

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENEOSCOPY, INC.,
Petitioner,

v.

EXACT SCIENCES CORPORATION,
Patent Owner.

Case No.: IPR2024-01330
U.S. Patent 11,970,746

PETITIONER'S AMENDED EXHIBIT LIST

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Exhibit No.	Short Name	Description
EX1001	'746 patent	U.S. Patent No. 11,970,746.
EX1002	Whitney Declaration	Expert Declaration of Dr. Whitney Ph.D.
EX1003	Whitney CV	Curriculum Vitae of Dr. Duncan Whitney
EX1004	Lenhard	Konstanze Lenhard et al., “Analysis of Promoter Methylation in Stool: A Novel Method for the Detection of Colorectal Cancer,” <i>Clinical Gastroenterology and Hepatology</i> , 3:142-149 (2005).
EX1005	Vilkin	Alex Vilkin et al., “Performance Characteristics and Evaluation of an Automated-Developed and Quantitative, Immunochemical Fecal Occult Blood Screening Test,” <i>American Journal of Gastroenterology</i> , 100:2519-2525 (2005).
EX1006	Itzkowitz	Steven Itzkowitz et al., “Improved Fecal DNA Test for Colorectal Cancer Screening,” <i>Clinical Gastroenterology and Hepatology</i> , 5:111-117 (2007).
EX1007	Kanaoka	U.S. Patent Publication Number US 2006/0216714.
EX1008	Shuber	International Patent Application Publication Number WO2005/113769.
EX1009	Inbar	International Patent Application Publication Number WO97/25925.
EX1010	Melvin	Dorothy Melvin and Marion Brooke, “Laboratory Procedures for the Diagnosis of Intestinal Parasites”, <i>U.S. Department of Health and Human Services Centers for Disease Control</i> (1982).

Exhibit No.	Short Name	Description
EX1011	Nishikawa	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,” <i>Clinica Chimica Acta</i> , 318 107–112 (2002).
EX1012	Kutzner	Nadie Kutzner et al., “Non-Invasive Detection of Colorectal Tumours by the Combined Application of Molecular Diagnosis and the Faecal Occult Blood Test,” <i>Cancer Letters</i> , 229:33-41 (2005).
EX1013	Levin	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,” <i>Gastroenterology</i> , 134:1570–1595 (2008).
EX1014	'581 Provisional Application	US Provisional Patent Application US61/149,581.
EX1015	'581 Transmittal	Transmittal Notice for U.S. Provisional Patent Application US61/149,581.
EX1016	Joost Louwagie Profile	LinkedIn Page of Joost Louwagie.
EX1017	Recorded Assignment	Recorded Assignment of OncoMethylome patent family dated April 25, 2017.
EX1018	Nonfinal Office Action	Nonfinal Office Action of July 6, 2023 issued during prosecution of '746 patent
EX1019	Response to Nonfinal Office Action	Response to Nonfinal Office Action filed on October 26, 2023 during prosecution of '746 patent
EX1020	Young 2007	GP Young et al., “New Stool Screening Tests for Colorectal Cancer,” <i>Digestion</i> , 76:26-33 (2007).

Exhibit No.	Short Name	Description
EX1021	Guittet	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," <i>Gut</i> , 56:210-214 (2007).
EX1022	Olson	Jeff Olson et al., "DNA Stabilization is Critical for Maximizing Performance of Fecal DNA-Based Colorectal Cancer Tests," <i>Diagnostic Molecular Pathology</i> , 3:183-191 (2005).
EX1023	Hoepffner	N. Hoepffner et al., "Comparative Evaluation of a New Bedside Faecal Occult Blood Test in a Prospective Multicentre Study," <i>Alimentary Pharmacology & Therapeutics</i> , 23:145-154 (2006).
EX1024	Nechvatal	Jordan Nechvatal et al., "Fecal Collection, Ambient Preservation, and DNA Extraction for PCR Amplification of Bacterial and Human Markers from Human Feces," <i>Journal of Microbiological Methods</i> , 72(2):124-32 (2008).
EX1025	Cologuard Launch Press Release`	"FDA Approves Exact Sciences' Cologuard; First and Only Stool DNA Noninvasive Colorectal Cancer Screening Test" PR Newswire Association LLC, August 12, 2014
EX1026	Cologuard Patent Coverage, 2024	Printout of Exact Sciences' "Patents and Trademarks" page from their website, as visited on August 9, 2024.
EX1027	Cologuard Patent Coverage, 2014	Printout of Exact Sciences' "Patents and Trademarks" page from their website as of December 6, 2104. Downloaded from Wayback Machine on August 9, 2024.
EX1028	'278 patent	U.S. Patent No. 9,163,278
EX1029	'278 patent Office Action Response	Response to Nonfinal Office Action filed on July 31, 2015 during prosecution of '278 patent

