IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXACT SCIENCES CORPORATION, Plaintiff, v. GENEOSCOPY, INC., Defendant.	))))))))))	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Exact Sciences Corporation ("Exact Sciences" or "Plaintiff"), for its Complaint against Defendant Geneoscopy, Inc. ("Geneoscopy" or "Defendant"), alleges as follows:

OVERVIEW OF THE ACTION

1. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

2. Exact Sciences, with its suite of cancer screening and diagnostic products including its revolutionary stool-based, at-home Cologuard® test, has been helping save lives through early cancer detection and treatment guidance for nearly a decade. The Cologuard test is the first noninvasive stool (or fecal) DNA-based test approved by the U.S. Food and Drug Administration ("FDA") for detecting colorectal cancer ("CRC") and precancerous lesions in adults aged 45 and older with average risk of CRC. Exact Sciences brings this action to protect its intellectual property against Geneoscopy, a flagrant infringer whose actions flout Exact Sciences' patent rights.

3. Exact Sciences' claims are based on Geneoscopy's imminent infringement of Exact Sciences' U.S. Patent No. 11,970,746 (the "'746 Patent" or "Asserted Patent") (attached as **Exhibit A**). To the extent it is not already infringing, Geneoscopy will imminently infringe multiple claims of the '746 Patent, directly or indirectly, through its use, sale, offer for sale, or

importation in the United States of its products and services for detecting CRC and precancerous lesions, including its stool-based, at-home ColoSense™ test and related kits, devices, and services, and through its contribution to or its inducement of others to use its products and services in an infringing manner in the United States.

4. Exact Sciences is a proven innovator and leader in cancer screening and diagnostic technologies. Since its founding in 1995, Exact Sciences has developed some of the most advanced and effective technologies for cancer screening and detection in the world. Exact Sciences is perhaps best known for its flagship CRC screening test, commonly referred to as the Cologuard® test.

5. CRC is the second leading cause of cancer deaths in the United States.[1] Because it is relatively slow to develop, CRC is highly treatable if detected early enough through screening.

6. The Cologuard test first came to prominence in March 2014 when Exact Sciences published the results of an unprecedented, nearly 10,000-patient clinical trial in *The New England Journal of Medicine*, demonstrating the test's high sensitivity and specificity for detecting CRC. Shortly thereafter, in August 2014, the FDA approved the Cologuard test as the world's first at-home, noninvasive stool DNA-based test for CRC screening.

7. Nearly a decade later, the Cologuard test has been used more than 14 million times. It has revolutionized early screening for CRC by providing a convenient and accurate testing option for those at average risk, changing countless lives in the process.

8. As a result of its substantial efforts to develop and advance at-home cancer screening technology, and its expenditure of hundreds of millions of dollars in support of those

[1] https://nccrt.org/our-impact/data-and-progress/ (last visited May 14, 2024).

efforts, Exact Sciences possesses a substantial patent portfolio. These patents—including the '746 Patent asserted here—protect its technological innovations relating to its Cologuard products.[2]

9. The '746 Patent is directed to clinically important methods of processing fecal samples. Under the '746 Patent's novel and innovative approach, a fecal sample for both nucleic acid and blood testing can be conveniently collected in the privacy of a patient's own home, easily processed, and shipped from virtually anywhere for analysis—even when a patient does not live nearby to a hospital, laboratory freezer, or clinical facility where a colonoscopy would otherwise have to be performed. Inventions described in the '746 Patent relating to at-home sample collection have enabled many patients to get screened for CRC who otherwise might not be screened before it is too late.

10. Exact Sciences' numerous groundbreaking technologies, including the methods claimed in the '746 Patent, enable effective screening for CRC in adults as early as age 45. Thanks to the Cologuard test, today a higher percentage of eligible patients participate in CRC screening than ever before, and the number is growing.[3]

11. Geneoscopy is a private start-up company founded in 2015. Geneoscopy has developed a non-invasive stool-based test for detecting gastrointestinal diseases, including CRC, which Geneoscopy refers to as "ColoSense." Geneoscopy's ColoSense product, including related kits, devices, and services, is designed to use the '746 Patent's methods for processing stool samples without permission from Exact Sciences and in violation of U.S. patent laws.

12. As explained in further detail herein, to the extent it is not already infringing, Geneoscopy will imminently infringe the '746 Patent. On May 3, 2024, the FDA approved

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2 *See* https://www.exactsciences.com/patents-and-trademarks (last visited May 14, 2024).

3 https://nccrt.org/our-impact/data-and-progress/ (last visited May 14, 2024).

Geneoscopy's premarket approval ("PMA") application for ColoSense, which allows Geneoscopy to begin distribution and sales of the FDA-approved ColoSense device.[4] Even before FDA approval, in numerous public statements, Geneoscopy made clear its intention to broadly market, use, offer for sale, and sell its ColoSense product, including related kits, devices, and services, to the general public upon FDA approval. Most notably, in April 2024, Geneoscopy presented a slide deck to investors that showed a mid-2024 commercial launch to cover tens of millions of patients almost immediately in 2024.

13. Moreover, in the months leading up to FDA approval, Geneoscopy engaged in extensive preparations for a nationwide product launch of ColoSense upon FDA approval. For example, on November 14, 2023, Geneoscopy announced that it had entered into a multi-year agreement with Labcorp to distribute and sell ColoSense. As explained to the press and others, partnering with Labcorp, the largest laboratory provider, provides Geneoscopy with "the infrastructure, reach, and access for a scalable launch" of ColoSense.[5]

14. Geneoscopy also applied for and obtained a CPT® Proprietary Laboratory Analyses ("PLA") code[6] for ColoSense, representing in the application (made in or about July 2023) that ColoSense was commercially available in the United States and could be ordered by providers for patients' use in the United States. The ColoSense PLA code remains active as of the date of this submission. On information and belief, Geneoscopy obtained the PLA code in preparation for the nationwide distribution and sales of ColoSense, so that it could participate in pricing discussions

[4] **Exhibit N**, *available at* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230001 (last visited May 14, 2024).

[5] **Exhibit V** (April 2024 presentation by Geneoscopy CEO Andrew Barnell).

[6] Current Procedural Terminology ("CPT") codes refer to a set of medical codes created and maintained by the American Medical Association ("AMA").

with the Centers for Medicare and Medicaid Services ("CMS") regarding ColoSense that will take place in the summer of 2024.[7] If successful, ColoSense will be priced by CMS this year.

15. In addition, on information and belief, Geneoscopy has been actively interfacing with CMS about Medicare reimbursement for ColoSense, including meeting with CMS multiple times prior to FDA approval, in an effort to obtain national coverage of ColoSense on the heels of FDA approval.

16. Within three days of FDA approval, Geneoscopy launched a product webpage to commercially promote ColoSense and connect with potential customers.[8]

17. By its own admission, Geneoscopy has grand intentions for ColoSense. In an April 2024 presentation to investors, for example, Geneoscopy's CEO projected post-FDA-approval sales of ColoSense in 2024 in a market that covers 85 million patients in the United States—specifically stating in the presentation "85M lives covered in first year of launch."[9]

18. Geneoscopy's imminent nationwide commercial sales and use of ColoSense will infringe the '746 Patent, directly and indirectly. Given Geneoscopy's stated plan to exploit the market created by Exact Sciences, this widespread infringement will be at Exact Sciences' expense.

19. Having spent years and millions of dollars developing a best-in-class, at-home CRC screening test and obtaining the patent rights necessary to protect that test from would-be copyists, Exact Sciences cannot stand idly by while Geneoscopy willfully flouts Exact Sciences' intellectual property. Exact Sciences thus brings this action for relief, including to enjoin Geneoscopy from direct and indirect infringement of the '746 Patent through, among other acts, its commercial

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[7] Public Meeting on June 25, 2024 Regarding New and Reconsidered Clinical Diagnostic Laboratory Test Codes for the Clinical Laboratory Fee Schedule for Calendar Year 2025, 89 Fed. Reg. 26,889 (Apr. 16, 2024).

[8] **Exhibit S**, *available at* https://www.geneoscopy.com/colosense/ (last visited May 14, 2024).

[9] **Exhibit V**.

promotion, use, sale, offer for sale, or importation of its ColoSense product, including related kits, devices, and services, in the United States.

THE PARTIES

20. Exact Sciences is a corporation organized and existing under the laws of the State of Delaware having a place of business at 5505 Endeavor Lane, Madison, WI 53719. Exact Sciences is the assignee and owner of the '746 Patent.

21. On information and belief, Geneoscopy is a corporation organized and existing under the laws of the State of Delaware having a place of business at 2220 Welsch Industrial Court, St. Louis, MO 63146.

JURISDICTION AND VENUE

22. This Court has jurisdiction over the subject matter of this action, without regard to the amount in controversy, under 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. § 271, and 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

23. This Court has jurisdiction over the subject matter of this action at least because of the actual, justiciable controversies between Exact Sciences and Geneoscopy that are substantial, definite, concrete, and of sufficient immediacy and reality, arising from Geneoscopy's imminent infringement of the claims of the '746 Patent, directly or indirectly, by its use, offer for sale, sale, or importation of its CRC screening products and services, including its ColoSense test and related kits, devices, and services, in the United States, and its contribution to or inducement of others to use the same in an infringing manner in the United States, as described herein.

24. This Court has personal jurisdiction over Geneoscopy at least because it is a Delaware corporation.

25. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) at least because Geneoscopy is incorporated in this District, and thus resides in this District.

FACTUAL BACKGROUND

EXACT SCIENCES AND THE COLOGUARD® TEST TRANSFORMED CRC SCREENING

26. Founded in 1995, Exact Sciences is an established leader in the field of cancer screening and diagnostic tests whose mission is to eradicate cancer and the suffering it causes. Since its founding, Exact Sciences has invested hundreds of millions of dollars in the research, development, and advancement of innovative new tools and methods for cancer screening and diagnosis. Exact Sciences' efforts have given rise to novel and proprietary cancer screening and diagnostic tests that are available to patients to assist with life-saving decisions on cancer care and health management.

27. Through its years of groundbreaking work, Exact Sciences has developed and commercialized some of the most impactful tests for cancer screening and diagnosis ever made available to patients, including its flagship Cologuard® test for CRC screening, and other commercially available tests that help identify and treat colon, liver, and breast cancers. Exact Sciences' tests help doctors and patients get the answers they need to make more informed decisions on cancer care.

28. Exact Sciences presently employs more than 6,000 full-time employees, most of whom are based in the United States. Most of Exact Sciences' revenues are generated from its Cologuard test. Exact Sciences invests substantial amounts of its revenues in the development and commercialization of new products that implement its innovations for cancer prevention and diagnosis, as well as improvements on existing technologies and products like its Cologuard test.

29. The importance of effective, widely-available early cancer screening, particularly for a cancer like CRC, cannot be understated. Cancer is not just one disease. Different forms of cancer develop at different speeds, and can be more or less treatable and more or less deadly. CRC

in particular is the second most common cause of cancer deaths in America, claiming approximately 50,000 lives every year.[10] This tragedy is magnified by the fact that CRC, because of how slowly it develops, is widely regarded to be one of the most preventable, yet least prevented, cancers.

30. Routine screenings for and early detection of CRC or its precursor lesions are the key to prevention and treatment. Nine out of ten people whose cancer is found early and treated are alive five years later. Leading organizations like the U.S. Preventive Services Task Force ("USPSTF") and the American Cancer Society recommend screening for average-risk individuals starting at age 45. Early detection of CRC saves lives and healthcare costs. Despite the effectiveness of routine screening, adherence to recommended screening procedures and intervals remains well below national participation targets. Millions of eligible patients avoid screening.

31. One reason for the low rates of patient adherence to the recommended screening guidelines is that colonoscopies—the most commonly utilized screening method—can be unpleasant and burdensome for patients. The procedure itself can be intrusive and inconvenient. Colonoscopies must be preceded by an unpleasant cleansing preparation and typically involve sedation or anesthesia during the invasive procedure. Patients undergoing a colonoscopy frequently must take time off work, and have someone accompany them to the appointment and drive them home. Colonoscopies, despite being generally safe, also present certain risks for the patient, including the potential for infection or bowel perforation.

