

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENEOSCOPY, INC.,
Petitioner,

v.

EXACT SCIENCES CORPORATION,
Patent Owner.

Case No.: IPR2024-01330
U.S. Patent 11,970,746

PETITIONER'S OBJECTIONS TO EVIDENCE

Pursuant to 37 C.F.R. § 42.64, Petitioner Geneoscopy, Inc.

(“Geneoscopy”) submits the following objections to **Exhibits 2054 through 2057** filed by Exact Sciences Corporation (“Exact”) with Patent Owner’s Sur-Reply to Geneoscopy’s Reply.

Section II.I of the Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019 (“Trial Practice Guide”), at page 73, sets forth that “[t]he sur-reply may not be accompanied by new evidence other than deposition transcripts of the cross-examination of any reply witness.” None of **Exhibits 2054 to 2056** is a deposition transcript of the cross-examination of any reply witness, nor does any of these exhibits otherwise provide any context for the deposition testimony of “any reply witness” – i.e., Dr. Duncan Whitney. Petitioner therefore objects to **EX2054-2056**, and in addition, each should be stricken as late-filed.

1. Geneoscopy objects to **EX2054**, “Geneoscopy’s New FDA-Approved Stool Collection Method Simplifies At-Home Colorectal Cancer Screening,” as late-filed. Section II.I of the Trial Practice Guide, at page 73, provides that “[t]he sur-reply may not be accompanied by new evidence other than deposition transcripts of the cross-examination of any reply witness.” **EX2054** is not a deposition transcript of the cross-examination of Dr. Whitney, the only “reply witness,” nor does it otherwise provide any context for the

deposition testimony of Dr. Whitney. Geneoscopy further objects to **EX2054** under Federal Rules of Evidence (“FRE”) 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2054** under FRE 401, 402, and 403 as not relevant to the merits of the proceeding and because any probative value of **EX2054** with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing of the issues, undue delay, wasting of time, or needlessly presenting cumulative evidence. Geneoscopy also objects to **EX2054** on the ground that it is not cited in Patent Owner’s Sur-Reply. Geneoscopy further objects to **EX2054** under FRE 801, 802, and 803 as containing inadmissible hearsay not falling within any exception for which Exact relies upon for the truth of the matters asserted.

2. Geneoscopy objects to **EX2055**, Erica K. Barnell et al., *Analytical validation of a scrape-free multitarget stool RNA test for colorectal cancer screening*, Practical Laboratory Medicine 47 (2025) e00502, 1-7, as late-filed. Section II.I of the Trial Practice Guide, at page 73, provides that “[t]he sur-reply may not be accompanied by new evidence other than deposition transcripts of the cross-examination of any reply witness.” **EX2055** is not a deposition transcript of the cross-examination of Dr. Whitney, the only “reply witness,” nor does it otherwise provide any context for the deposition

testimony of Dr. Whitney. Geneoscopy further objects to **EX2055** under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2055** under FRE 401, 402, and 403 as not relevant to the merits of the proceeding and because any probative value of **EX2055** with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing of the issues, undue delay, wasting of time, or needlessly presenting cumulative evidence. Geneoscopy also objects to **EX2055** on the ground that it is not cited in Patent Owner's Sur-Reply. Geneoscopy further objects to **EX2055** under FRE 801, 802, and 803 as containing inadmissible hearsay not falling within any exception for which Exact relies upon for the truth of the matters asserted.

3. Geneoscopy objects to **EX2056**, Anthony J. Alberg et al., *The Use of "Overall Accuracy" to Evaluate the Validity of Screening or Diagnostic Tests*, JGIM, Vol. 19, May 2004, 460-465, as late-filed on the ground that Section II.I of the Trial Practice Guide, at page 73, sets forth that "[t]he sur-reply may not be accompanied by new evidence other than deposition transcripts of the cross-examination of any reply witness." **EX2056** is not a deposition transcript of the cross-examination of Dr. Whitney, the only "reply witness," nor does it otherwise provide any context for the deposition testimony of Dr. Whitney. Geneoscopy further objects to **EX2056** under FRE

901 as insufficiently authenticated and not self-authenticating under FRE 902.

Geneoscopy also objects to **EX2056** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2056**'s probative value with respect to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence. Geneoscopy further objects to **EX2056** on the ground that it is not cited in Patent Owner's Sur-Reply. Geneoscopy also objects to **EX2056** under FRE 801, 802, and 803 as containing inadmissible hearsay not falling within any exception for which Exact relies upon for the truth of the matters asserted.

4. Geneoscopy objects to **EX2057**, the Deposition Transcript of Duncan H. Whitney, Ph.D., in IPR2024-01330, dated September 26, 2025, under FRE 401 and 402 as containing testimony that is not relevant to the proceeding and is outside the scope of Dr. Whitney's Declarations (EX1002, EX1086), including, for example, on pages 28 through 53 of EX2057.

Dated: October 10, 2025

Respectfully submitted,

/Brendan T. Jones/

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(c), the undersigned hereby certifies that on October 10, 2025 I caused a true and correct copy to be served on the following attorneys of record:

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