

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENEOSCOPY, INC.,
Petitioner,

v.

EXACT SCIENCES CORPORATION,
Patent Owner.

Case No.: IPR2024-00459
U.S. Patent 11,634,781

PETITIONER'S OBJECTIONS TO EVIDENCE

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

(“Geneoscopy”) submits the following objections to the exhibits filed by Exact Sciences Corporation (“Exact”).

1. Geneoscopy objects to **EX2022**, “Declaration of Vadim Backman, Ph.D., October 24, 2024,” under Federal Rules of Evidence (“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, and for failing to comply with the requirements of 37 C.F.R. § 42.65(a) and (b).

2. Geneoscopy objects to **EX2023**, “Declaration of Peter Wood, October 24, 2024,” 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, and for failing to comply with the requirements of 37 C.F.R. § 42.65(a) and (b). Geneoscopy further objects to **EX2023** under FRE 401, 402, and 403 as irrelevant to the merits of this proceeding and prejudicial. Geneoscopy further objects to **EX2023** under FRE 602 and 901 for lack of foundation due to insufficient personal knowledge.

3. Geneoscopy objects to **EX2024**, “Declaration of June Munford, October 23, 2024,” 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. Geneoscopy also objects to **EX2024** under FRE 401 and 402 as containing testimony irrelevant to the proceeding.

4. Geneoscopy objects to **EX2025**, the Appendix to the Declaration of June Munford, under FRE 401 and 402 as containing testimony irrelevant to the proceeding. Geneoscopy also objects to **EX2025** 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, and that is not provided in the form of direct testimony meeting the requirements of 37 C.F.R. § 42.65(a) and (b).

5. Geneoscopy objects to **EX2027**, the Deposition Transcript of Duncan Whitney Ph.D., dated October 10, 2024, under FRE 401 and 402 as containing testimony irrelevant to the proceeding.

6. Geneoscopy objects to **EX2029**, “Geneoscopy Series C Investor Presentation, Second Quarter 2024,” under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2029** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2029’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 also objects to

EX2029 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.

7. Geneoscopy objects to **EX2030**, “FDA Colosense Approval Letter,” dated May 3, 2024, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2030** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2030**’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 also objects to **EX2030** 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.

8. Geneoscopy objects to **EX2031**, “Vital Signs: Colorectal Cancer Tests Save Lives,” dated November 7, 2013, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2031** FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2031**’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 also objects to **EX2031** 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.

9. Geneoscopy objects to **EX2032**, “Cologuard Patient Guide,” under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2032** under FRE 401 and 402 as irrelevant to the merits of the proceeding. Geneoscopy also objects to **EX2032** 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, and that is not provided in the form of direct testimony meeting the requirements of 37 C.F.R. § 42.65(a) and (b).

10. Geneoscopy objects to **EX2033**, U.S. Patent Application No. 11,845,991, “Fecal Sample Processing and Analysis Comprising Detection of Blood,” filed December 23, 2023, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2033** under FRE 401 and 402 as irrelevant to the merits of the proceeding. Geneoscopy objects to **EX2033** as it is not cited by Patent Owner’s Response. Geneoscopy also objects to **EX2033** 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.

11. Geneoscopy objects to **EX2034**, Exact Sciences' 2004 Form 10-K, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2034** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2034'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 also objects to **EX2034** 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.

12. Geneoscopy objects to **EX2035**, Exact Sciences' 2008 Form 10-K, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2035** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2035'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 also objects to **EX2035** 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.

13. Geneoscopy objects to **EX2036**, Exact Sciences' 2014 Form 10-K, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2036** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2036'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 also objects to **EX2036** 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.

14. Geneoscopy objects to **EX2037**, Exact Sciences' 2016 Form 10-K, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2037** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2037'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 also objects to **EX2037** 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.

15. Geneoscopy objects to **EX2038**, Exact Sciences' 2018 Form 10-K, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2038** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2038'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 also objects to **EX2038** 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.