32. Studies have shown that seven out of ten people age 50 and older who were told they should get a colonoscopy did not do so. For example, one recent study found that "patients are far less likely to undergo screening for colon cancer if their doctors recommend only

[10] https://nccrt.org/our-impact/data-and-progress/ (last visited May 14, 2024).

colonoscopy, rather than offering other screening options."[11] As Dr. John M. Inadomi, a former professor and chief of the division of gastroenterology at the University of Washington, has recognized, "[n]o matter how effective we believe a colonoscopy is … if a patient doesn't do it, then it's not doing anything for them."[12]

33. CRC is eminently treatable if caught early but, because many patients are hesitant to undergo colonoscopies, they do not do what they should to get screened. As a result, too often CRC goes undiagnosed until it becomes symptomatic and then may be too late to be easily treated or cured. This delayed (or absent) detection leads directly to tens of thousands of unnecessary deaths annually, amounting to lost time with loved ones and millions of dollars in avoidable health care expenditures.[13]

34. In addition to the issues noted above about the colonoscopy procedure itself, there are also significant logistical hurdles that can prevent patients from getting screened. For example, studies have shown that the capacity for screening by colonoscopy is relatively fixed and insufficient to address the full patient population eligible for screening in the United States. Accessibility problems are especially acute for patients living in rural parts of the country, where per capita there are fewer trained colonoscopy providers, meaning fewer choices and longer distances for patients to travel.[14] In 2022, the *Journal of Primary Care and Community Health* reported findings demonstrating that "[r]ural residents in underserved areas face many barriers to health services, including colonoscopies for colorectal cancer (CRC) screening."[15] As reported in

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11 https://nccrt.org/giving-patients-choices/ (last visited May 14, 2024).
12 *Id.*
13 https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2020-2022.pdf (last visited May 14, 2024).
14 https://pubmed.ncbi.nlm.nih.gov/24740165/ (last visited May 14, 2024).
15 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9829879/ (last visited May 14, 2024).

the same article, "[p]ervasive and persistent poverty in rural areas exacerbates challenges associated with distance, given the need for gas money, access to a working car, and travel time."[16] What's more, many endoscopists not only require pre-colonoscopy appointments, but also require patients to provide an adult escort to drive them home after colonoscopy (due to the sedation).[17] Indeed, several sources have named distance to specialized care as a barrier for people living in rural communities.[18]

35. Exact Sciences developed its Cologuard test to further its mission of eradicating cancer by expanding the CRC screening landscape. From the outset, Exact Sciences aimed to increase the number of individuals getting routinely screened for CRC, in order to detect CRC earlier and in more patients, by developing an at-home, non-invasive approach to CRC screening that patients would more willingly undergo.

36. The Cologuard test is available by prescription from a healthcare provider. A provider submits a requisition form to Exact Sciences to order the Cologuard test for delivery to the patient. A Cologuard® kit, complete with everything necessary for collecting the patient sample, is then shipped to the patient's home with easy instructions, stool collection and handling materials, and a pre-paid return shipping label. The patient collects their stool sample at home following the instructions, including by partitioning it into two separate portions stored separately in two different stabilizing buffers (necessary to ensure the integrity of the sample for downstream analysis), and then returns the sample to Exact Sciences for laboratory testing.

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16 *Id.*

17 *Id.*

18 *Id.*; https://pubmed.ncbi.nlm.nih.gov/31394041/ ("distance to test facilities were reported as rural-specific barriers for CRC screening") (last visited May 14, 2024).

37. Exact Sciences' Cologuard test has the distinction of being the first and only FDA-approved noninvasive stool (or fecal) DNA-based test for CRC screening in patients with average risk of CRC. The Cologuard test is able to detect CRC by analyzing stool samples for abnormal DNA biomarkers associated with CRC or precancer, and also analyzing the sample for blood in the stool. The Cologuard test accurately detects CRC in the early stages when it is more treatable.

38. Both effective and simple to use, the Cologuard test has been widely adopted, having been used over 14 million times by patients worldwide. About half of the individuals newly tested by the Cologuard test had never been screened for CRC before.

39. Cologuard sample collection can be completed in the privacy and convenience of a patient's own home. In contrast to a colonoscopy, the Cologuard test offers an at-home, noninvasive screening option that requires no unpleasant bowel preparation, no invasive procedures that require anesthesia and recovery, no need for time off from work, and no changes to a patient's diet or medication.

EXACT SCIENCES OBTAINS FDA APPROVAL FOR THE COLOGUARD® TEST IN 2014

40. In March 2014, after numerous years of research and development, Exact Sciences and its collaborators from Mayo Clinic published the results of a large prospective nearly 10,000-patient clinical trial on Exact Sciences' Cologuard® test, also known as the DeeP-C study, in *The New England Journal of Medicine* (attached as **Exhibit B**). The results of the DeeP-C study demonstrated the high sensitivity and high specificity of this non-invasive test (*e.g.*, an overall 92.3% sensitivity and 86.6% specificity) that had not been achieved by any other non-invasive tests.

41. Based on this robust clinical data and unprecedented performance for an at-home test, the FDA approved Exact Sciences' Cologuard test in August 2014 as the first ever noninvasive

multi-target stool DNA-based test for the detection of CRC and related precancer in individuals aged 50 and older with average risk of CRC. The Cologuard test cleared the review process known as pre-market approval (PMA), and received unanimous votes of approval from a 10-person panel advising the FDA. Not long after, in October 2014, CMS issued a National Coverage Determination for the Cologuard test, establishing that Medicare insurance would fully cover the test once every three years for eligible patients with no co-pay.

42. The Cologuard test was the first medical device product approved by the FDA and CMS through a process of parallel review by the two agencies. It is also the ***first*** FDA-approved non-invasive, at-home stool DNA-based test for CRC screening.

43. In 2016, the USPSTF recommended the Cologuard test as a preventive care service that should be fully covered by insurance, in order to maximize the total number of individuals getting CRC screening and reduce deaths caused by CRC. In addition, the American Cancer Society has included the Cologuard test in its CRC screening guidelines, and the National Comprehensive Cancer Network (NCCN) has recommended the Cologuard test for CRC screening.

44. In 2019, the FDA further expanded its approval of Exact Sciences' Cologuard test to include individuals aged 45 to 49. The Cologuard test is currently approved for CRC screening in average-risk adults 45 years of age and older. For nearly a decade after its initial FDA approval, the Cologuard test had been the only established, FDA-approved, non-invasive, at-home stool-based test with high sensitivity and high specificity for CRC. The test is proven by years of rigorous clinical research and many years of widely accepted use by the medical community.

45. Since the FDA approval of its Cologuard test in 2014, Exact Sciences has continued to dedicate resources to the research and development of next-generation cancer screening and diagnostic tests. For example, in October 2019, Exact Sciences initiated a large prospective

clinical trial involving over 26,000 enrolled participants, known as the BLUE-C study, to support FDA approval of the next-generation Cologuard product. In October 2023, at the American College of Gastroenterology Annual Scientific Meeting ("ACG 2023 Meeting"), Exact Sciences presented data from the BLUE-C study, in which the next-generation Cologuard test met all study endpoints, demonstrating a 94% sensitivity for CRC at 91% specificity.[19] Exact Sciences submitted its PMA application for FDA approval of the next-generation Cologuard test in December 2023 and, subject to FDA approval, plans to market the FDA-approved next-generation Cologuard in 2025.[20] In March 2024, Exact Sciences and its collaborators published the results of the BLUE-C study on the next-generation Cologuard test in *The New England Journal of Medicine* (attached as **Exhibit C**). Like the original Cologuard, the next-generation Cologuard also practices the '746 Patent.

EXACT SCIENCES' ASSERTED '746 PATENT

46. Since its founding, Exact Sciences has expended substantial resources developing and advancing cancer screening technologies and establishing its reputation among the medical community, insurers, and regulators as a company that promotes sound science and consistently accurate and reliable results. As a result of those efforts and its commitment to intellectual property, Exact Sciences possesses a substantial, worldwide patent portfolio, including the '746 Patent asserted here.

[19] https://www.exactsciences.com/newsroom/press-releases/next-generation-cologuard-test-demonstrates-high-sensitivity-and-specificity-in-pivotal-blue-c-stud (last visited May 14, 2024).
[20] https://investor.exactsciences.com/investor-relations/press-releases/press-release-details/2024/The-New-England-Journal-of-Medicine-Publishes-Cologuard-Plus-Test-Results-from-Pivotal-BLUE-C-Study/default.aspx (last visited May 14, 2024).

47. On April 30, 2024, the United States Patent and Trademark Office ("USPTO") issued the '746 Patent, titled "Fecal Sample Processing and Analysis Comprising Detection of Blood." A true and correct copy of the '746 Patent is attached as **Exhibit A**.

48. Exact Sciences is the owner of the '746 Patent. Exact Sciences acquired all rights to the patent filings that led to the '746 Patent and related patent applications through an assignment from MDXHealth SA in 2017. Prior to this assignment, in 2010, Exact Sciences exclusively licensed the patent filings that led to the '746 Patent and related patent applications from MDXHealth SA, then operating as Oncomethylome Sciences, S.A. Exact Sciences has the right to enforce the '746 Patent and seek damages for Geneoscopy's infringement.

49. The '746 Patent was filed on March 7, 2023 as a continuation of the application that later issued as the related U.S. Patent No. 11,634,781 (the "'781 Patent"). The '746 Patent claims priority to February 3, 2009.

50. The '746 Patent was issued only after its underlying application, and its parent applications, were thoroughly vetted against the prior art during prosecution by the USPTO. For example, the '746 Patent issued after the USPTO reaffirmed the patentability of all the claims of the related '781 Patent in an *ex parte* reexamination requested by Geneoscopy, and also after the USPTO Examiner for the '746 Patent specifically considered not only Geneoscopy's Request for *Ex Parte* Reexamination of the '781 Patent, but also a Petition for *Inter Partes* Review ("IPR") of the '781 Patent filed by Geneoscopy, as part of Information Disclosure Statements submitted during prosecution of the '746 Patent.

51. Specifically, on April 25, 2023, the USPTO issued the '781 Patent, titled "Fecal Sample Processing and Analysis Comprising Detection of Blood" (attached as **Exhibit D**). On May 22, 2023, Geneoscopy filed a Request for *Ex Parte* Reexamination of the '781 Patent. The

USPTO granted the request on June 29, 2023. The request ultimately failed, and on October 18, 2023, the USPTO issued a Notice of Intent to Issue a Reexamination Certificate, confirming the patentability of ***all*** the claims in the '781 Patent. On November 17, 2023, Exact Sciences filed a patent infringement action against Geneoscopy in this Court, asserting the '781 Patent (Case No. 23-1319 (D. Del.)). On December 4, 2023, the USPTO issued the *Ex Parte* Reexamination Certificate (attached as **Exhibit E**), again confirming the patentability of all the claims in the '781 Patent. The application underlying the '746 Patent was then pending before the USPTO, and Exact Sciences filed Information Disclosure Statements to submit Geneoscopy's Request for *Ex Parte* Reexamination of the '781 Patent (including all accompanying exhibits) for the Examiner's consideration.

52. Despite its failed attempt at invalidating the claims of the '781 Patent through *ex parte* reexamination, on January 11, 2024, Geneoscopy filed a Petition for *Inter Partes* Review of the '781 Patent (Case No. IPR2024-00459 (PTAB)). The application underlying the '746 Patent was then pending, and Exact Sciences filed an Information Disclosure Statement to submit Geneoscopy's Petition for IPR (including all accompanying exhibits) for the Examiner's consideration.

53. Upon considering Geneoscopy's reexamination request and IPR petition, including the accompanying exhibits, the Examiner allowed all the claims of the '746 Patent without rejecting any claim based on any of the prior art asserted in Geneoscopy's reexamination request or its IPR petition.

54. Claim 1 of the '746 Patent reads:

> A method of processing a freshly-collected fecal sample without freezing, the method comprising:

a) collecting a fecal sample from a human subject, wherein the fecal sample is collected at home by the human subject;

b) in a sealable vessel, combining a first portion of the fecal sample with a stabilizing buffer, and sealing the sealable vessel; and

c) in a sealable container, combining a second portion of the fecal sample with a solution that prevents denaturation or degradation of blood proteins found in a fecal sample, and sealing the sealable container.

