UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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GENEOSCOPY, INC.,
Petitioner,

v.

EXACT SCIENCES CORPORATION,
Patent Owner.

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U.S. Patent 11,634,781

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DECLARATION OF BRENDAN T. JONES

1. I am an attorney at Foley Hoag LLP, and counsel of record for Geneoscopy, Inc. in the above-captioned matter. I am registered to practice before the United States Patent and Trademark Office.

2. Attached as EX1004 is a true and correct copy of Konstanze Lenhard et al., "Analysis of Promoter Methylation in Stool: A Novel Method for the Detection of Colorectal Cancer," *Clinical Gastroenterology and Hepatology,* 3:142-149 (2005).

3. Attached as Ex. 1005 is a true and correct copy of Alex Vilkin et al., "Performance Characteristics and Evaluation of an Automated-Developed and Quantitative, Immunochemical Fecal Occult Blood Screening Test," *American Journal of Gastroenterology*, 100:2519-2525 (2005).

4. Attached as Ex. 1006 is a true and correct copy of Steven Itzkowitz et al., "Improved Fecal DNA Test for Colorectal Cancer Screening," *Clinical Gastroenterology and Hepatology,* 5:111-117 (2007).

5. Attached as Ex. 1008 is a true and correct copy of Sarah Derks et al., "Promoter Methylation Precedes Chromosomal Alterations in Colorectal Cancer Development," *Cellular Oncology,* 28:247-257 (2006).

6. Attached as Ex. 1010 is a true and correct copy of Lydia Guittet et al., "Comparison of A Guaiac Based And An Immunochemical Faecal Occult Blood Test In Screening For Colorectal Cancer In A General Average Risk Population," *Gut*, 56:210-214 (2007).

7.   Attached as Ex. 1011 is a true and correct copy of Takashi Nishikawa et al., "A Simple Method Of Detecting K-Ras Point Mutations in Stool Samples for Colorectal Cancer Screening Using One-Step Polymerase Chain Reaction/Restriction Fragment Length Polymorphism Analysis," *Clinica Chimica Acta,* 318 107–112 (2002).

8.   Attached as Ex. 1012 is a true and correct copy of Nadie Kutzner et al., "Non-Invasive Detection of Colorectal Tumours by the Combined Application Of Molecular Diagnosis and the Faecal Occult Blood Test," *Cancer Letters,* 229:33-41 (2005).

9.   Attached as Ex. 1013 is a true and correct copy of Bernard Levin et al., "Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, a Joint Guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology," *Gastroenterology,* 134:1570–1595 (2008).

10.   Attached as Ex. 1016 is a true and correct copy of the LinkedIn profile of Dr. Joost Louwagie as obtained from https://www.linkedin.com/in/joost-louwagie/?originalSubdomain=ch on January 10, 2024.

11.   Attached as Ex. 1024 is a true and correct copy of GP Young et al., "New Stool Screening Tests for Colorectal Cancer," *Digestion,* 76:26-33 (2007).

12.   Attached as Ex. 1025 is a true and correct copy of Jeff Olson et al., "DNA Stabilization is Critical for Maximizing Performance of Fecal DNA-Based Colorectal Cancer Tests," *Diagnostic Molecular Pathology,* 3:183-191 (2005).

13.   Attached as Ex. 1026 is a true and correct copy of Dorothy Melvin and Marion Brooke, "Laboratory Procedures for the Diagnosis of Intestinal Parasites", *U.S. Department of Health and Human Services Centers for Disease Control* (1982).

14.   Attached as Ex. 1029 is a true and correct copy of N. Hoepffner et al., "Comparative Evaluation of a New Bedside Faecal Occult Blood Test in a Prospective Multicentre Study," *Alimentary Pharmacology & Therapeutics,* 23:145-154 (2006).

15.   Attached as Ex. 1030 is a true and correct copy of Jordan Nechvatal et al., "Fecal Collection, Ambient Preservation, and DNA Extraction for PCR Amplification of Bacterial And Human Markers from Human Feces," *Journal of Microbiological Methods*, 72(2):124-32 (2008).

16.   Attached as Ex. 1033 is a true and correct copy of JB Simon, "Occult Blood Screening for Colorectal Carcinoma: A Critical Review," *Gastroenterology*, 88:820-837 (1985).

17.   Attached as Ex. 1035 is a true and accurate copy of D. Sidransky, "Identification of Ras Oncogene Mutations in the Stool of Patients with Curable Colorectal Tumors," *Science*, 256:102–105 (1992).

18.   Attached as Ex. 1037 is a true and correct copy of Hannes Müller et al., "Methylation Changes in Faecal DNA: A Marker for Colorectal Cancer Screening?" *Lancet*, 63:1283-1285 (2004).

19.   Attached as Ex. 1038 is a true and correct copy of Kornel Schuebel et al., "Comparing the DNA Hypermethylome with Gene Mutations in Human Colorectal Cancer," *PLoS Genet.* 3:1709–1723 (2007).

20.   Attached as Ex. 1039 is a true and correct copy of Lanlan Shen, et al., "Integrated Genetic and Epigenetic Analysis Identifies Three Different Subclasses of Colon Cancer," *Proc Natl. Acad. Sci. U.S.A.* 104(47): 18654–18659 (2007).

21.   Attached as Ex. 1040 is a true and correct copy of Tagore, K.S., et al., "Review Article: the Evolution to Stool DNA Testing for Colorectal Cancer," *Aliment Pharmacol. Ther.* 19: 1225-1233 (2004).

22.   Attached as Ex. 1041 is a true and correct copy of the abstract of Sarah Derks et al., "Promoter Methylation Precedes Chromosomal Alterations in Colorectal Cancer Development," *Cellular Oncology,* 28:247-257 (2006), obtained from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4618222/ on January 9, 2024.

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