Exhibit No.	Short Name	Description
EX1030	'781 patent	U.S. Patent No. 11,634,781.
EX1031	IPR2024-00459 Petition	IPR2024-00459 Petition
EX1032	IPR2024-00459 POPR	IPR2024-00459 Patent Owner's Preliminary Response
EX1033	IPR2024-00459 Institution Decision	IPR2024-00459 Institution Decision
EX1034	Simon	JB Simon, "Occult Blood Screening for Colorectal Carcinoma: A Critical Review," <i>Gastroenterology</i> , 88:820-837 (1985).
EX1035	Sidransky	D. Sidransky, "Identification of Ras Oncogene Mutations in the Stool of Patients with Curable Colorectal Tumors," <i>Science</i> , 256:102-105 (1992).
EX1036	Müller	Hannes Müller et al., "Methylation Changes in Faecal DNA: A Marker for Colorectal Cancer Screening?" <i>Lancet</i> , 63:1283-1285 (2004).
EX1037	Schuebel	Kornel Schuebel et al., "Comparing the DNA Hypermethylome with Gene Mutations in Human Colorectal Cancer," <i>PLoS Genet.</i> , 3:1709-1723 (2007).
EX1038	Shen	Lanlan Shen et al., "Integrated Genetic and Epigenetic Analysis Identifies Three Different Subclasses of Colon Cancer." <i>Proc Natl. Acad. Sci. U.S.A.</i> , 104(47): 18654-18659 (2007).
EX1039	Tagore	K.S. Tagore et al. "Review Article: The Evolution to Stool DNA Testing for Colorectal Cancer," <i>Aliment Pharmacol. Ther.</i> , 19: 1225-1233 (2004).
EX1040	Rennert	Rennert et al., "Detecting K-Ras Mutations in Stool from Fecal Occult Blood Test Cards in Multiphasic Screening for Colorectal Cancer," <i>Cancer Letters</i> , 253: 258-264 (2007).

Exhibit No.	Short Name	Description
EX1041	Grow	U.S. Patent No. 5,198,365.
EX1042	Imperiale 2004	Thomas Imperiale et al., “Fecal DNA Versus Fecal Occult Blood for Colorectal-Cancer Screening in an Average-Risk Population,” <i>New England Journal of Medicine</i> , 351(26): 2704-2714 (2004).
EX1043	Ahlquist 2008	David Ahlquist et al., “Stool DNA and Occult Blood Testing for Screen Detection of Colorectal Neoplasia,” <i>Annals of Internal Medicine</i> , 149(7): 441–W81 (2008).
EX1044	Young 2004	G.P. Young, “Fecal Immunochemical Tests (FIT) vs. Office-Based Guaiac Fecal Occult Blood Test (FOBT),” <i>Practical Gastroenterology</i> 28(6): 46-56 (2004).
EX1045	Karl	Karl, et al., Improved Diagnosis of Colorectal Cancer Using a Combination of Fecal Occult Blood and Novel Fecal Protein Markers,” <i>Clinical Gastroenterology and Hepatology</i> , 6:1122–1128 (2008).
EX1046	White	Victoria White and Richard Miller, “Colorectal Cancer: Prevention and Early Diagnosis,” <i>Medicine</i> , 35(6) 297-301 (2007).
EX1047	Mahon	Suzanne Mahon, “ Prevention and Screening of Gastrointestinal Cancers,” <i>Seminars in Oncology Nursing</i> , 25(1): 15-31 (2009).
EX1048	Beaulieu	U.S. Patent No. 9,891,223.
EX1049	Ostrow	Donald Ostrow, “Tests for Fecal Occult Blood, in Clinical Methods: The History, Physical, and Laboratory Examinations.” Boston: Butterworths; Chapter 98 (1990).
EX1050	Cleator	U.S. Patent No. 7,195,878.