55. Claim 3 of the '746 Patent reads:

A method of processing a fecal sample, the method comprising:

a) obtaining a pair of portions of a fecal sample collected from a human subject, the pair of portions comprising:

i) a sealed sealable vessel containing a first portion of a fecal sample and a stabilizing buffer; and

ii) a sealed sealable container containing a second portion of a fecal sample and a solution that prevents denaturation or degradation of blood proteins found in a fecal sample,

wherein the pair of portions are obtained by the method of claim 1;

b) extracting nucleic acid from the first portion of the fecal sample;

c) testing nucleic acid extracted from the first portion of the fecal sample for an amount of a human nucleic acid; and

d) testing the second portion of the fecal sample for an amount of a blood protein present in the second portion of the fecal sample.

56. The '746 Patent is directed to clinically important methods of processing fecal samples that enable, among other things, "mass screening of asymptomatic patients" for CRC.[21] These methods allow for patient-friendly collection of fecal samples at home, in a manner that preserves the integrity of biomarkers contained in the fecal sample so as to allow subsequent

[21] '746 Patent (**Exhibit A**) at 1:51-55.

analysis of the biomarkers in a laboratory.[22] The fecal sample is processed in two portions, one portion of the fecal sample in a sealable container combined with a buffer that prevents denaturation or degradation of blood proteins, and another portion of the fecal sample in a sealable vessel combined with a stabilizing buffer.[23]

57. The combination of a patient-friendly collection procedure with the biomarker-compatible segregation and preservation of samples is critical to effective, accessible at-home CRC screening.

58. The claims of the '746 Patent are not directed to a natural law, natural phenomenon, or other ineligible subject matter. Rather, they are directed to processing fecal samples for laboratory analysis by taking steps to separately treat two different portions of the sample for transport and analysis, permitting both blood and nucleic acid testing at the laboratory site. The claims of the '746 Patent, considered both as individual elements and as ordered combinations, are directed to specific, unconventional, and non-routine methods for overcoming previously unresolved problems in this area.

59. As referenced above, Exact Sciences' Cologuard test practices the '746 Patent's claimed methods. Before the Cologuard test, at-home stool tests were generally limited to testing for the presence of blood only. This limitation was the result of an unmet need: an effective mechanism for processing a second or additional sample for nucleic acid testing, and for handling the sample such that the nucleic acid integrity would be maintained without requiring the user to freeze the sample and ship it with appropriate temperature controls (a step that users are not generally equipped to accomplish on their own in a reliable manner).

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[22] *See, e.g.*, *id.* at 17:37-19:16.
[23] *See, e.g.*, *id.* at 17:37-19:16.

60. By providing a sensitive, specific, and non-invasive screening option that implements the '746 Patent's technology for collecting samples for two separate testing methods in a reliable fashion, the Cologuard test may have helped many of its millions of users avoid the devastating impact of CRC.

GENEOSCOPY'S INFRINGING ACTS

A. Geneoscopy, through its imminent commercial use, sale, or offer for sale of its CRC screening products, will directly and indirectly infringe the '746 Patent

61. Geneoscopy was founded in 2015,[24] shortly after Exact Sciences published its breakthrough clinical trial results on its Cologuard test in the widely disseminated medical journal, *The New England Journal of Medicine*, and the FDA's approval of the Cologuard test in 2014.

62. As described on its website, Geneoscopy develops products for detecting gastrointestinal diseases, such as CRC, using stool samples that patients can collect at home. These products apply what Geneoscopy refers to as a "multi-target stool RNA (mt-sRNA) biomarker panel" and include the test branded as "ColoSense" for CRC screening (formerly known as "ColonoSight").[25] The Accused Products as used herein refer to all products, devices, kits, and services associated with Geneoscopy's mt-sRNA biomarker panel for CRC screening, including ColoSense.

63. Geneoscopy developed the accused ColoSense test for at-home CRC screening to compete with Exact Sciences' Cologuard test, using the fecal sample processing methods claimed in the '746 Patent. Geneoscopy's ColoSense uses an RNA (nucleic acid) biomarker panel, along

[24] https://www.geneoscopy.com/about-us/#timeline (last visited May 14, 2024).
[25] https://www.geneoscopy.com/gastrointestinal-health/colorectal-cancer-screening/ (last visited May 14, 2024).

with a test component that detects the presence or absence of blood protein in the stool, similar to the DNA biomarker-based Cologuard test.

64. On information and belief, to the extent it is not already infringing, Geneoscopy will imminently infringe the '746 Patent, directly and indirectly, by commercially marketing, using, selling, offering for sale, or importing in the United States Geneoscopy's CRC screening products or services (including its ColoSense test and related kits and devices), and by contributing to or inducing others to use the same in an infringing manner in the United States, as illustrated herein.

65. Geneoscopy will be a direct competitor of Exact Sciences in the market for non-invasive stool sample-based test for CRC screening.

66. As described in further detail below, Geneoscopy filed a PMA application for its ColoSense test in 2023. On May 3, 2024, the FDA approved Geneoscopy's PMA application, which allows Geneoscopy to begin distribution and sale of the FDA-approved ColoSense device.[26] Prior to FDA approval, in numerous public announcements, Geneoscopy disclosed its intention and meaningful preparations to imminently and commercially launch the ColoSense test widely to millions of patients immediately upon FDA approval of its PMA application on ColoSense.

67. In particular, in April 2021, Geneoscopy initiated a clinical trial on its ColoSense test in individuals with average risk of CRC to support clinical validation of the test.[27] This clinical trial is also known as the CRC-PREVENT trial (with a clinicaltrial.gov ID of NCT04739722).[28] On January 24, 2023, Geneoscopy announced that it submitted a PMA application to the FDA "for

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[26] **Exhibit N**, *available at* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230001 (last visited May 14, 2024); *see also Exact Sciences Corp. v. Geneoscopy, Inc.*, C.A. No. 23-1319-MN, D.I. 27 (May 6, 2024) (FDA approval letter).

[27] https://clinicaltrials.gov/study/NCT04739722?term=colosense&rank=1 (last visited May 14, 2024).

[28] *Id.*

its noninvasive, stool-based, at-home screening test to detect colorectal cancer (CRC) and advanced adenomas (AA) in average-risk individuals."[29]

68. On April 12, 2023, Geneoscopy announced "the assignment of a unique DEX Z-code from Palmetto GBA's MolDX program for the company's noninvasive multi-target stool RNA (mt-sRNA) colorectal cancer screening test."[30] This unique Z-code for ColoSense paved the path for Geneoscopy to commercially market, offer for sale, and sell its ColoSense product to patients and healthcare providers. Geneoscopy's press release states:

> "Obtaining this Z-code is vital for market access and aligns with our plans for commercial launch," said Andrew Barnell, Chief Executive Officer of Geneoscopy. "Once approved and launched, we anticipate Geneoscopy's noninvasive mt-sRNA colorectal cancer screening test will offer patients and healthcare providers a convenient and reliable CRC screening option for earlier detection and treatment."
>
> The assignment of the DEX Z-code as a test identifier is a significant step as Geneoscopy awaits the US Food and Drug Administration's decision regarding the PMA submitted in January 2023.[31]

69. On October 23, 2023, Geneoscopy published the results from its CRC-PREVENT clinical trial on ColoSense in *JAMA*, titled "Multitarget Stool RNA Test for Colorectal Cancer Screening," naming Dr. Erica Barnell as the lead and corresponding author, and four other Geneoscopy employees (Elizabeth Wurtzler, Julie La Rocca, Thomas Fitzgerald, and Yiming

[29] https://www.geneoscopy.com/geneoscopy-submits-premarket-approval-application-to-fda-for-its-noninvasive-colorectal-cancer-rna-biomarker-screening-test/ (last visited May 14, 2024).
[30] https://www.geneoscopy.com/geneoscopy-receives-z-code-from-palmetto-gba-for-its-noninvasive-multi-target-stool-rna-colorectal-cancer-screening-test/ (last visited May 14, 2024).
[31] *Id.*

Kang) as co-authors ("the Barnell Study").[32] The Barnell Study "was funded by Geneoscopy."[33] A true and correct copy of the *JAMA* paper on the Barnell Study is attached hereto as **Exhibit F**. A true and correct copy of its supplemental content 1 (hereinafter "Barnell Study Supplement 1") is attached hereto as **Exhibit G**. A true and correct copy of its supplemental content 3 (hereinafter "Barnell Study Supplement 3") is attached hereto as **Exhibit H**.

70. In an October 23, 2023 press release about the Barnell Study, Geneoscopy claimed that its ColoSense test has the "highest sensitivity" for detecting CRC among available noninvasive screening tests.[34]

71. In a November 2023 interview, Geneoscopy's Chief Science Officer, Dr. Erica Barnell, stated that Geneoscopy has submitted CRC-PREVENT study results to the FDA to support its PMA application for ColoSense."[35] For example, she stated:

> **Please detail the CRC-PREVENT study. What kind of patients did you enroll, from where were they sampled, and what were ColoSense test samples compared against?**
>
> **Dr. Barnell:** The ColoSense pivotal study, known as CRC-PREVENT, was a cross-sectional prospective pivotal trial designed to support a pre-market approval application to the FDA. This study was unique in how we recruited patients. We utilized social media advertising to reach patients where they are. Once a patient expressed interest and enrolled in the clinical trial, we would send them a stool sample collection kit, which they would use to provide a stool sample. They would then send the sample back to our

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[32] **Exhibit F** at 1760; *see also* https://www.geneoscopy.com/jama-publishes-geneoscopys-pivotal-crc-prevent-trial-results-reporting-highest-sensitivity-for-detecting-colorectal-cancer-and-advanced-adenomas-among-available-noninvasive-screening-tests/ (last visited May 14, 2024); https://www.geneoscopy.com/gastrointestinal-health/colorectal-cancer-screening/ (last visited May 14, 2024).

[33] **Exhibit F** at 1766.

[34] https://www.geneoscopy.com/jama-publishes-geneoscopys-pivotal-crc-prevent-trial-results-reporting-highest-sensitivity-for-detecting-colorectal-cancer-and-advanced-adenomas-among-available-noninvasive-screening-tests/ (last visited May 14, 2024).

[35] **Exhibit I**, *available at* https://www.geneoscopy.com/noninvasive-multitarget-stool-rna-test-proves-sensitive-for-colorectal-cancer-advanced-adenomas/ (last visited May 14, 2024).

> laboratory. Afterward, we would facilitate their access to a follow-up colonoscopy. We compared the results of the ColoSense test, whether it was positive or negative, with the results of the colonoscopy to assess the test's sensitivity for colorectal cancer, sensitivity for advanced adenomas, and specificity for detecting no findings on a colonoscopy.'
>
> . . .
>
> **How scalable is the ColoSense test to be commonly used as a noninvasive colorectal cancer screening option?**
>
> **Dr. Barnell:** The ColoSense test has been developed with scalability in mind. We have submitted the data from the pivotal study to the FDA as part of a pre-market approval application. Currently, the FDA is reviewing the data, and we anticipate receiving their decision within the next 3 months. ***Once we receive FDA approval, we plan to launch the ColoSense test commercially, making it available to healthcare providers and patients. We have established a partnership with a large decentralized laboratory, which will allow us to successfully commercialize this test and reach the 150 million Americans who require colorectal cancer screening.*** The scalability of the ColoSense test makes it feasible to become a widely used noninvasive colorectal cancer screening option.[36]

72. Then, in a November 14, 2023 press release, Geneoscopy announced that it has signed a multi-year agreement with Labcorp to distribute its ColoSense test upon FDA approval.[37] The press release explained that this multi-year agreement "will increase access to Geneoscopy's next-generation colorectal cancer screening test, which offers at-home collection," and that "[o]nce approved by the FDA, Labcorp will offer the test, which will be performed by Geneoscopy, enabling health care customers to conveniently order it through Labcorp as part of their comprehensive screening programs."[38]

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[36] *Id.* All emphases in this pleading are supplied unless otherwise noted.

[37] **Exhibit J**, *available at* https://www.geneoscopy.com/geneoscopy-signs-multi-year-agreement-with-labcorp-to-distribute-noninvasive-multi-target-stool-rna-mt-srna-colorectal-cancer-screening-test/ (last visited May 14, 2024).

