Court Dismisses Exact Sciences' '781 Patent Infringement Claim Against Geneoscopy

Geneoscopy Continues Path Toward Commercialization of ColoSense, Bringing New Innovations in Gastrointestinal Health to Patients in Need

ST. LOUIS, Mo. – May 22, 2024 – Geneoscopy, Inc., a life sciences company focused on developing diagnostic tests for the advancement of gastrointestinal health, today announced that the United States District Court for the District of Delaware dismissed Exact Sciences' claim of infringement regarding United States Patent No. 11,634,781 ("the '781 patent"). The Court's ruling concluded that the allegations did not support a claim that Geneoscopy has infringed, or currently is infringing, the '781 patent.

The Court's order directed Exact Sciences to file an amended complaint. It also denied certain technical objections Geneoscopy raised related to other claims. At this stage of the litigation, the Court did not address, nor was it asked to determine, whether the '781 patent is valid or enforceable.

"At Geneoscopy, our goal is to advance RNA biomarker technology to provide accurate, reliable screening solutions for detecting CRC and advanced adenomas," said Andrew Barnell, CEO and co-founder of Geneoscopy. "Geneoscopy is pleased with the Court's recent dismissal ruling, as we seek to ensure that Exact Sciences cannot impede innovation and advancement in the field of cancer detection by claiming exclusive rights to diagnostic methods it did not invent. We are highly confident in the strength of our intellectual property. We will continue our efforts to bring ColoSense to market, offering a new screening option for the millions of Americans in need."

Recently FDA-approved, ColoSense is indicated as a screening test for adults 45 years of age or older who are at a typical average risk for developing colorectal cancer (CRC). Geneoscopy is working with payors, professional societies, and advocacy partners to support a commercial launch of ColoSense later this year or early in 2025 to ensure physicians and their patients have timely access to reliable CRC screening options for all eligible age groups.

Related Proceeding

Geneoscopy has separately petitioned the United States Patent and Trademark Office (USPTO) to institute an inter partes review challenging the patentability of the '781 patent. As Geneoscopy's petition explains, nothing in that patent is inventive. Fecal tests for detecting blood protein and nucleic acids recited by the claims are standard, routine methods for preparing a fecal sample for the performance of well-established complementary diagnostic assays. Separating a fecal sample so it can be tested for both blood proteins and nucleic acids is reported throughout the prior art. The claimed method of the '781 patent is obvious, and the claims directed to the method are invalid.

Exact Sciences recently filed a second complaint in the District of Delaware seeking a declaration that Geneoscopy's test will infringe U.S. Patent No. 11,970,746, a related patent to the '781 patent. Geneoscopy believes that this new complaint is likewise baseless and will not disrupt Geneoscopy's commercialization of ColoSense.

About ColoSense
ColoSense is intended for the qualitative detection of colorectal neoplasia-associated RNA markers and for the presence of occult hemoglobin in human stool. ColoSense is for use with the ColoSense Collection Kit, the ColoSense Test Kit, the ColoSense Software, and the following instruments: Polymedco iFOBT Analyzer; bioMérieux EMAG Nucleic Acid Extraction System; and Bio-Rad QXDx ddPCR System. ColoSense is a single-site test performed at Geneoscopy, Inc.

A positive ColoSense result may indicate the presence of colorectal cancer (CRC), advanced adenomas (AA), or serrated precancerous lesions (SPL) and should be followed by a colonoscopy. ColoSense is indicated as a screening test for adults, 45 years of age or older, who are at typical average risk for developing CRC. ColoSense is not a replacement for diagnostic or surveillance colonoscopy in high-risk individuals.

Results from Geneoscopy's pivotal CRC-PREVENT trial were published in *The Journal of the American Medical Association (JAMA)* in October 2023. For more information, visit www.colosense.com.

About Geneoscopy, Inc.
Geneoscopy, Inc. is a life sciences company focused on developing diagnostic tests for gastrointestinal health. Leveraging its proprietary, patented stool-derived eukaryotic RNA (seRNA) biomarker platform, Geneoscopy's mission is to empower patients and providers to transform gastrointestinal health through innovative diagnostics. Beyond colorectal cancer screening, Geneoscopy is developing diagnostic tests for treatment selection and therapy monitoring in other disease areas in partnership with leading universities and biopharmaceutical companies. For more information, visit www.geneoscopy.com and follow the company on LinkedIn.

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Geneoscopy Media and IR Contacts
Media:
Andrea Sampson
Sampson Public Relations Group
asampson@sampsonprgroup.com

Investor Relations:
Carrie Mendivil / Ji-Yon Yi
Gilmartin Group
investors@geneoscopy.com