Exhibit No.	Short Name	Description
EX1051	Kahi	Charles Kahi et al., “Screening, Surveillance, and Primary Prevention for Colorectal Cancer: A Review of the Recent Literature,” <i>Gastroenterology</i> , 135: 380-399 (2008).
EX1052	Zou	H Zou et al., “Highly Methylated Genes in Colorectal Neoplasia: Implications for Screening,” <i>Cancer Epidemiol Biomarkers Preview</i> , 16(12):2686-96 (2007).
EX1053	Eguchi	Susumu Eguchi et al., “Mutations of the P53 Gene in Stool of Patients with Resectable Colorectal Cancer,” <i>Cancer</i> , 77:1707–1710 (1996).
EX1054	Villa	E. Villa, et al., “Identification of Subjects at Risk for Colorectal Carcinoma through a Test Based on K-Ras Determination in the Stool,” <i>Gastroenterology</i> , 110:1346–1353 (1996).
EX1055	Boynton	Boynton et al., “DNA Integrity as a Potential Marker for Stool-based Detection of Colorectal Cancer,” <i>Clinical Chemistry</i> , 49:7 1058–1065 (2003).
EX1056	Jessup	J. Milburn Jessup et al., “Diagnosing Colorectal Carcinoma: Clinical and Molecular Approaches,” <i>A Cancer Journal for Clinicians</i> , 47(2):70-92 (1997).
EX1057	Chen	WD Chen et al., “Detection in Fecal DNA of Colon Cancer-Specific Methylation of the Nonexpressed Vimentin Gene.” <i>Journal of National Cancer Institute</i> , 97:1124-1132 (2005).
EX1058	Itzkowitz 2008	Steven Itzkowitz, “A Simplified, Noninvasive Stool DNA Test for Colorectal Cancer Detection,” <i>American Journal of Gastroenterology</i> , 103: 2862-2870 (2008).

Exhibit No.	Short Name	Description
EX1059	Li	L-C Li and R. Dahiya, "MethPrimer: Designing Primers for Methylation Pcrs," <i>Bioinformatics</i> , 18(11): 1427-1431 (2002).
EX1060	Kanaoka 2004	Shigeru Kanaoka et al., "Potential Usefulness of Detecting Cyclooxygenase 2 Messenger RNA in Feces for Colorectal Cancer Screening," <i>Gastroenterology</i> , 127:422-427 (2004).
EX1061	Matsumura 1992	Y Matsumura and D Tarin "Significance of CD44 Gene Products for Cancer Diagnosis and Disease Evaluation," <i>Lancet</i> , 340: 1053-1058 (1992).
EX1062	Matsumura 1994	Y Mastumura et al., "Non-Invasive Detection of Malignancy by Identification of Unusual CD44 Gene Activity in Exfoliated Cancer Cells," <i>BMJ</i> , 308:619-624 (1994).
EX1063	Leung	Wai Leung et al., "Detection of Hypermethylated DNA or Cyclooxygenase-2 Messenger RNA in Fecal Samples of Patients with Colorectal Cancer or Polyps" <i>American Journal Gastroenterology</i> , 102: 1070-1076 (2007).
EX1064	Ahmed	Farid Ahmed et al., "Transcriptomic Molecular Markers for Screening Human Colon Cancer in Stool and Tissue," <i>Cancer Genomics and Proteomics</i> 4:1-20 (2007).
EX1065	Ahlquist 2000	D.A. Ahlquist et al., "Colorectal Cancer Screening by Detection of Altered Human DNA in Stool: Feasibility of a Multitarget Assay Panel," <i>Gastroenterology</i> , 119(5):1219-1227 (2000).
EX1066	Ahlquist 2000(b)	D.A. Ahlquist et al., "Molecular Stool Screening for Colorectal Cancer. Using DNA Markers May Be Beneficial, But Large Scale Evaluation is Needed." <i>BMJ</i> , 29;321(7256):254-5 (2000).