[38] *Id.*

73. In the November 14, 2023 press release, Geneoscopy's then Chief Commercial Officer, Vince Wong,[39] further explained that Geneoscopy is working with Labcorp because it is "an organization trusted daily by thousands of clinicians and millions of patients" with "extensive access to communities across the country," which will "expand patient and clinician access to" Geneoscopy's infringing ColoSense test.[40] Also in the same press release, Labcorp's Chief Medical and Scientific Officer, Dr. Brian Caveney, stated that "[t]his agreement builds on Labcorp's commitment to bring the latest advancements in cancer screening and diagnostic testing to healthcare providers and patients," and that "Geneoscopy's highly sensitive colorectal cancer screening test, ***once approved***, will be another innovative, accessible and reliable option available to providers and patients nationwide for the detection of colorectal cancer."[41]

74. On November 14, 2023, the same day Geneoscopy issued its press release on the agreement with Labcorp, the *St. Louis Business Journal* published an article, titled "St. Louis startup Geneoscopy, developer of colon cancer test, inks distribution deal," regarding the multi-year agreement between Geneoscopy and Labcorp:[42]

> Geneoscopy has entered into a multiyear agreement with Labcorp (NYSE: LH) to provide its preventive, at-home screening test for colorectal cancer. With the agreement, Labcorp will be able to provide Geneoscopy's test, called ColoSense, to health care providers as part of their patient screening programs, the startup said. Financial terms of the distribution deal were not disclosed.
>
> The agreement partners Geneoscopy with a major laboratory and diagnostics firm, with Burlington, North Carolina-based Labcorp having more than 80,000 employees and $14.9 billion in 2022 revenue. Labcorp has previous ties to Geneoscopy, having been an investor in a $105 million financing closed by the St. Louis startup in 2021.

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39 Mr. Wong left Geneoscopy in February 2024.
40 *Id.*
41 *Id.*
42 **Exhibit K** (Nov. 14, 2023 *St. Louis Business Journal* article).

> ***Labcorp will begin offering Geneoscopy's colorectal cancer screening test once it is approved by the U.S. Food and Drug Administration, a news release said.*** Geneoscopy anticipates FDA approval in the first half of 2024, Chief Commercial Officer Vince Wong said in an interview. . . .
>
> Labcorp will have exclusive distribution in the primary care and gastrointestinal health care segments, Wong said. Geneoscopy could seek out distribution partnerships in other channels, including telemedicine, retail, obstetrics and gynecology, and senior living, according to Wong.[43]

75. On November 15, 2023, Medical Device Network published an online news article regarding the multi-year agreement between Geneoscopy and Labcorp.[44] The article states:

> Geneoscopy chief commercial officer Vince Wong said: "Working with Labcorp, an organisation trusted daily by thousands of clinicians and millions of patients, is an incredible opportunity to expand patient and clinician access to our noninvasive screening test.
>
> "Given Labcorp's extensive access to communities across the country, we believe this collaboration will help reduce the barriers to screening and address health inequities."
>
> ***Upon FDA approval, Labcorp will provide the test, to be conducted by Geneoscopy, allowing healthcare customers to easily order it through the former as part of their screening programmes***.[45]

76. In a January 2024 interview with Scope Forward, Geneoscopy's Chief Science Officer, Dr. Erica Barnell, stated the following regarding FDA approval of ColoSense and the commercialization of ColoSense "very shortly after FDA approval":[46]

> **Question:** How far are you from commercialization?
>
> **Dr. Barnell**: That's a great question. We base it on kind of the recommended guidance from the FDA. They put out guidance related to

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[43] *Id.*

[44] https://www.medicaldevice-network.com/news/geneoscopy-labcorp-colorectal-cancer-test/?cf-view (last visited May 14, 2024).

[45] *Id.*

[46] https://scopeforward.com/dr-erica-barnell-non-invasive-diagnostics-will-play-an-important-role-in-preventing-disease-through-early-detection/ (last visited May 14, 2024).

> kind of their timelines and what they do on their end. There's an FDA clock that we're on and it can stop or go at any time based on kind of where we sit on that clock. ***We have a couple months left to have a final decision on our PMA application.*** I'd say it's kind of like football, where the last two minutes can take a really long time if they've got enough timeouts left. And things like, you know, there's certainly uncertainty around exactly when we're going to get FDA approval, but ***we've had a number of amazing communications with the FDA, and we think we're hopefully getting close to that decision***.
>
> **Question:** So once that happens, I think what I want to ask is, I understand what you're saying, so there's uncertainty there. ***And let's say you cross that gate, would you be ready to go live soon after? Would physicians, gastroenterologists be able to prescribe your test? How is that going to work? How is it going to look operationally?***
>
> **Dr. Barnell**: Yeah, ***so that's one of the biggest benefits with our partnership with Labcorp,*** right? You know***, they're selling tests every single day. They have reference labs around the country. They have a huge sales force. So we're working with them right now to integrate into their software so that when we get FDA approval, we can go live as quickly as possible. And, you know, anybody who orders a CBC through Labcorp or a lipid panel could, you know, find the ColoSense test as well and order that. And that's something our software team is actively working on.*** I think, you know, there's two things with healthcare. You know, the person who prescribes the test, the person who takes the test, and the person who pays for the test. They're all different entities, so we definitely have to get our ducks in a row on all three of those fronts. I'd say with the ordering from a physician, getting that FDA approval, the main goal there, you know, with getting paid for, we definitely need to get CMS approval and kind of go through those pathways and negotiate with payors. We have an amazing market access team, so I think, and those conversations are going really well, you know, it does take time. That being said, I think ***we'll be able to be in the hands of patients very shortly after FDA approval***.[47]

77. On information and belief, since at least August 2023, Geneoscopy has been working with Copper Hill Consulting to build a scalable order management system for ColoSense. A "customer story" on the Copper Hill Consulting website regarding Geneoscopy, dated August 9, 2023, disclosed that Geneoscopy purchased products such as "Salesforce Health Cloud,

[47] *Id.*

Salesforce Maps with Territory Planning, Salesforce Marketing Cloud, Salesforce Experience Cloud, Salesforce Shield, Conga, and Integration."[48] Geneoscopy hired Copper Hill Consulting because "Geneoscopy will be launching a new noninvasive colorectal cancer screening test that will assist patients with at-home testing, and wanted to leverage Salesforce for order management, healthcare provider engagement, and patient engagement."[49]

78. Additionally, in a job posting Geneoscopy advertised in 2023, it sought to hire a "Vice President, Marketing" whose responsibilities include "the overall global marketing strategy of Geneoscopy's diagnostic products into diverse, global end markets, with an initial focus on the U.S.," "the development, training, and distribution of all marketing materials, sales aids, advertisements, reimbursement guides, etc. to support Geneoscopy's products," and "lead[ing the] execution of detailed new product launch plans."[50] This job posting now states that this position has been closed, indicating, on information and belief, that Geneoscopy has hired its Vice President of Marketing.[51]

79. Geneoscopy had a Vice President of Market Access, who recently left Geneoscopy in April 2024.[52] Geneoscopy is currently advertising to hire a "Director of Market Access" whose responsibilities include "establishing, maintaining, and growing working relationships with national and regional payors" with the following detailed descriptions of the job responsibilities:[53]

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[48] https://web.archive.org/web/20231206163201/https://www.copperhillconsulting.com/2023/08/09/customer-story-geneoscopy (last visited May 14, 2024).
[49] *Id.*
[50] **Exhibit L**, *available at* https://geneoscopy.isolvedhire.com/jobs/1016799 (last visited May 14, 2024).
[51] *Id.*
[52] *See* https://www.linkedin.com/in/jeffsalzman/ (last visited May 14, 2024).
[53] **Exhibit M**, *available at* https://geneoscopy.isolvedhire.com/jobs/1184383 (last visited May 14, 2024).

- Establish and organize activities leading to expanded coverage and/or in-network statuses such as Payor Advisory Boards, state and national health plan conferences, third-party collaborations, etc.
- Communicate and converse in clinical utility and cost-effectiveness for specialty tests in support of improving market access and reimbursement. Provide expert insight into reimbursement and coverage scenarios for novel technologies prior to acquiring or developing technologies.
- Identify self-funded employer groups and pursue opportunities for coverage and collaboration.
- Serve as a Managed Care SME within a cross-functional team responsible for developing market access plans for the company.
- Work internally with clinical resources to evaluate current literature, relating to analytical and clinical validity and utility. Identify gaps and offer recommendations.
- Support the development of proposals for clinical studies to ensure the study outcomes will support positive medical policies. Identify partners and opportunities to engage payors in clinical utility studies.
- Collaborate with marketing to develop payor messaging, ensuring that Market Access messaging to HCPs is accurate and consistent.
- Lead conversations with national and regional payor medical directors and medical policy teams to secure coverage, target reimbursement, and remove administrative barriers to achieve reimbursement. Develop and execute comprehensive strategies to broaden payor coverage policies and maximize reimbursement.
- Coordinate with RCM to ensure Geneoscopy recognizes revenue consistent with reimbursement and coverage policies and in line with in-network agreements.
- Articulate the company value proposition to national payors, lab benefit managers, regional payors, and ACOs.
- Aid in developing a payer strategy and a comprehensive presentation slide deck to communicate the Geneoscopy value proposition effectively.
- Join the field-based sales team on client calls and visits as required.
- Offer and report on value and education around payors, reimbursement, and the evolving managed care and healthcare environment proactively.
- Keep current with the latest clinical utility study data and findings, society guideline changes, payor policy changes, competitive offerings, and trends relating to all areas of the company and managed care plans.
- Other duties as assigned.[54]

80. Moreover, in or about July 2023, while its PMA was pending, Geneoscopy applied for a CPT® PLA code for ColoSense with the AMA. On information and belief, when applying

[54] *Id.*

for the PLA code, Geneoscopy represented on the application that ColoSense is commercially available in the United States and available for U.S. healthcare providers to order for patient use.[55] On information and belief, when applying for the PLA code, Geneoscopy further provided a website link that demonstrated how U.S. healthcare providers could access and order this test for patients.[56]

81. Commercial availability and availability for patient use are requirements of the AMA for assigning PLA codes to diagnostic tests. To be included in the PLA section of the CPT® codes, ColoSense "must be commercially available in the United States for use on human specimens."[57]

82. The proposed agenda for the August 2023 CPT® PLA panel meeting (dated July 31, 2023) shows that ColoSense was included as an agenda item:[58]

101399	Colosense	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 8 RNA markers (GAPDH, SMAD4, ACY1, AREG, CDH1, KRAS, TNFRSF10B, and EGLN2) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result

83. The AMA assigned a PLA code for ColoSense, 0421U, which was released on the AMA website on or about September 29, 2023, with an effective date of January 1, 2024.[59] The ColoSense PLA code remains available and active, as reflected in the April 1, 2024 AMA update and shown below:[60]

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[55] https://www.ama-assn.org/practice-management/cpt/cpt-code-change-applications.
[56] *Id.*
[57] CPT® 2024 Professional Edition at 713.
[58] **Exhibit O**, *available at* https://www.ama-assn.org/system/files/august-2023-pla-public-agenda.pdf (last visited May 14, 2024).
[59] **Exhibit P**, *available at* https://www.ama-assn.org/system/files/cpt-pla-codes-long.pdf (last visited May 14, 2024).
[60] *Id.*; **Exhibit Q**, *available at* https://www.ama-assn.org/practice-management/cpt/cpt-pla-codes (last visited May 14, 2024).

Colosense™, Geneoscopy, Inc, Geneoscopy, Inc	●0421U	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 8 RNA markers *(GAPDH, SMAD4, ACY1, AREG, CDH1, KRAS, TNFRSF10B, EGLN2)* and fecal hemoglobin, algorithm reported as a positive or negative for colorectal cancer risk	September 29, 2023	January 1, 2024	CPT® 2025

84. By applying for and maintaining the PLA code for ColoSense, Geneoscopy has an ongoing obligation to meet the criteria set forth by the AMA, including the commercial availability of the ColoSense test. Geneoscopy has the option to, but did not, request deletion of the PLA code for ColoSense based on the test's commercial unavailability, thus representing to the public, the AMA, and CMS, that the test remains commercially available and can be ordered for patient use.

