

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

PATENT OWNER'S OBJECTION TO EVIDENCE

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner and Exclusive Licensee hereby submit its notice of objections to certain evidence Petitioner filed on February 21, 2024, in connection with the Petition in IPR2024-00580.

Exhibit No.	Objections
1005 (Schaffer Decl.)	Lacking relevance (FRE 401-403). In particular, paragraphs of Exhibit 1005 are neither cited nor relied on in the Petition. <i>See, e.g.</i> , Ex. 1005, ¶¶ 26-84, 86-96, 100-103, 105-110, 116-119, 161, 167-173, 183, 190-197, 201, 203, 206, 208-209, 214-222, 224-225, 231, 248, 250-251, 253-255, 270, 290, 294, and 301. Thus, portions of Exhibit 1005 are irrelevant, or at least their probative value is substantially outweighed by a danger of unfair prejudice or confusing the issues. <i>See, e.g., SK Innovation Co., Ltd. v. Celgard, LLC</i> , IPR2014-00679, Paper 58, at 49 (PTAB Sept. 25, 2015) (granting a motion to exclude because the challenged exhibits were not cited in the IPR); <i>Shimano, Inc v. Globeride, Inc.</i> , IPR2015-00273, Paper 40, at 27–28 (PTAB June 16, 2016) (excluding exhibits because the proffering party did not rely on those exhibits). Further, Patent Owner objects to Exhibit 1005 in its entirety as an improper extension of the word limit, under 37 CFR § 42.24, to the Petition.
1011	Lacking relevance (FRE 401-403); Hearsay (FRE 802); Incomplete (FRE 106). In particular, Exhibit

(Leone Opening Report)	1011 contains excerpts from an expert report offered on behalf of Patent Owner in <i>REGENXBIO Inc. et al. v. Sarepta Therapeutics, Inc. et al.</i>, C.A. No. 20-1226-RGA, a district court proceeding where Patent Owner asserts infringement of U.S. Pat. No. 10,526,617—a different patent that is unrelated to the '274 patent challenged in this proceeding. This report is not relevant to this proceeding because (i) the expert did not opine on the '274 patent; (ii) the claims of the '617 patent are materially different from the claims of the '274 patent; (iii) the specification of the '617 patent is different from the specification of the '274 patent; and (iv) the expert did not opine on any issue relevant to the issues presented in this proceeding. Further, Petitioner cannot make this expert—retained by Patent Owner in a separate litigation—available for cross-examination in this proceeding, in contravention of 37 C.F.R. § 42.51(b)(2).
1012 (Leone Rebuttal Report)	Lacking relevance (FRE 401-403); Hearsay (FRE 802); Incomplete (FRE 106). In particular, Exhibit 1012 contains excerpts from an expert report offered on behalf of Patent Owner in <i>REGENXBIO Inc. et al. v. Sarepta Therapeutics, Inc. et al.</i>, C.A. No. 20-1226-RGA, a district court proceeding where Patent Owner asserts infringement of U.S. Pat. No. 10,526,617—a different patent that is unrelated to the '274 patent challenged in this proceeding. This report is not relevant to this proceeding because (i) the expert did not opine on the '274 patent; (ii) the claims of the '617 patent are materially different from the claims of the '274 patent; (iii) the

	specification of the '617 patent is different from the specification of the '274 patent; and (iv) the expert did not opine on any issue relevant to the issues presented in this proceeding. Further, Petitioner cannot make this expert—retained by Patent Owner in a separate litigation—available for cross-examination in this proceeding, in contravention of 37 C.F.R. § 42.51(b)(2).
1013 (Metzker Rebuttal Report)	Lacking relevance (FRE 401-403); Hearsay (FRE 802); Incomplete (FRE 106). In particular, Exhibit 1013 contains excerpts from an expert report offered on behalf of Patent Owner in <i>REGENXBIO Inc. et al. v. Sarepta Therapeutics, Inc. et al.</i>, C.A. No. 20-1226-RGA, a district court proceeding where Patent Owner asserts infringement of U.S. Pat. No. 10,526,617—a different patent that is unrelated to the '274 patent challenged in this proceeding. This report is not relevant to this proceeding because (i) the expert did not opine on the '274 patent; (ii) the claims of the '617 patent are materially different from the claims of the '274 patent; (iii) the specification of the '617 patent is different from the specification of the '274 patent; and (iv) the expert did not opine on any issue relevant to the issues presented in this proceeding. Further, Petitioner cannot make this expert—retained by Patent Owner in a separate litigation—available for cross-examination in this proceeding, in contravention of 37 C.F.R. § 42.51(b)(2).

1018 (AAVrh.10/AAVrh.46 Alignment)	Lacking foundation (FRE 703); Hearsay (FRE 802); Lacking authenticity (FRE 901)
1019 (AAVrh.10/AAV8 Alignment)	Lacking foundation (FRE 703); Hearsay (FRE 802); Lacking authenticity (FRE 901)
1020 (AAV2/AAVrh.10/AAV8 Alignment)	Lacking foundation (FRE 703); Hearsay (FRE 802); Lacking authenticity (FRE 901)
1021 (NetPhos-AAVrh.10)	Lacking foundation (FRE 703); Hearsay (FRE 802); Lacking authenticity (FRE 901)
1022 (AAVrh.10/AAV8 Phosphorylation Sites)	Lacking foundation (FRE 703); Hearsay (FRE 802); Lacking authenticity (FRE 901)
1023 (Xie Surface Table)	Lacking foundation (FRE 703); Hearsay (FRE 802); Lacking authenticity (FRE 901)
1041 (DNA Fact Sheet)	Lacking foundation (FRE 703); Hearsay (FRE 802); Lacking authenticity (FRE 901)

1042 (Genomic Variation)	Lacking foundation (FRE 703); Hearsay (FRE 802); Lacking authenticity (FRE 901)
1043 (Central Dogma)	Lacking foundation (FRE 703); Hearsay (FRE 802); Lacking authenticity (FRE 901)
1044 (Genetic Code)	Lacking foundation (FRE 703); Hearsay (FRE 802); Lacking authenticity (FRE 901)
1045 (PCR Fact Sheet)	Lacking relevance (FRE 401-403); Lacking foundation (FRE 703); Hearsay (FRE 802); Lacking authenticity (FRE 901). Further, Patent Owner objects to this evidence because it was neither cited nor relied on in the Petition. <i>See, e.g., SK</i> <i>Innovation</i> , Paper 58, at 49; <i>Shimano</i> , Paper 40, at 27–28.
1046 (Gene Therapy)	Lacking foundation (FRE 703); Hearsay (FRE 802); Lacking authenticity (FRE 901)
1047 (Vectors 101)	Lacking foundation (FRE 703); Hearsay (FRE 802); Lacking authenticity (FRE 901)

For at least these reasons, Patent Owner and Exclusive Licensee object to Exhibits 1005, 1011-1013, 1018-1023, and 1041-1047 and reserve the right to move to exclude these exhibits as inadmissible.

Respectfully submitted,

Date: September 6, 2024

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e), the undersigned certifies that on September 6, 2024, a complete and entire copy of this Patent Owner's Objections to Evidence was provided via email to Petitioners by serving the correspondence email address of record as follows:

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