

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 11,970,746

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 EX1001 is a true and correct copy of U.S. Patent No. 11,970,746.

3. 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) available at [https://www.cghjournal.org/article/S1542-3565\(04\)00624-X/fulltext](https://www.cghjournal.org/article/S1542-3565(04)00624-X/fulltext).

4. Attached as EX1005 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) available at https://journals.lww.com/ajg/abstract/2005/11000/performance_characteristics_and_evaluation_of_an.26.aspx.

5. Attached as EX1006 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) available at [https://www.cghjournal.org/article/S1542-3565\(06\)01044-5/fulltext](https://www.cghjournal.org/article/S1542-3565(06)01044-5/fulltext).

6. Attached as EX1007 is a true and correct copy of U.S. Patent Publication No. US2006/0216714.

7. Attached as EX1008 is a true and correct copy of International Patent Application No. WO2005/113769.

8. Attached as EX1009 is a true and correct copy of International Patent Application Publication No. WO97/25925.

9. Attached as EX1010 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).

10. Attached as EX1011 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) available at <https://www.sciencedirect.com/science/article/abs/pii/S0009898101008063>.

11. Attached as EX1012 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) available at

<https://www.sciencedirect.com/science/article/abs/pii/S0304383504009796>.

12. Attached as EX1013 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) available at <https://www.sciencedirect.com/science/article/abs/pii/S0016508508002321>.

13. Attached as EX1014 is a true and correct copy of U.S. Provisional Patent Application US61/149,581.

14. Attached as EX1015 is a true and correct copy of the transmittal notice for U.S. Provisional Patent Application US61/149,581.

15. Attached as EX1016 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.

16. Attached as EX1017 is a true and correct copy of Recorded Assignment of US Patent No. 11,634,781 dated April 25, 2017.

17. Attached as EX1018 is a true and correct copy the USPTO Nonfinal Office Action, dated July 6, 2023.

18. Attached as EX1019 is a true and correct copy of the Response to the USPTO Nonfinal Office Action filed on October 26, 2023.

19. Attached as EX1020 is a true and correct copy of is a true and correct copy of GP Young et al., “New Stool Screening Tests for Colorectal Cancer,” *Digestion*, 76:26-33 (2007) available at <https://karger.com/dig/article-abstract/76/1/26/105075/New-Stool-Screening-Tests-for-Colorectal-Cancer>.

20. Attached as EX1021 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) available at <https://gut.bmj.com/content/56/2/210.short>.

21. Attached as EX1022 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) available at https://journals.lww.com/molecularpathology/abstract/2005/09000/dna_stabilization_is_critical_for_maximizing.11.aspx.

22. Attached as EX1023 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*,

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