85. On information and belief, Geneoscopy obtained the PLA code for ColoSense to participate in pricing discussions with CMS that will take place in the summer of 2024, which will accelerate market access for ColoSense. If ColoSense did not have a code, its next opportunity for pricing through this process with CMS would be in the summer of 2025. CMS is set to hold a public meeting regarding the pricing of ColoSense and other clinical diagnostic laboratory tests with recently assigned PLA codes on June 25, 2024.[61] Receiving a recommended price from CMS will allow Geneoscopy to, among other things, amplify its commercialization of ColoSense and begin meaningful discussions with commercial payors.

86. On May 3, 2024, after more than a year of back and forth with the FDA, the FDA finally approved Geneoscopy's PMA application for ColoSense, with the following approval order statement:[62]

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[61] Public Meeting on June 25, 2024 Regarding New and Reconsidered Clinical Diagnostic Laboratory Test Codes for the Clinical Laboratory Fee Schedule for Calendar Year 2025, 89 Fed. Reg. 26,889 (Apr. 16, 2024).

[62] **Exhibit N**, *available at* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230001 (last visited May 14, 2024); *see also Exact Sciences Corp. v. Geneoscopy, Inc.*, C.A. No. 23-1319-MN, D.I. 27 (May 6, 2024) (FDA approval letter).

Approval Order Statement
ColoSense is a qualitative in vitro diagnostic test intended for the detection of colorectal neoplasia associated RNA markers and for the presence of occult hemoglobin in human stool. 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 average-risk for developing CRC. ColoSense is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals.

87. This is the moment that Geneoscopy has long been waiting for and for which it has been preparing for more than a year. With FDA approval of Geneoscopy's PMA application for ColoSense, Geneoscopy may begin commercial distribution and sale of the FDA approved ColoSense device any time it chooses to do so (regardless of insurance coverage or CMS pricing).

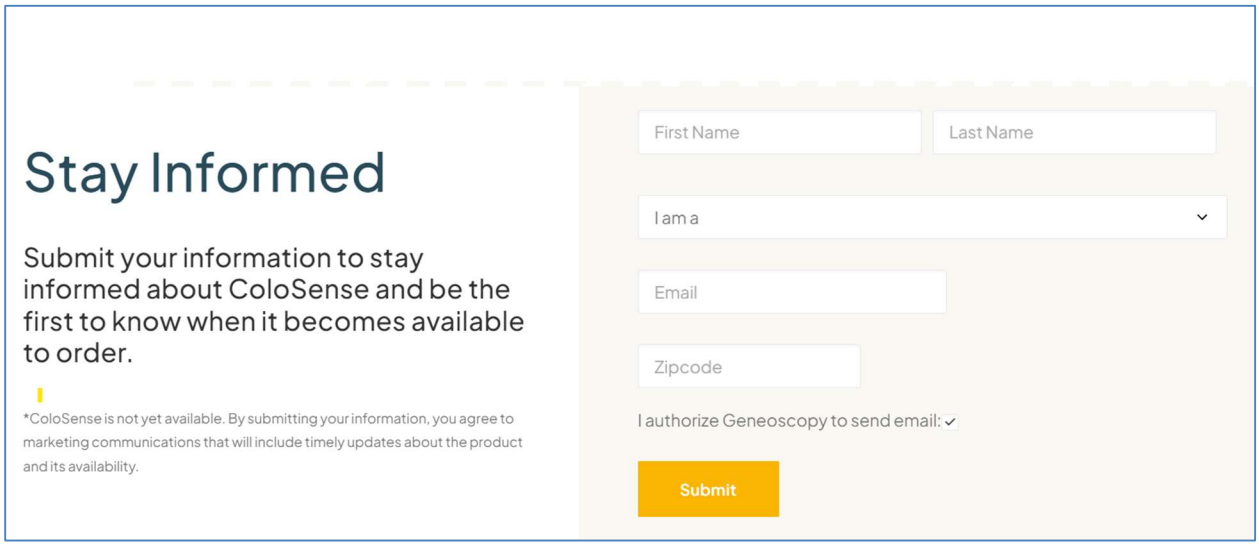
88. On May 6, 2024, Geneoscopy issued a press release announcing the FDA approval of Geneoscopy's PMA application on ColoSense.[63] In the press release, Geneoscopy's CEO, Andrew Barnell, stated that "[s]ecuring FDA approval for ColoSense marks a significant milestone for Geneoscopy . . . ."[64] With regard to commercial launch, the press release also states that launch is expected this year or early next year:

> ***Geneoscopy is working with payors, professional societies, and advocacy partners to support a commercial launch later this year or early in 2025 to ensure patients have timely access to ColoSense to support CRC screening. Geneoscopy will launch ColoSense in collaboration with Labcorp*** (NYSE: LH), a global leader of innovative and comprehensive laboratory services.[65]

89. Almost immediately after approval, on or about May 6, 2024, Geneoscopy launched a product website for ColoSense: https://www.geneoscopy.com/colosense/. The product

[63] **Exhibit R**, *available at* https://www.geneoscopy.com/fda-approves-colosense-geneoscopys-noninvasive-multi-target-stool-rna-mtrna-colorectal-cancer-screening-test/ (last visited May 14, 2024).
[64] *Id.*
[65] *Id.*

website describes ColoSense as "[t]he first FDA-approved RNA-based molecular screening test for qualitative detection of colorectal cancer and advanced adenomas in average-risk individuals."[66] Contrary to Geneoscopy's representations to the AMA, the website indicates that ColoSense is not commercially available. The website invites prospective customers to submit their information to "stay informed about ColoSense and be the first to know when it becomes available to order."[67]



90. Although Geneoscopy's press release and product website suggest that ColoSense could take months to launch, just last month in an April 2024 presentation to investors, Geneoscopy's CEO Andrew Barnell projected a nationwide product launch of ColoSense in ***3Q 2024***, immediately following FDA approval.[68] He also projected post-FDA-approval sales of ColoSense to a market that covers 85 million patients in the United States in 2024 alone, specifically stating on the presentation "***85M lives covered in first year of launch***."[69]

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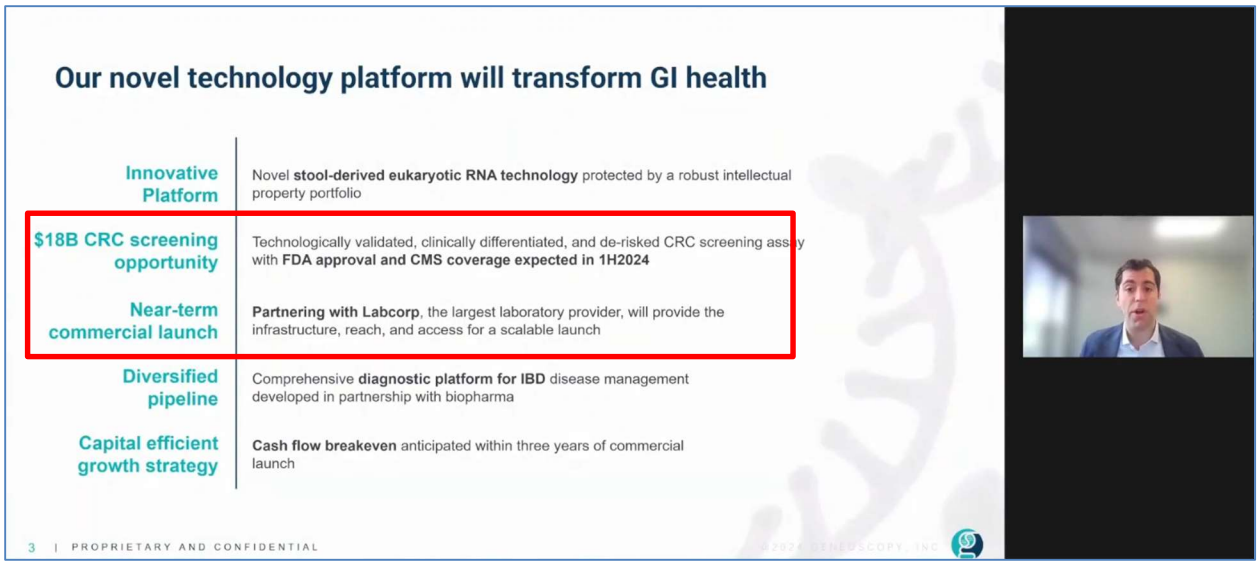
66 **Exhibit S**, *available at* https://www.geneoscopy.com/colosense/ (last visited May 14, 2024).
67 *Id.*
68 **Exhibit V**.
69 *Id.*

91. In that April 2024 investor presentation, Mr. Barnell presented a summary slide, which states that "FDA approval and CMS coverage" of ColoSense were both "expected in ***1H2024***."[70] He also outlined Geneoscopy's plan for "[n]ear-term commercial launch" by "[p]artnering with Labcorp, the largest laboratory provider" that "will provide the infrastructure, reach, and access for a scalable launch."[71]



92. In another slide, Mr. Barnell described the noninvasive CRC screening market as having "[o]ne large player in at-home stool testing," i.e., Exact Sciences, "making this segment primed for a fast follower."[72] During the presentation, Mr. Barnell referred to Geneoscopy as a "second mover" in the noninvasive CRC screening market.

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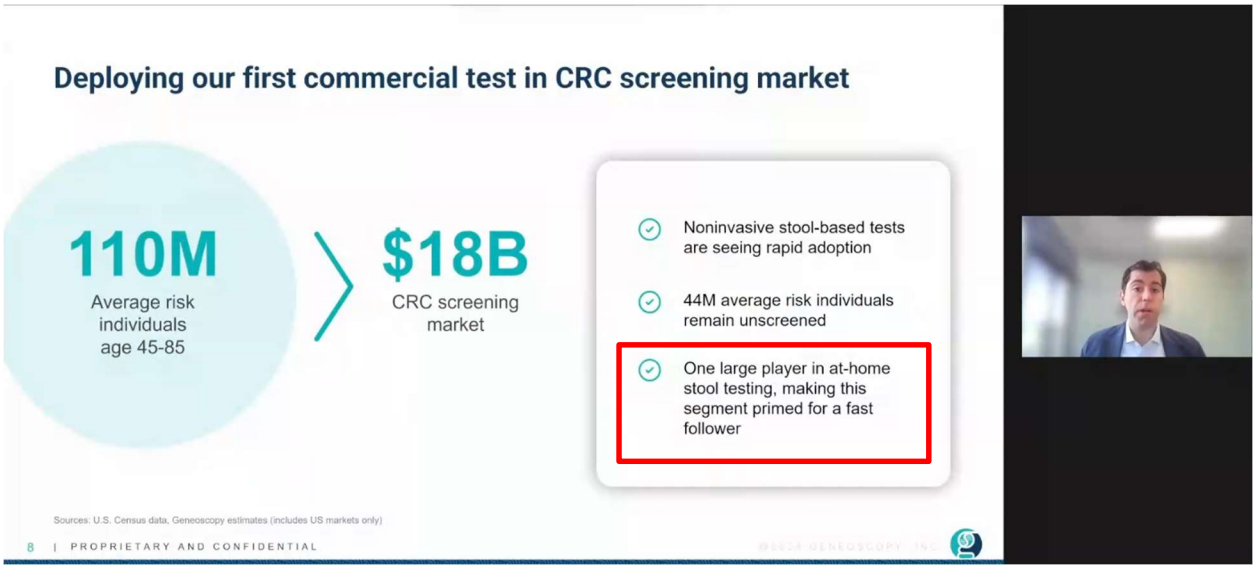
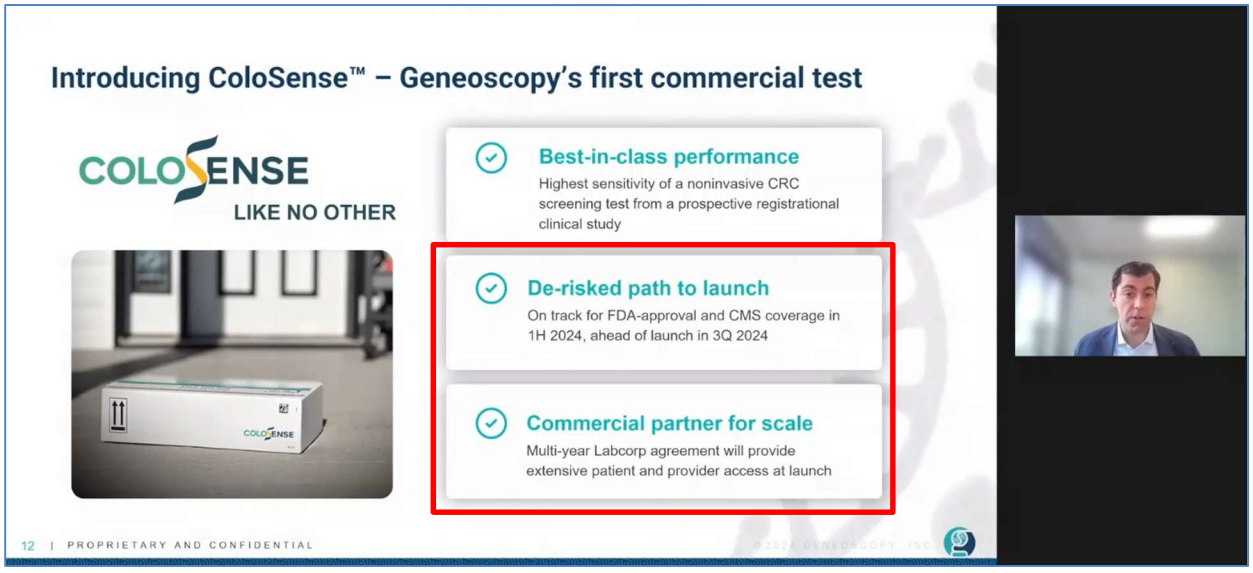
70 *Id.*
71 *Id.*
72 *Id.*

