



Geneoscopy Files Inter Partes Review Petition Challenging Exact Sciences' Patent

Extensive prior art renders Exact Sciences' patent relating to stool collection and processing invalid

ST. LOUIS, Mo. – Jan. 12, 2024 – Geneoscopy, Inc., a life sciences company focused on developing diagnostic tests for the advancement of gastrointestinal health, today announced that it has petitioned the United States Patent and Trademark Office (USPTO) for inter partes review challenging the patentability of United States Patent No. 11,634,781 (“the ’781 patent”) owned by Exact Sciences.

Nothing in the ’781 patent’s claims is inventive. The petition explains that the claims of the ’781 patent are directed to the separation of a fecal sample into two portions to permit two standard diagnostic tests – one detecting blood proteins and the other detecting nucleic acids – to be performed on the sample. The fecal tests for detecting blood protein and nucleic acids recited by the claims were known and routine. The method claimed by the ’781 patent amounts to no more than the routine use of standard methods to prepare 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.

“Geneoscopy stands deeply committed to advancing our patented RNA biomarker technology, which helps enable the early detection and prevention of pre-cancerous polyps and colorectal cancer (CRC), with the highest, consistent sensitivity levels for patients of all ages,” said Andrew Barnell, CEO and co-founder of Geneoscopy. “With the goal of expanding cancer screening options and improving outcomes for millions of patients, Geneoscopy seeks to ensure that Exact Sciences does not foreclose innovation and advancement in the field of cancer detection by claiming exclusive rights to diagnostic methods it did not invent. We strongly deny Exact Sciences’ allegations and will vigorously defend our ability to fulfill our mission to empower patients and providers to transform gastrointestinal health.”

Related Litigation

On December 22, 2023, Geneoscopy moved to dismiss the civil action pending in the United States District Court for the District of Delaware entitled *Exact Sciences Corp. v. Geneoscopy, Inc.*, in which Exact Sciences has asserted baseless claims of infringement of the ’781 patent. Geneoscopy’s motion requests the dismissal of the complaint in its entirety.

CRC-PREVENT Study

Results from Geneoscopy’s 8,920 patient CRC-PREVENT clinical study to assess the clinical validity of Geneoscopy’s CRC screening test, ColoSense™, were recently published in the *Journal of American Medical Association (JAMA)*. JAMA reported that ColoSense demonstrated the highest level of sensitivity for CRC (94%) and advanced adenomas (AA) (46%) reported by any other commercially available non-invasive screening test. For stage 1 cancers, ColoSense demonstrated 100% sensitivity. Additionally, CRC-PREVENT showed that ColoSense’s RNA-based platform offers consistent sensitivity performance for CRC and AA detection across eligible age groups. In contrast, prospective studies of an existing DNA-methylation-based test have yet to demonstrate its CRC sensitivity and reveal a material decline in its ability to detect AA in average-risk individuals ages 45-49, a group that consists of 19 million Americans.¹ Given the rising CRC incidence in younger Americans, upon approval from the FDA, ColoSense will

represent a promising new tool to help reduce incidence and mortality from this prevalent, yet preventable type of cancer.

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, 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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References:

1. Hyams, T., Mueller, N., Curbow, B., King-Marshall, E., & Sultan, S. (2022). Screening for colorectal cancer in people ages 45-49: research gaps, challenges and future directions for research and practice. *Translational behavioral medicine*, 12(2), 198–202. <https://doi.org/10.1093/tbm/ibab079>