Exhibit No.	Short Name	Description
EX1067	Taylor	International Patent Application Publication Number WO2009/102788.
EX1068	Lapidus '650	U.S. Patent No. 5,741,650
EX1069	Lapidus '178	U.S. Patent No. 5,952,178
EX1070	Hirata	I Hirata et al., "Usefulness of Fecal Lactoferrin and Hemoglobin in Diagnosis of Colorectal Diseases," <i>World Journal of Gastroenterology</i> , 14;13(10):1569-74 (2007).
EX1071	Ahlquist 1988	D.A. Ahlquist et al., "A Stool Collection Device: The First Step in Occult Blood Testing," <i>Annals of Internal Medicine</i> , (108)4:609-612 (1988).
EX1072	Lenhard Printout	Printout of <i>Clinical Gastroenterology and Hepatology</i> Website.
EX1073	Van Engeland	International Patent Application Publication Number WO2008/084219.
EX1074	Itzkowitz Printout	Printout of <i>Clinical Gastroenterology and Hepatology</i> Website.
EX1075	Itzkowitz Press Release	Exact Sciences and Mount Sinai School of Medicine Press Release issued December 13, 2006.
EX1076	Cologuard Patient Guide	Cologuard Patient Guide as approved by the Food and Drug Administration
EX1077	Imperiale 2014	Imperiale, et al., "Multitarget Stool DNA Testing for Colorectal-Cancer Screening," <i>The New England Journal of Medicine</i> , 370(14):1287-1297 (2014)
EX1078	Exact Sciences 2023 Form 10-K	Exact Sciences Corporation's 2023 Form 10-K.
EX1079	Exact Sciences Cologuard web page	Exact Science's webpage regarding the Cologuard test as obtained from https://www.exactsciences.com/our-tests/cologuard on August 15, 2024.

Exhibit No.	Short Name	Description
EX1080	Cologuard Physician Brochure	Cologuard Physician Brochure as approved by the Food and Drug Administration
EX1081	Cologuard Instructions for Use	Cologuard sDNA-based Colorectal Cancer Screening Test Instructions for Use as approved by the Food and Drug Administration
EX1082	Whitney Declaration in IPR2024-00459	Duncan Whitney Ph.D.'s Declaration submitted in IPR2024-00459
EX1083	Jones Declaration	Declaration of Brendan T. Jones
EX1084	Burg Declaration	Declaration of Sarah S. Burg
EX1085	Ware Declaration	Declaration of Donald R. Ware
EX1086	Second Whitney Declaration	Second Declaration of Duncan Whitney, Ph.D.
EX1087	FWD	IPR2024-00459 Final Written Decision
EX1088	Backman IPR2024-00459 Transcript	Transcript of Deposition of Dr. Vadim Backman on January 15, 2025 in IPR2024-00459
EX1089	Backman IPR2024-01330 Transcript	Transcript of Deposition of Dr. Vadim Backman on August 7, 2024 in IPR2024-01330
EX1090	Van Rossum	Van Rossum, et al "Random Comparison of Guaiac and Immunochemical Fecal Occult Blood Tests for Colorectal Cancer in a Screening Population," <i>Gastroenterology</i> , 135:82–90 (2008)
EX1091	Feiger	Feiger, Chase, "How This CEO Consumerized Cancer Into a \$13B Enterprise" <i>Forbes</i> , April 8, 2024
EX1092	Second Jones Declaration	Second Declaration of Brendan T. Jones

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing **PETITIONER'S AMENDED EXHIBIT LIST** was served on August 22, 2025 via the delivery method indicated to the attorneys of record for the Patent Owners as follows:

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