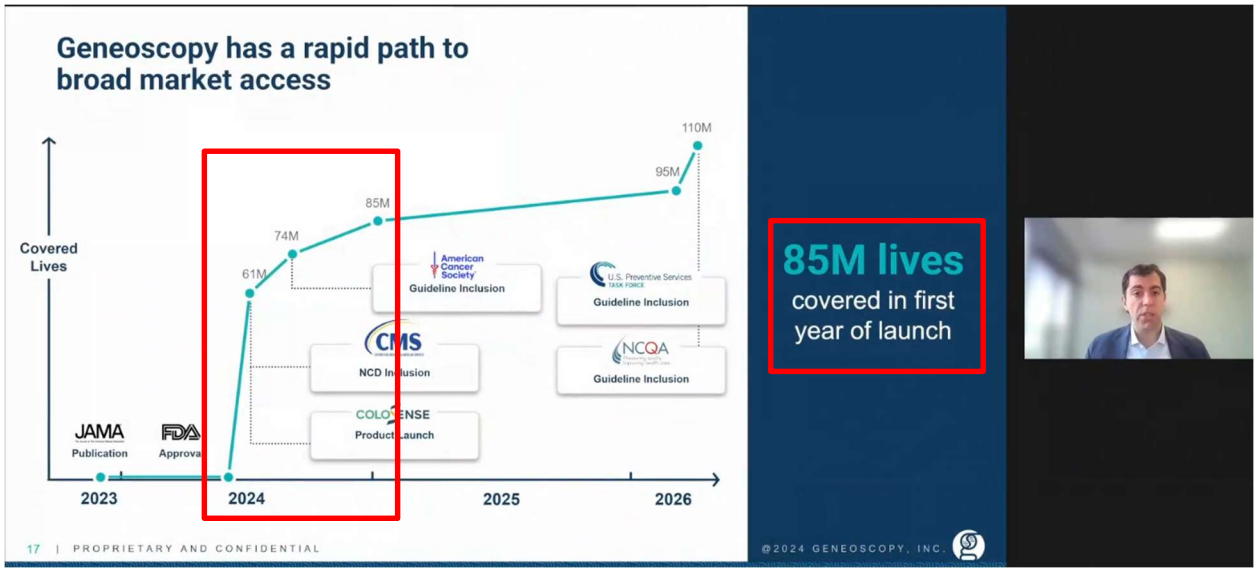


93. In another slide, Mr. Barnell projected a "[d]e-risked path to launch" with "FDA-approval and CMS coverage" of ColoSense in "1H 2024, ahead of ***launch in 3Q 2024***,"[73] demonstrating that the near-term product launch of ColoSense is inevitable. Mr. Barnell explained that the multi-year agreement between Geneoscopy and Labcorp "will provide extensive patient and provider access at launch," referring to Labcorp as a "[c]ommercial partner for scale."[74]



73 *Id.*
74 *Id.*

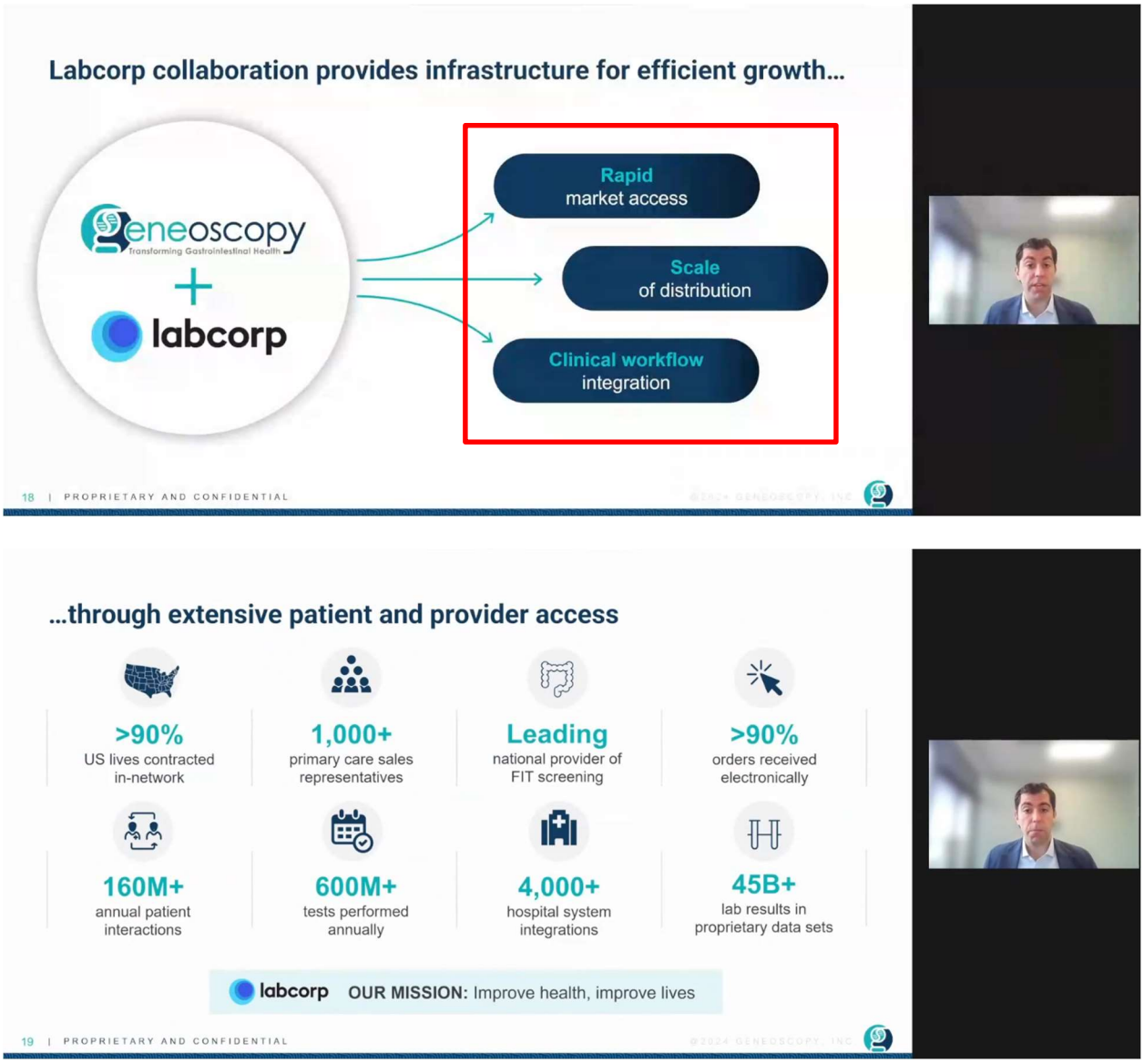
94. Mr. Barnell also presented a slide regarding market access and sales of ColoSense after FDA-approval (reproduced below). This slide depicts a product launch of ColoSense in **mid-2024**, with sales quickly reaching a market that covers 85 millions patients by the end of 2024.[75] Mr. Barnell explained during the presentation that Geneoscopy expects to have "***85 million lives covered within our first year of launch***."



95. Mr. Barnell emphasized the importance of the multi-year agreement between Geneoscopy and Labcorp, "provid[ing] infrastructure for efficient growth" "through extensive patient and provider access."[76] During the presentation, Mr. Barnell explained that Labcorp provides a streamlined contracting approach that integrates ColoSense into Labcorp's existing contracts, enabling the market access coverage curve he had shown earlier (reproduced above). He noted that Labcorp has "a tremendously large direct sales force," with over 1,000 PCP reps and over 100 specialty reps, many of whom have extensive experience detailing CRC screening tests.

[75] *Id.*
[76] *Id.*

He also noted that integrating ColoSense into Labcorp's clinical workflow would make it easy for physicians to order ColoSense.



96. Labcorp will be a critical part of the ColoSense product launch, and enable Geneoscopy to have a nationwide reach in terms of healthcare providers. On information and belief, Labcorp will grant the ColoSense test "Tier 1" status, which would incentivize Labcorp's over a thousand primary care and specialty sales representatives across the country to actively

promote the ColoSense test. As such, Geneoscopy will almost immediately have access to nearly all healthcare providers in the country.

97. Consistent with its plan for an imminent nationwide product launch of ColoSense, on May 15, 2024, Geneoscopy issued a press release announcing that it has "expand[ed] leadership team to support ColoSense™ rollout and advance precision IBD solution."[77] In that press release, Geneoscopy announced that it "has appointed Matt Sargent as Chief Commercial Officer and Tyler Aldredge as Vice President of Operations to support commercialization of ColoSense, which recently received FDA approval for colorectal cancer screening (CRC) in average-risk individuals over 45 years of age." The press release further states:

> "We are pleased to welcome Matt and Tyler to the Geneoscopy team at such a pivotal time for the company," said Andrew Barnell, Geneoscopy's co-founder and Chief Executive Officer. "***Matt's proven experience commercializing oncology diagnostic products and Tyler's expertise in operational process and management will be critical as we accelerate toward bringing ColoSense to market*** and hit several key clinical and development milestones with IBD."
>
> "As I step into this new role, I look forward to collaborating with our talented team and partners to realize the full potential of our innovative RNA technology and bring valuable solutions to patients and providers," said Sargent. "With our focus on advancing ColoSense and expanding precision diagnostics for IBD, we are poised to make a meaningful impact in improving outcomes for the 60-70 million Americans suffering from GI diseases."
>
> Sargent brings 20 years of experience leading high-performance commercial teams in the oncology space. Most recently, he served as Chief Business Officer at Harbinger Health, responsible for business development related to the company's blood-based cancer early detection test. Before Harbinger Health, he was Vice President of Commercial Oncology at Hologic, responsible for sales, commercial strategy, and business development for the CLIA oncology diagnostics service business, following Hologic's acquisition of Biotheranostics, where he served as Chief Commercial Officer.

[77] **Exhibit X**, *available at* https://www.geneoscopy.com/geneoscopy-expands-leadership-team-to-support-colosense-rollout-and-advance-precision-ibd-solution/ (last visited May 15, 2024).

> Aldredge brings more than 30 years of leadership, operations management, and operational quality experience across a range of multi-site laboratories and facilities, along with extensive proficiency in process development and laboratory set-up, scale-up, and automation. Before joining Geneoscopy, Aldredge served as Vice President of Lab Operations, Facilities, and Real Estate with Bluerock Therapeutics. He is a member of the Society for Laboratory Automation and Screening and serves on the Lab-of-the-Future Committee.
>
> Sargent and members of Geneoscopy's leadership team will attend Digestive Disease Week 2024 in Washington, D.C., May 18-21 (booth #1407).[78]

98. As illustrated above by Geneoscopy's public announcements regarding, and its extensive and meaningful preparations for, the nationwide product launch of ColoSense, now with FDA approval, Geneoscopy can commercially sell and use the FDA-approved ColoSense test at any time, including prior to receiving Medicare reimbursement coverage from CMS. This is precisely what Geneoscopy was waiting for, as shown by its recent presentation projecting an immediate post-approval, full-scale launch. On information and belief, Geneoscopy is seeking private payor coverage in parallel with Medicare reimbursement and ColoSense may receive private payor insurance coverage more quickly than Medicare reimbursement.

