

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAREPTA THERAPEUTICS, INC.,
Petitioner,

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,
Patent Owner
And REGENXBIO INC.,
Exclusive Licensee.

Case IPR2024-00580
Patent 11,680,274 B2

PATENT OWNER'S OBJECTIONS TO EVIDENCE

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner, The Trustees of the University of Pennsylvania (“Patent Owner”), and Exclusive Licensee, REGENXBIO INC. (“Exclusive Licensee”), hereby submit their notice of objections to certain evidence that Petitioner’s filed on March 20, 2025, in connection with the Petitioner’s Response in IPR2024-00580.

No.	Description	Objections
EX1058	Haberman et al., “Therapeutic Liabilities of in vivo Viral Vector Tropism: Adeno-Associated Virus Vectors, NMDAR1 Antisense, and Focal Seizure Sensitivity,” Molecular Therapy (2002): 495-500 (“Haberman”)	<u>Introduces New or Belated Arguments.</u> 37 C.F.R. § 42.23(b) and Consolidated Trial Practice Guide at 73. This exhibit introduces evidence that Petitioner could have presented earlier to attempt to make a prima facie case of unpatentability. <u>Irrelevant.</u> Fed. R. Evid. 401-403. This exhibit is not relevant and its probative value with respect to any ground upon which trial was instituted and is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence.

No.	Description	Objections
EX1059	U.S. Provisional Patent Application 60/636,126 (“the ’126 provisional”)	<u>Introduces New or Belated Arguments.</u> 37 C.F.R. § 42.23(b) and Consolidated Trial Practice Guide at 73. This exhibit introduces evidence that Petitioner could have presented earlier to attempt to make a prima facie case of unpatentability. <u>Irrelevant.</u> Fed. R. Evid. 401-403. This exhibit is not relevant and its probative value with respect to any ground upon which trial was instituted and is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. Further, EX1059 is not relevant because neither the exhibit itself, Petitioner, nor Petitioner's declarants explain that this exhibit was publicly available prior to the time of the invention.

No.	Description	Objections
EX1060	Wu et al., “Single Amino Acid Changes Can Influence Titer, Heparin Binding, and Tissue Tropism in Different Adeno-Associated Virus Serotypes,” Journal of Virology (2006): 11393-97 (“Wu 2006”)	<u>Introduces New or Belated Arguments.</u> 37 C.F.R. § 42.23(b) and Consolidated Trial Practice Guide at 73. This exhibit introduces evidence that Petitioner could have presented earlier to attempt to make a prima facie case of unpatentability. <u>Irrelevant.</u> Fed. R. Evid. 401-403. This exhibit is not relevant and its probative value with respect to any ground upon which trial was instituted and is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. Further, EX1060 is not relevant because neither the exhibit itself, Petitioner, nor Petitioner's declarants explain that this exhibit was publicly available prior to the time of the invention.

No.	Description	Objections
EX1061	U.S. Patent No. 7,892,809 (“the ‘809 patent”)	<u>Introduces New or Belated Arguments.</u> 37 C.F.R. § 42.23(b) and Consolidated Trial Practice Guide at 73. This exhibit introduces evidence that Petitioner could have presented earlier to attempt to make a prima facie case of unpatentability. <u>Irrelevant.</u> Fed. R. Evid. 401-403. This exhibit is not relevant and its probative value with respect to any ground upon which trial was instituted and is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. Further, EX1061 is not relevant because neither the exhibit itself, Petitioner, nor Petitioner's declarants explain that this exhibit was publicly available prior to the time of the invention.

