

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENEOSCOPY, INC.,
Petitioner,

v.

EXACT SCIENCES CORPORATION,
Patent Owner.

U.S. Patent 11,634,781

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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