99. With FDA approval behind it, Geneoscopy's imminent future infringing activities are not reasonably related to obtaining FDA regulatory approval of ColoSense, and do not fall within the safe harbor of 35 U.S.C. § 271(e)(1).

B. Geneoscopy knew of the '746 Patent and that its conduct will infringe the '746 Patent

100. On information and belief, Geneoscopy knew or should have known of the inventions claimed in the '746 Patent, and that its launch of ColoSense would infringe the '746 Patent, since the issuance of the '746 Patent on April 30, 2024.

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[78] *Id.*

101. On May 1, 2023, Exact Sciences sent a notice letter by email to Geneoscopy's Chief Executive Officer, Andrew Barnell, identifying Geneoscopy's ColoSense test as infringing multiple claims of the '781 Patent, which is a direct parent of the '746 Patent. Exact Sciences explained that Geneoscopy's activities relating to ColoSense included "commercial and non-exempt research use" that both directly and indirectly infringed multiple specified claims of the '781 Patent. Geneoscopy was aware of the '781 Patent and its infringement of the '781 Patent at least as early as the date it received this notice letter.

102. Rather than respecting Exact Sciences' patent rights, three weeks later, Geneoscopy requested *ex parte* reexamination of the '781 Patent at the USPTO on May 22, 2023, based on a 282-page *ex parte* reexamination request, with an accompanying declaration, alleging numerous combinations of prior art references. The relatively rapid filing of the reexamination request alleging numerous prior art references, within three weeks of Exact Sciences' notice letter, indicates that Geneoscopy was monitoring Exact Sciences' patent portfolio and was preparing the reexamination request prior to Exact Sciences' May 1, 2023 letter.

103. Nearly four weeks after requesting *ex parte* reexamination of the '781 Patent, on June 16, 2023, Geneoscopy finally acknowledged and responded to the May 1, 2023 notice letter with a response letter. Although the response letter asserted that Geneoscopy disagrees with Exact Sciences' accusation of infringement, it provided no basis for that assertion. The letter also did not dispute Geneoscopy's "commercial and non-exempt research use" of ColoSense. The response letter contended that Geneoscopy has requested *ex parte* reexamination of the '781 Patent and that Geneoscopy is confident that the USPTO will reject and cancel the claims of the '781 Patent.

104. Notably, shortly after or around June 16, 2023, when Geneoscopy responded to Exact Sciences' notice letter, despite its knowledge of the '781 Patent and its infringement,

Geneoscopy created a dedicated product webpage on its company website for its ColoSense at-home CRC screening test.[79] This webpage advertised that "ColoSense is indicated for individuals 45 years and older, at average risk for colorectal cancer." This webpage also included a link to another webpage from which to download an order form for the ColoSense test, titled "CRC Screening Test Requisition Form" (attached hereto as **Exhibit T**).[80]

105. The USPTO granted the reexamination request on June 29, 2023. After a thorough review of Geneoscopy's arguments over the next several months, the USPTO found each and every argument unpersuasive. The USPTO confirmed the patentability of ***all twenty claims*** of the '781 Patent in a reexamination communication mailed October 18, 2023. A true and correct copy of the reexamination communication is attached hereto as **Exhibit U**.

106. In view of the USPTO's affirmation of the validity of the '781 Patent claims, on October 20, 2023, Exact Sciences sent another letter to Geneoscopy's counsel noting the outcome of the reexamination proceeding, and Geneoscopy's lack of any articulated non-infringement position. The letter demanded again that Geneoscopy cease and desist infringement of the '781 Patent. To ascertain the full scope of infringement up to that point, the letter also requested that Geneoscopy provide an accounting, by November 1, 2023, of uses and sales of the ColoSense product, and the identity of any third parties that manufactured, distributed, or used the ColoSense product.

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[79] https://www.geneoscopy.com/gastrointestinal-health/colorectal-cancer-screening/colosense/. This webpage is no longer accessible.

[80] https://www.geneoscopy.com/wp-content/uploads/Test-Requisition-Form-LBL-TD-0007v1.pdf. Geneoscopy took down this second webpage sometime in November 2023 after Exact Sciences sued Geneoscopy for infringement of the '781 Patent on November 17, 2023. This second webpage for the order form was available for public access at least between July and November 17, 2023.

107. Despite its knowledge of the '781 Patent, its knowledge of its infringement, and its failed reexamination request, Geneoscopy responded with a letter of its own on October 31, 2023, doubling down on its willful infringement of a patent that the USPTO has examined and allowed not just once, but ***twice***. Geneoscopy's letter, sent by new counsel, repeated the baseless assertion that Geneoscopy's product does not fall within the scope of the '781 Patent claims and—without a word about the failed reexamination—asserted that the claims are invalid. Furthermore, the letter not only failed to provide any of the information requested by Exact Sciences, but further failed to even acknowledge those requests. Geneoscopy gave no indication that it had any intent to cease and desist from its infringement; its actions instead reflected a refusal to do so. Subsequent correspondences between the parties in November did not suggest any different course by Geneoscopy.

108. On November 17, 2023, Exact Sciences filed a complaint against Geneoscopy for patent infringement, which set forth in detail how Geneoscopy has infringed and will infringe the '781 Patent. Accordingly, Geneoscopy had further knowledge of its infringement of the '781 Patent since at least November 17, 2023, the filing date of that complaint.

109. The '746 Patent was filed on March 7, 2023, as a continuation of the '781 Patent, and the application underlying the '746 Patent was published on October 5, 2023, under U.S. Patent Application Publication No. 2023/0313317 A1. The prosecution history of the '746 Patent, including the claims being prosecuted and examined in the underlying application, was publicly available and accessible since at least October 5, 2023.

110. On April 10, 2024, the USPTO posted an Issue Notification in the publicly available prosecution history of the application underlying the '746 Patent. This Issue Notification states that the '746 Patent would issue on April 30, 2024 as U.S. Patent No. 11,970,746.

111. On April 30, 2024, the USPTO issued the '746 Patent.

112. On information and belief, Geneoscopy has had actual knowledge of the '746 Patent since at least April 30, 2024, when the '746 Patent issued, and also had actual knowledge of the allowed claims of the '746 Patent at least since April 10, 2024, when the USPTO posted the Issue Notification. On information and belief, Geneoscopy has known that its commercial activities relating to ColoSense will infringe one or more claims of the '746 Patent, directly and indirectly, since at least April 30, 2024.

113. On information and belief, Geneoscopy has had knowledge of the '746 Patent and its infringement of that patent as of the date the '746 Patent issued, at least based on the fact that the '746 Patent is a continuation of the '781 Patent, which Geneoscopy had actual knowledge of since at least May 1, 2023 and had knowledge of its infringement of that patent as of the same date.

114. On information and belief, Geneoscopy has had knowledge of the '746 Patent since the date that patent issued because Geneoscopy monitors Exact Sciences' patent filings, including the prosecution of applications related to the '781 Patent, for which Exact Sciences has sued Geneoscopy of patent infringement and against which Geneoscopy has filed not only an *ex parte* reexamination request but also a petition for IPR.

115. Geneoscopy filed a reexamination request within four weeks of the '781 Patent issuing. The speed with which Geneoscopy filed its reexamination request against the '781 Patent indicates that Geneoscopy monitors Exact Sciences' patent filings and that Geneoscopy would have known of the application underlying the '746 Patent prior to its issuance, and the issuance of the '746 Patent on or about the day that the patent issued.

116. With knowledge of the '746 Patent since at least April 30, 2024, Geneoscopy has acted and will act with a specific intent to induce others to infringe the '746 Patent.

C. Geneoscopy's Accused Products, including ColoSense, Infringe One or More Claims of the '746 Patent

117. Geneoscopy's infringing products include, but are not limited to, the Accused Products, and any other infringing method, product, device, kit, service, or test developed by Geneoscopy, that (1) apply Exact Sciences' patented methods for processing a stool or fecal sample, (2) induce others to apply Exact Sciences' patented methods for processing a stool or fecal sample, and/or (3) are designed and intended for exclusive use in Exact Sciences' patented methods for processing a stool or fecal sample and are not a staple article or commodity of commerce suitable for substantial non-infringing use.

118. Geneoscopy's Accused Products use stool samples that are collected applying the methods claimed in the '746 Patent (*e.g.*, claims 1 and 2). Geneoscopy's Accused Products process such stool samples applying the methods claimed in the '746 Patent (*e.g.*, claim 3 and its dependent claims).

119. As provided in more detail below, each element of at least one claim of the '746 Patent is literally present in the Accused Products or is literally practiced by the processes through which the Accused Products are practiced. To the extent that any element is not literally present or practiced, each such element is present or practiced under the doctrine of equivalents.

120. The allegations provided below are exemplary and without prejudice to Exact Sciences' infringement contentions. In providing these allegations, Exact Sciences does not convey or imply any particular claim constructions or the precise scope of the claims. Exact Sciences' claim construction contentions regarding the meaning and scope of the claim terms will be provided under the Court's scheduling order and local rules.

1. Geneoscopy will infringe claims 1 and 2 of the '746 Patent, directly and indirectly

121. To the extent it is not already infringing, Geneoscopy will directly infringe, induce others to infringe, and/or contribute to the infringement of claims 1 and 2 of the '746 Patent, literally or under the doctrine of equivalents. For example, Geneoscopy will provide instructions to users of its Accused Products to carry out the steps of claims 1 and 2 in the United States. Geneoscopy will also make, use, sell, offer to sell, or import kits or devices that are especially designed and intended for exclusive use in Exact Sciences' patented methods for processing a stool or fecal sample, and such kits or devices are not a staple article or commodity of commerce suitable for substantial non-infringing use. Geneoscopy will infringe claims 1 and 2 of the '746 Patent, directly and indirectly.

122. As discussed *supra*, on information and belief, Geneoscopy has had actual knowledge of the '746 Patent since at least April 30, 2024. As also discussed *supra*, on information and belief, since at least April 30, 2024, Geneoscopy has known and specifically intended that its actions upon launch of ColoSense, including providing instructions to users of its Accused Products or to others, would induce actual infringement of the '746 Patent.

123. Geneoscopy's knowledge of the '746 Patent and of its infringement of that patent, as discussed *supra*, also demonstrates that Geneoscopy knew or was at a minimum willfully blind to the fact that its Accused Products including kits and devices are especially made or especially adapted for use in an infringement of the '746 Patent and are not staple articles or commodities of commerce suitable for substantial non-infringing use.

124. For example, Section 5 of the Barnell Study Supplement 1 (**Exhibit G**) describes the instructions provided to patients and users of Geneoscopy's ColoSense test ("Once the collection kit is sent to the participant's house, the subject will be instructed to follow the collection

kit IFU booklet. The collection kit IFU will provide step-by-step instructions with associated images for how to complete sample collection. Briefly, these instructions are provided below").

125. The FDA approval of ColoSense references the CRC-PREVENT trial (with a clinicaltrial.gov ID of NCT04739722).[81] On information and belief, the FDA approval does not impose any changes on the stool sample collection process or test operation.[82] On information and belief, Geneoscopy will provide the same or substantially the same instructions as those used in and described for the Barnell Study (**Exhibits F, G, and H**), to users or prospective users of its ColoSense test for commercial purposes, not related to any clinical trial on ColoSense for FDA approval, including through its commercial marketing, use, offer for sale, or sale of the ColoSense product, including related kits, devices, and services, for example, through solicitation material and order form posted on Geneoscopy's company website, and through the user instructions provided in the ColoSense stool sample collection kits, as discussed herein. Geneoscopy designed its ColoSense test as an at-home CRC screening test that instructs patients to collect the stool sample in two portions combined with stabilizing buffers that are shipped to Geneoscopy's lab for RNA and hemoglobin analyses, as discussed herein. Geneoscopy also applied for FDA regulatory approval of its ColoSense test based on the Barnell Study that was conducted using the testing protocol described for the Barnell Study (including Barnell Study Supplements 1 and 3), and obtained FDA approval on May 3, 2024. Upon FDA approval, the relevant portions of the ColoSense test protocol do not materially differ from the protocol described for the Barnell Study,

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[81] **Exhibit N**, *available at* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230001 (last visited May 14, 2024); *see also Exact Sciences Corp. v. Geneoscopy, Inc.*, C.A. No. 23-1319-MN, D.I. 27 (May 6, 2024) (FDA approval letter).