No.	Description	Objections
EX1062	Bowles et al. “Phase 1 Gene Therapy for Duchenne Muscular Dystrophy Using a Translational Optimized AAV Vector,” Molecular Therapy (2012): 443-55 (“Bowles”)	<u>Introduces New or Belated Arguments.</u> 37 C.F.R. § 42.23(b) and Consolidated Trial Practice Guide at 73. This exhibit introduces evidence that Petitioner could have presented earlier to attempt to make a prima facie case of unpatentability. <u>Irrelevant.</u> Fed. R. Evid. 401-403. This exhibit is not relevant and its probative value with respect to any ground upon which trial was instituted and is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. Further, EX1062 is not relevant because neither the exhibit itself, Petitioner, nor Petitioner's declarants explain that this exhibit was publicly available prior to the time of the invention.
EX1063	March 6, 2025 Samulski Deposition Transcript (“Samulski Dep. Tr.”)	Patent Owners preserve all objections made on the record in the deposition transcript.
EX1064	Nov. 1, 2024 Schaffer Deposition Transcript, with errata (“Schaffer Dep. Tr.”)	

No.	Description	Objections
EX1065	U.S. Patent No. 9,012,224 (“the ‘224 patent”)	<u>Introduces New or Belated Arguments.</u> 37 C.F.R. § 42.23(b) and Consolidated Trial Practice Guide at 73. This exhibit introduces evidence that Petitioner could have presented earlier to attempt to make a prima facie case of unpatentability. <u>Irrelevant.</u> Fed. R. Evid. 401-403. This exhibit is not relevant and its probative value with respect to any ground upon which trial was instituted and is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. Further, EX1065 is not relevant because neither the exhibit itself, Petitioner, nor Petitioner's declarants explain that this exhibit was publicly available prior to the time of the invention.

No.	Description	Objections
EX1066	U.S. Patent Application Publication 2005/0053922 (“the ’922 publication”)	<u>Introduces New or Belated Arguments.</u> 37 C.F.R. § 42.23(b) and Consolidated Trial Practice Guide at 73. This exhibit introduces evidence that Petitioner could have presented earlier to attempt to make a prima facie case of unpatentability. <u>Irrelevant.</u> Fed. R. Evid. 401-403. This exhibit is not relevant and its probative value with respect to any ground upon which trial was instituted and is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence.

No.	Description	Objections
EX1067	PCT/US2005/045552 (“the ’552 PCT”)	<u>Introduces New or Belated Arguments.</u> 37 C.F.R. § 42.23(b) and Consolidated Trial Practice Guide at 73. This exhibit introduces evidence that Petitioner could have presented earlier to attempt to make a prima facie case of unpatentability. <u>Irrelevant.</u> Fed. R. Evid. 401-403. This exhibit is not relevant and its probative value with respect to any ground upon which trial was instituted and is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence.
EX1068	Kern et al., “Identification of a Heparin-Binding Motif on Adeno-Associated Virus Type 2 Capsids,” Journal of Virology (2003): 11072-81 (“Kern”)	<u>Introduces New or Belated Arguments.</u> 37 C.F.R. § 42.23(b) and Consolidated Trial Practice Guide at 73. This exhibit introduces evidence that Petitioner could have presented earlier to attempt to make a prima facie case of unpatentability.

No.	Description	Objections
EX1069	U.S. Provisional Patent Application 60/484,111 (“the ’111 provisional”)	<u>Introduces New or Belated Arguments.</u> 37 C.F.R. § 42.23(b) and Consolidated Trial Practice Guide at 73. This exhibit introduces evidence that Petitioner could have presented earlier to attempt to make a prima facie case of unpatentability. <u>Irrelevant.</u> Fed. R. Evid. 401-403. This exhibit is not relevant and its probative value with respect to any ground upon which trial was instituted and is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence.

No.	Description	Objections
EX1070	Maersch et al. "Optimization of stealth adeno-associated virus vectors by randomization of immunogenic epitopes," Virology (2010): 167-75 ("Maersch")	<u>Introduces New or Belated Arguments.</u> 37 C.F.R. § 42.23(b) and Consolidated Trial Practice Guide at 73. This exhibit introduces evidence that Petitioner could have presented earlier to attempt to make a prima facie case of unpatentability. <u>Irrelevant.</u> Fed. R. Evid. 401-403. This exhibit is not relevant and its probative value with respect to any ground upon which trial was instituted and is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. Further, EX1070 is not relevant because neither the exhibit itself, Petitioner, nor Petitioner's declarants explain that this exhibit was publicly available prior to the time of the invention.