16. Geneoscopy objects to **EX2039**, Exact Sciences' 2021 Form 10-K, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2039** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2039'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 also objects to **EX2039** 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.

17. Geneoscopy objects to **EX2040**, Exact Sciences' 2023 Form 10-K, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2040** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2040'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 also objects to **EX2040** 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.

18. Geneoscopy objects to **EX2041**, "Prior Screening VOC Data," under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2041** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2041'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 objects to **EX2033** as it is not cited by Patent Owner's Response. Geneoscopy also objects to **EX2041** 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. Geneoscopy also objects to **EX2041** for failing to meet the requirements of 37 C.F.R. § 42.65(a) and (b).

19. Geneoscopy objects to **EX2042**, “Exact Sciences’ Cologuard Wins prestigious Prix Galien Award for Best Medical Technology Product,” dated October 28, 2016, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2042** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2042**’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 also objects to **EX2042** 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.

20. Geneoscopy objects to **EX2043**, “Cologuard Wins Popular Science Magazine’s 2014 ‘Best of What’s New’ Award,” dated November 12, 2014, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2043** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2043**’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 also objects to **EX2043** 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.

21. Geneoscopy objects to **EX2044**, “Everyday Health Awards for Innovation Winners Announced at 2015 International CES,” dated January 7, 2015, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2044** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2044**’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 also objects to **EX2044** 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.

22. Geneoscopy objects to **EX2045**, “Exact Sciences Wins Wisconsin Innovation Award,” dated August 19, 2015, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2045** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2045**’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 also objects to **EX2045** 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.

23. Geneoscopy objects to **EX2046**, “Exact Sciences Honored as 2016 Big Award Company of the Year in Healthcare,” dated October 2, 2016, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2046** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2046**’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 also objects to **EX2046** 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.

24. Geneoscopy objects to **EX2048**, P. Schroy III et al., *Patient Perceptions of Stool-Based DNA Testing for Colorectal Screening Cancer*, 28 AM. J. PREVENTATIVE MED. 208-214 (2005), under FRE 901 as insufficiently

authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2048** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2048**'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 also objects to **EX2048** 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.

25. Geneoscopy objects to **EX2049**, Lesley-Ann Miller-Wilson et al., *Cross-Sectional Adherence with the Multi-Target Stool DNA Test for Colorectal Cancer Screening in A Large, Nationally Insured Cohort*, 36 INT'L J. OF COLORECTAL DISEASE 2471-2480 (2021), under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2049** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2049**'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 also objects to **EX2049** 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.

26. Geneoscopy objects to **EX2050**, John B. Kisiel et al., *Multitarget Stool DNA for Average Risk Colorectal Cancer Screening*, 30 GASTROINTESTINAL ENDOSCOPY CLINICS OF N. AMERICA 553-568 (2020), under 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2050** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2050** 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 also objects to **EX2050** 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.

27. Geneoscopy objects to **EX2051**, Rebecca Swartz et al., *Colorectal Cancer Screening: Compliance with Multitarget Stool DNA Testing Among Medicate Beneficiaries*, AGA ABSTRACTS S-601 (2019), under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2051** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2051'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 objects to EX2033 as it is not cited by Patent Owner's Response. Geneoscopy also objects to **EX2051** 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.

28. Geneoscopy objects to **EX2052**, Jason D. Eckmann et al., *Multi-Target Stool DNA Testing for Colorectal Cancer Screening: Emerging Learning on Real-World Performance*, 18 CURRENT TREATMENT OPTIONS GASTRO. 109-119 (2020), under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2052** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2052'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 also objects to **EX2052** 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.

29. Geneoscopy objects to **EX2053**, “ColoSense Clinician Brochure”, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2053** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2053’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 also objects to **EX2053** 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.

Dated: November 1, 2024

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 November 1, 2024 I caused a true and correct copy to be served on the following attorneys of record:

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Dated: November 1, 2024

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