[82] *See* **Exhibit N**, *available at* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230001 (last visited May 14, 2024); *see also Exact Sciences Corp. v. Geneoscopy, Inc.*, C.A. No. 23-1319-MN, D.I. 27 (May 6, 2024) (FDA approval letter).

including because Geneoscopy has consistently promoted and touted ColoSense as a convenient at-home CRC screening test that instructs patients to collect the stool sample in two portions combined with stabilizing buffers that are shipped to Geneoscopy's lab for RNA and hemoglobin analyses, as discussed herein, and because any change to the ColoSense test protocol would require a different clinical study to satisfy FDA that the new sample collection and processing process works.

126. Attached as **Exhibit W** is a preliminary and exemplary claim chart illustrating Geneoscopy's imminent direct and indirect infringement of claim 1 of the '746 Patent based on the test protocol disclosed in the *JAMA* paper which, as noted above, is the same or substantially the same as the protocol or instruction that Geneoscopy will provide, after FDA approval, to users or prospective users of its ColoSense test for commercial purposes. The claim chart is not intended to limit Exact Sciences' right to modify the chart or to allege that other products or activities of Geneoscopy infringe the identified claim or any other claims of the '746 Patent or any other patents. Geneoscopy will infringe more than one claim of the '746 Patent. **Exhibit W** is hereby incorporated by reference in its entirety.

127. As described *supra*, on information and belief, Geneoscopy knows about the '746 Patent and knows that the practice of the ColoSense product technology, as described in the instructions to patients and other users, will infringe the claims of the '746 Patent. The text of the instructions, which follows the method steps of the '746 Patent claims, demonstrates that Geneoscopy has both knowledge and specific intent that the patients and other users would infringe the claims of the '746 Patent.

128. It is also expected that discovery will likely reveal additional evidentiary support that Geneoscopy will perform, or induce others to perform, or contribute to the performance of, the limitations of claims 1 and 2 of the '746 Patent.

129. As discussed *supra*, Geneoscopy's actions are egregious and beyond typical infringement. Geneoscopy could not have reasonably or subjectively believed that its actions would not constitute infringement of the '746 Patent. Nor could Geneoscopy reasonably or subjectively believe that the '746 Patent is invalid.

130. By its actions, Geneoscopy's infringement of the '746 Patent will irreparably harm Exact Sciences. Unless Geneoscopy's infringing acts are enjoined by this Court, Exact Sciences will suffer irreparable injury. Exact Sciences has no adequate remedy at law.

131. By its actions, Geneoscopy's imminent infringement of the '746 Patent will damage Exact Sciences in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that Exact Sciences would have made but for Geneoscopy's infringing acts.

2. Geneoscopy will infringe claim 3 and its dependent claims of the '746 Patent, directly and indirectly

132. To the extent it is not already infringing, Geneoscopy will directly infringe, induce others to infringe, and/or contribute to the infringement of, at least claims 3-4 and 12-19 of the '746 Patent, literally or under the doctrine of equivalents. For example, Geneoscopy will perform or instruct others to perform the methods of claim 3 and its dependent claims in the United States. Geneoscopy will also make, use, sell, offer to sell, or import kits and devices that are especially designed and intended for exclusive use in Exact Sciences' patented methods, and such kits or devices are not a staple article or commodity of commerce suitable for substantial non-infringing use. Geneoscopy will infringe at least claims 3-4 and 12-19 of the '746 Patent, directly and indirectly.

133. As discussed *supra*, on information and belief, since at least April 30, 2024, Geneoscopy has had actual knowledge of the '746 Patent and has known and specifically intended that its actions upon launch of ColoSense, including providing instructions to others, would induce actual infringement of the '746 Patent.

134. Geneoscopy's knowledge of the '746 Patent and of its infringement of that patent, as discussed *supra*, also demonstrates that Geneoscopy knew or was at a minimum willfully blind to the fact that its Accused Products including kits and devices are especially made or especially adapted for use in an infringement of the '746 Patent and are not staple articles or commodities of commerce suitable for substantial non-infringing use.

135. The FDA approval of ColoSense references the CRC-PREVENT trial (with a clinicaltrial.gov ID of NCT04739722).[83] On information and belief, the FDA approval does not impose any changes on the stool sample collection process or test operation.[84] On information and belief, Geneoscopy will use the same or substantially the same protocols as those used in and described for the Barnell Study (**Exhibits F, G, and H**), to process and analyze stool samples for its ColoSense test for commercial purposes, not related to any clinical trial on ColoSense for FDA approval, including through its commercial marketing, use, offer for sale, or sale of the ColoSense product, including related kits, devices, and services, as discussed herein. Geneoscopy designed its ColoSense test as an at-home CRC screening test that collects the stool sample in two portions combined with stabilizing buffers that are shipped to Geneoscopy's lab for RNA and hemoglobin

[83] **Exhibit N**, *available at* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230001 (last visited May 14, 2024); *see also Exact Sciences Corp. v. Geneoscopy, Inc.*, C.A. No. 23-1319-MN, D.I. 27 (May 6, 2024) (FDA approval letter).

[84] *See* **Exhibit N**, *available at* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230001 (last visited May 14, 2024); *see also Exact Sciences Corp. v. Geneoscopy, Inc.*, C.A. No. 23-1319-MN, D.I. 27 (May 6, 2024) (FDA approval letter).

analyses by the lab, as discussed herein. Geneoscopy also applied for FDA regulatory approval of its ColoSense test based on the Barnell Study that was conducted using the testing protocol described for the Barnell Study (including Barnell Study Supplements 1 and 3), and obtained FDA approval on May 3, 2024. Upon FDA approval, the relevant portions of the ColoSense test protocol do not materially differ from the protocol described for the Barnell Study, including because Geneoscopy has consistently promoted and touted ColoSense as a convenient at-home CRC screening test that instructs patients to collect the stool sample in two portions combined with stabilizing buffers that are shipped to Geneoscopy's lab for RNA and hemoglobin analyses by the lab, as discussed herein, and because any change to the ColoSense test protocol would require a different clinical study to satisfy FDA that the new sample collection and processing process works.

136. Attached hereto as **Exhibit W** is a preliminary and exemplary claim chart illustrating Geneoscopy's imminent direct and indirect infringement of claim 3 of the '746 Patent based on the test protocol disclosed in the *JAMA* paper which, as noted above, is the same or substantially the same as the protocol that Geneoscopy will use commercially after FDA approval. The claim chart is not intended to limit Exact Sciences' right to modify the chart or to allege that other products or activities of Geneoscopy infringe the identified claim or any other claims of the '746 Patent or any other patents. Geneoscopy will infringe more than one claim of the '746 Patent. **Exhibit W** is hereby incorporated by reference in its entirety.

137. As described *supra*, on information and belief, Geneoscopy knows about the '746 Patent and knows that the practice of the ColoSense product technology by Geneoscopy or by others, as described in the ColoSense test protocol, will infringe the claims of the '746 Patent, directly and indirectly. The text of the ColoSense test protocol, which follows the method steps

of the ’746 Patent claims, demonstrates that Geneoscopy has both knowledge and specific intent to infringe the claims of the ’746 Patent.

138. It is also expected that discovery will likely reveal additional evidentiary support that Geneoscopy will perform, or induce others to perform, or contribute to the performance of, the limitations of at least claims 3-4 and 12-19 of the ’746 Patent.

139. As discussed *supra*, Geneoscopy’s actions are egregious and beyond typical infringement. Geneoscopy could not have reasonably or subjectively believed that its actions would not constitute infringement of the ’746 Patent. Nor could Geneoscopy reasonably or subjectively believe that the ’746 Patent is invalid.

140. By its actions, Geneoscopy’s infringement of the ’746 Patent will irreparably harm Exact Sciences. Unless Geneoscopy’s infringing acts are enjoined by this Court, Exact Sciences will suffer irreparable injury. Exact Sciences has no adequate remedy at law.

141. By its actions, Geneoscopy’s imminent infringement of the ’746 Patent will damage Exact Sciences in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that Exact Sciences would have made but for Geneoscopy’s infringing acts.

COUNT I: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,970,746

142. Exact Sciences realleges and incorporates by reference the foregoing paragraphs as if fully set forth herein, including without limitation the allegations in **Exhibit W**.

143. Exact Sciences is the owner of the ’746 Patent, which was duly and legally issued by the USPTO on April 30, 2024.

144. Geneoscopy’s imminent offer for sale, sale, distribution, use and/or importation in the United States of the Accused Products including its ColoSense product will infringe the ’746 Patent under one or more subsections of 35 U.S.C. § 271.

145. Geneoscopy will infringe at least one claim of the '746 Patent pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by performing the claimed methods within the United States and without authority.

146. Geneoscopy will act with the requisite knowledge and specific intent to induce others to infringe at least one claim of the '746 Patent pursuant to 35 U.S.C. § 271(b), literally or under the doctrine of equivalents, by instructing others to perform the claimed methods within the United States and without authority.

147. Geneoscopy will act with the requisite knowledge to contribute to the infringement of at least one claim of the '746 Patent pursuant to 35 U.S.C. § 271(c), literally or under the doctrine of equivalents, by contributing to the performance of the claimed methods within the United States and without authority. Geneoscopy's Accused Products have no substantial non-infringing uses and Geneoscopy knows that its Accused Products are especially made or especially adapted for use to infringe the '746 Patent.

148. Geneoscopy's infringement will damage Exact Sciences, which is entitled to recover the damages resulting from Geneoscopy's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

149. Exact Sciences will suffer irreparable harm with no adequate remedy at law unless this Court enjoins Geneoscopy from directly infringing, inducing infringement, or contributing to infringement of the '746 Patent.

150. The balance of hardships favors an injunction, and such injunction would not disserve the public interest.

151. Geneoscopy's infringement will be deliberate, willful, and unlicensed, justifying an award of enhanced damages under 35 U.S.C. § 284.

152. A substantial controversy exists of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Therefore, Exact Sciences seeks a judicial determination and declaration that Geneoscopy will infringe, directly or indirectly, one or more claims of the '746 Patent by its offer for sale, sale, distribution, make, use and/or importation in the United States of the Accused Products.

PRAYER FOR RELIEF

WHEREFORE, Exact Sciences respectfully requests the following relief:

153. A judgment that Geneoscopy infringes the '746 Patent;

154. A judgment that Geneoscopy actively induces and contributes to infringement of the '746 Patent;

155. A judgment declaring that Geneoscopy's use, sale, offer for sale, or importation into the United States of the Accused Products will infringe the '746 Patent;

156. A judgment declaring that Geneoscopy's use, sale, offer for sale, or importation into the United States of the Accused Products will actively induce and/or contribute to infringement of the '746 Patent;

157. Preliminary and permanent injunctions enjoining Geneoscopy and its officers, directors, agents, servants, affiliates, employees, divisions, branches, subsidiaries, parents, and all others acting on behalf of or in active concert or participation therewith, from acts that infringe the '746 Patent;

158. Preliminary and permanent injunctions enjoining Geneoscopy and its officers, directors, agents, servants, affiliates, employees, divisions, branches, subsidiaries, parents, and all others acting on behalf of or in active concert or participation therewith, from actively inducing others to infringe, or contributing to the infringement of, the '746 Patent;

159. An award of damages sufficient to compensate Exact Sciences for Geneoscopy's infringement under 35 U.S.C. § 284;

160. A determination that Geneoscopy's infringement of the '746 Patent has been willful;

161. An award of treble damages for Geneoscopy's willful infringement of the '746 Patent;

162. A determination that this is an exceptional case under 35 U.S.C. § 285 and that Exact Sciences be awarded attorneys' fees incurred in this action;

163. Costs and expenses that Exact Sciences incurred in this action, including expert witness fees;

164. An award of prejudgment and post-judgment interest; and

165. Such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Exact Sciences respectfully demands a trial by jury on all triable issues.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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