No.	Description	Objections
EX1071	Wang et al., “Comparative Study of Liver Gene Transfer with AAV Vectors Based on Natural and Engineered AAV Capsids,” Molecular Therapy (2015): 1877-87 (“Wang”)	<u>Introduces New or Belated Arguments.</u> 37 C.F.R. § 42.23(b) and Consolidated Trial Practice Guide at 73. This exhibit introduces evidence that Petitioner could have presented earlier to attempt to make a prima facie case of unpatentability. <u>Irrelevant.</u> Fed. R. Evid. 401-403. This exhibit is not relevant and its probative value with respect to any ground upon which trial was instituted and is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. Further, EX1071 is not relevant because neither the exhibit itself, Petitioner, nor Petitioner's declarants explain that this exhibit was publicly available prior to the time of the invention.

No.	Description	Objections
EX1072	Reply Declaration of David V. Schaffer, Ph.D.	<u>Introduces New or Belated Arguments.</u> 37 C.F.R. § 42.23(b) and Consolidated Trial Practice Guide at 73. This exhibit introduces extensive untimely analysis that it could have presented earlier to attempt to make a prima facie case of unpatentability. Patent Owners further object to EX1072 to the extent it relies on any other objectionable exhibit.

No.	Description	Objections
EX1073	Lu et al., “506. Transductional and Genome Biodistribution of Novel AAV Serotype Vectors after Systemic Delivery and Their Liver Specific Dose Response Profiles in Mice,” Molecular Therapy (2005): S196 (“Lu”)	<u>Introduces New or Belated Arguments.</u> 37 C.F.R. § 42.23(b) and Consolidated Trial Practice Guide at 73. This exhibit introduces evidence that Petitioner could have presented earlier to attempt to make a prima facie case of unpatentability. <u>Irrelevant.</u> Fed. R. Evid. 401-403. This exhibit is not relevant and its probative value with respect to any ground upon which trial was instituted and is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. Further, EX1073 is not relevant because neither the exhibit itself, Petitioner, nor Petitioner's declarants explain that this exhibit was publicly available prior to the time of the invention.

Respectfully submitted,

Date: March 27, 2025

/Casey M. Kraning/

Susan E. Morrison, Reg. No. 56,332
Casey M. Kraning (Pro Hac Vice)
Deanna J. Reichel (Pro Hac Vice)

Fish & Richardson P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402

Attorneys for REGENXBIO Inc.

Date: March 27, 2025

/Julie S. Goldemberg/

Dion M. Bregman, Reg. No. 45,645
MORGAN, LEWIS & BOCKIUS LLP
1400 Page Mill Rd., Palo Alto, CA
94304

Julie S. Goldemberg, Reg. No. 72,222
MORGAN LEWIS BOCKIUS LLP
1701 Market Street, Philadelphia, PA
19103-3007

*Attorneys for The Trustees of the
University of Pennsylvania.*

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e), the undersigned certifies that on March 27, 2025, a complete and entire copy of this Patent Owner and Exclusive Licensee's Objections to Evidence was provided via email to the Petitioner by serving the correspondence email address of record as follows:

Quinn Emanuel Urquhart & Sullivan, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
Robert Wilson, Reg. No. 45,227
robertwilson@quinnemanuel.com
Anne Toker, Reg. No. 53,692
annetoker@quinnemanuel.com
James Glass, Reg. No. 46,729
jimglass@quinnemanuel.com
Tel.: 212-849-7000

/Li Feng/

Li Feng
Fish & Richardson P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
lfeng@fr.com