-62 (1997)); Exhibit 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)); Exhibit 1017 (Douglas M. McCarty, *Self-complementary AAV Vectors; Advances and Applications*, Molecular Therapy 16(10): 1648-56 (2008)); Exhibit 1018 (Timothy R. Dafforn, *So how do you know you have a macromolecular complex?*, Acta Crystallographica D63:17-25 (2007)); and Exhibit 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)) for the following reasons:

- 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. 1020) purporting to rely on any of Exhibits 1004, 1005, 1006, 1007, 1008, 1009, 1010, 1011, 1013, 1014, 1016, 1017, 1018, and 1019.

### **III. Exhibit 1012**

Exhibit 1012 (European Patent Office, Third Party Observation for application Number EP20160703205 (July 30, 2020)) 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. 1020) purporting to rely on Exhibit 1012.

#### **IV. Exhibit 1020**

Patent Owner objects to Exhibit 1020 (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.

Respectfully submitted,

Dated: January 24, 2024

/ Blaine M. Hackman /

Blaine M. Hackman, Reg. No. 67,479

Amanda K. Antons, Reg. No. 65,236

Katherine A. Helm, *pro hac vice* to be applied for  
Dechert LLP

*Counsel for Patent Owner*

**CERTIFICATE OF SERVICE**

I certify that today in:

*Novartis Gene Therapies, Inc. & Novartis Pharmaceuticals Corporation v.  
Genzyme Corporation, IPR2023-01044 (U.S. Patent 10,429,288)*

I caused to be served a copy of:

PATENT OWNER'S OBJECTIONS TO  
EVIDENCE FILED WITH THE PETITION

upon:

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Dated: January 24, 2024

By: / Blaine M. Hackman /  
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