

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 **EX2001**, “Declaration of Vadim Backman, Ph.D., April 30, 2024,” under Federal Rules of Evidence (“FRE”) objects to **EX2001** 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, that is not provided in the form of direct testimony meeting the requirements of 37 C.F.R. § 42.53, and for failing to comply with the requirements of 37 C.F.R. § 42.65(a) and (b).

2. Geneoscopy objects to **EX2002**, the Curriculum Vitae for Vadim Backman, April 1, 2024, under FRE 702, 703, and 37 C.F.R. § 42.65 as offering inadmissible expert testimony. Geneoscopy also objects to **EX2002** under FRE 401 and 402 as containing testimony irrelevant to the proceeding. Geneoscopy also objects to **EX2002** 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). Geneoscopy further objects to **EX2002** under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902.

3. Geneoscopy objects to **EX2006**, European Patent Application No. 03011896.2, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2006** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2006'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 **EX2006** 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).

4. Geneoscopy objects to **EX2007**, Z. Levi et al., *A Quantitative Immunochemical Faecal Occult Blood Test Is More Efficient for detecting Significant Colorectal Neoplasia Than a Sensitive Guaiac Test*, AILMENT PHARMACOLOGY THER. 1359-1364 (2006), under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2007** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2007'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 **EX2007** 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 **EX2008**, Thomas Imperiale et al., *Multitarget Stool DNA Testing for Colorectal-Cancer Screening*, 370 NEW ENGL. J. MED. 1287-97 (2014), under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2008** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2008**'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 **EX2008** 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).

6. Geneoscopy objects to **EX2009**, Sidney J. Winawer and Ann G. Zauber, *The Advanced Adenoma as the Primary Target of Screening*, 12 GASTROINTESTINAL ENDOSCOPY CLINICS OF N. AMERICA 1-9 (2002), under 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2009** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2009'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 **EX2009** 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).

7. Geneoscopy objects to **EX2010**, Daniel C. Chung, *The Genetic Basis of Colorectal Cancer: Insights into Critical Pathways of Tumorigenesis*, GASTROENTEROLOGY 854-865 (2000), under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2010** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2010'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 **EX2010** 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).

8. Geneoscopy objects to **EX2011**, Hermann Brenner et al., *Risk of Progression of Advanced Adenomas to Colorectal Cancer by Age and Sex: Estimates Based on 840 149 Screening Colonoscopies*, GUT 1585-1589 (2007), under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2011** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2011'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 **EX2011** 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, that is not provided in the form of direct testimony meeting the requirements of 37 C.F.R. § 42.65(a) and (b).

9. Geneoscopy objects to **EX2012**, David L. Zack et al., *Colorectal Cancer Screening Compliance by Medicine Residents: Perceived and Actual*, 96 THE AMERICAN J. OF GASTROENTEROLOGY 3005-3008 (2001), under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2012** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2012'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 **EX2012** 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, 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 **EX2013**, Amnon Sonnenberg and Fabiola Delco, *Cost-effectiveness of A Single Colonoscopy in Screening for Colorectal Cancer*, 162 ARCH INTERNAL MED. 163-168 (2002), under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2013** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2013'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 **EX2013** 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, that is not provided in the form of direct testimony meeting the requirements of 37 C.F.R. § 42.65(a) and (b).

11. Geneoscopy objects to **EX2014**, Peter B. Cotton et al., *Computed Tomographic Colonography (Virtual Coloscopy)*, 291 JAMA 1713-1719 (2004), under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2014** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2014'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 **EX2014** 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, that is not provided in the form of direct testimony meeting the requirements of 37 C.F.R. § 42.65(a) and (b).

12. Geneoscopy objects to **EX2015**, N. Schoofs et al., *PillCam Colon Capsule Endoscopy Compared with Colonoscopy for Colorectal Tumor Diagnosis: A Prospective Pilot Study*, 38 ENDOSCOPY 971-977 (2006), under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2015** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2015'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 **EX2015** 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, that is not provided in the form of direct testimony meeting the requirements of 37 C.F.R. § 42.65(a) and (b).

13. Geneoscopy objects to **EX2016**, “Cologuard Patient Guide”, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2016** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2016'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.

14. Geneoscopy objects to **EX2017**, PRNewswire, “*FDA Approves Exact Sciences’ Cologuard®; First and Only Stool DNA Noninvasive Colorectal Cancer Screening Test*,” under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2017** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2017’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 **EX2017** 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).

15. Geneoscopy objects to **EX2018**, Exact Sciences, “*Get Off the Bench: Hoops-Themed Campaign Urges Colorectal Cancer Screening*,” March 07, 2024, under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2018** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2018’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 **EX2018** 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).

16. Geneoscopy objects to **EX2019**, PRNewswire, “*Geneoscopy Submits Premarket Approval Application to U.S. Food and Drug Administration for its Noninvasive Colorectal Cancer RNA Biomarker Screening Test*,” Jan. 24, 2023, under 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2019** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2019’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 **EX2019** 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).

17. Geneoscopy objects to **EX2020**, Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, “*Increase the Proportion of Adults Who Get Screened for Colorectal Cancer – C-07*,” under FRE 901 as insufficiently authenticated and not self-authenticating under FRE 902. Geneoscopy also objects to **EX2020** under FRE 401, 402, and 403 as irrelevant to the merits of the proceeding and because **EX2020**’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.

Dated: August 9, 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 August 9, 2024 I caused a true and correct copy to be served on the following attorneys of record:

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Dated: August 9, 2024

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