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. Exact Sciences, with its suite of cancer screening and diagnostic products including its revolutionary Cologuard® at-home test, has been helping save lives through early cancer detection and treatment guidance for nearly a decade. Exact Sciences brings this action to protect its intellectual property against a flagrant infringer whose actions flout Exact Sciences' patent rights.

2. 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, from Geneoscopy's past and ongoing infringement, and imminent future infringement, of Exact Sciences' U.S. Patent No. 11,634,781 (the "'781 Patent" or "Asserted Patent") (attached as **Exhibit A**). Geneoscopy has infringed, is infringing, and will infringe multiple claims of the '781 Patent, directly or indirectly, through its manufacture, use, offer for sale, sale, and/or importation of its colorectal cancer ("CRC") and related pre-cancer detection products and services in the

United States, and/or its contribution to and/or its inducement of others to use its products and services in an infringing manner in the United States.

3. 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 Cologuard®. The Cologuard test is the ***first and only*** noninvasive stool or fecal DNA-based test approved by U.S. Food and Drug Administration ("FDA") for screening patients with average risk of CRC.

4. 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.

5. 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.

6. Nearly a decade later, the Cologuard test has been used more than 13 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.

7. 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/.

efforts, Exact Sciences possesses a substantial patent portfolio. These patents—including the '781 Patent asserted here—protect its technological innovations relating to its Cologuard products.[2]

8. The '781 Patent is directed to clinically important methods of processing fecal samples. Under the '781 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. The '781 Patent's inventions 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.

9. Exact Sciences' numerous groundbreaking technologies, including the methods claimed in the '781 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]

10. In contrast to Exact Sciences, Geneoscopy is a private start-up company founded in 2015. Geneoscopy purports to have developed its own non-invasive stool-based test for detecting gastrointestinal diseases, including CRC.

11. Geneoscopy refers to its at-home test for CRC screening as "ColoSense" in its marketing materials. Geneoscopy's ColoSense product uses the '781 Patent's methods for processing stool samples without permission from Exact Sciences and in violation of U.S. patent laws.

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[2] *See* https://www.exactsciences.com/patents-and-trademarks.

[3] https://nccrt.org/our-impact/data-and-progress/.

12. As explained in further detail herein, Geneoscopy has infringed and is infringing the '781 Patent. On information and belief, Geneoscopy commercially marketed, used, offered for sale, and/or sold ColoSense as a laboratory developed test ("LDT") at least in or around July 2023. Geneoscopy has continued its infringement at least through its widespread commercial marketing, promotion, and offers for sale of ColoSense.

13. In addition, Geneoscopy is actively taking steps to expand its infringement of the '781 Patent. It has made clear its intention to broadly market, use, offer for sale, and/or sell its ColoSense test to the general public upon FDA approval, which it expects imminently. In recent public announcements, Geneoscopy expects a decision from the FDA "within the next 3 months."[4] And on November 14, 2023, Geneoscopy announced that it has signed a multi-year agreement with LabCorp to distribute the infringing ColoSense test. Geneoscopy is also actively hiring for its imminent commercialization, including on LinkedIn.

14. Geneoscopy's infringement of the '781 Patent is particularly egregious because it has known of the patent and its infringement since at least May 1, 2023, when Exact Sciences sent a cease and desist letter to Geneoscopy regarding its infringement of the '781 Patent by ColoSense.

15. Rather than respecting Exact Sciences' patent rights, however, Geneoscopy sought to take them on offensively. Three weeks later, on May 22, 2023, Geneoscopy filed an *ex parte* reexamination request against the '781 Patent at the United States Patent and Trademark Office

[4] 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/ (Oct. 23, 2023 press release on the publication of study results from the CRC-PREVENT trial); https://www.geneoscopy.com/noninvasive-multitarget-stool-rna-test-proves-sensitive-for-colorectal-cancer-advanced-adenomas/ (November 2023 interview of Geneoscopy's Chief Science Officer, noting that Geneoscopy had "submitted the data from the pivotal study to the FDA as part of a pre-market approval application" and "anticipate[d] receiving their decision within the next 3 months").

("USPTO"), which was ultimately rejected, resulting in the USPTO affirming the patentability of ***all*** of the originally issued claims of the '781 Patent.

16. Separate and apart from the activities above, Geneoscopy has also conducted clinical trials on ColoSense, including a clinical trial known as "CRC-PREVENT." On October 23, 2023, Geneoscopy published the study results in the *Journal of the American Medical Association* ("*JAMA*"). Geneoscopy had submitted these results to the FDA to support its pre-market approval ("PMA") application on ColoSense. While Exact Sciences has serious questions about Geneoscopy's research, data, and practices, it does not seek to impose liability on, or seek relief from, Geneoscopy based on any FDA approval activities falling within the safe harbor of 35 U.S.C. § 271(e)(1).

17. 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 ongoing and future direct and indirect infringement of the '781 Patent through, among other acts, its commercial promotion, use, offer for sale, and/or sale of ColoSense in the United States.

THE PARTIES

18. 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 '781 Patent.

19. 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

20. 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.

21. This Court has jurisdiction over the subject matter of this action at least because Geneoscopy has infringed, and continues to infringe, the claims of the '781 Patent, directly or indirectly, by its manufacture, use, offer for sale, sale, and/or importation of its CRC screening test, ColoSense, and services related thereto in the United States, and/or its contribution to and/or inducement of others to use the same in an infringing manner in the United States.

22. This Court has jurisdiction over the subject matter of this action also 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 threat of further infringement of the claims of the '781 Patent, directly or indirectly, by its manufacture, use, offer for sale, sale, and/or importation of its CRC screening products and services, including ColoSense, in the United States, and/or its contribution to and/or inducement of others to use the same in an infringing manner in the United States, upon FDA approval which Geneoscopy anticipates to take place in the coming months, as described *infra*.

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

24. Geneoscopy is subject to this Court's personal jurisdiction additionally because, on information and belief, Geneoscopy promotes, offers for sale, sells, or uses, and/or contributes to and/or induces others to use, the products and services that infringe the '781 Patent throughout the United States, including within the State of Delaware and this judicial District. Geneoscopy has infringed, continues to infringe, and will infringe the '781 Patent—both directly and indirectly—

in this District by, among other things, engaging in infringing conduct within, directed at, or from this District and purposely and voluntarily placing the infringing products and/or services into the stream of commerce with the expectation that the infringing products and/or services will be used in this District.

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 COLOGUARD® 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.[5] 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 Service Task Force 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

[5] https://nccrt.org/our-impact/data-and-progress/.

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 colonoscopy, rather than offering other screening options."[6] 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."[7]

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.[8]

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.

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[6] https://nccrt.org/giving-patients-choices/.

[7] *Id.*

[8] 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.

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.[9] 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."[10] As reported in 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."[11] 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).[12] Indeed, several sources have named distance to specialized care as a barrier for people living in rural communities.[13]

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

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9 https://pubmed.ncbi.nlm.nih.gov/24740165/.

10 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9829879/.

11 *Id*.

12 *Id.*

13 *Id*.; https://pubmed.ncbi.nlm.nih.gov/31394041/ ("distance to test facilities were reported as rural-specific barriers for CRC screening").

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 stabilizer buffers (necessary to ensure the integrity of the sample for downstream analysis), and then returns the sample to Exact Sciences for laboratory testing.

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 13 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 COLOGUARD® 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 age 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, the Centers for Medicare and Medicaid Services ("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 still the ***first and only*** FDA-approved non-invasive, at-home stool DNA-based test for CRC screening, with high sensitivity and high specificity.

43. In 2016, the U.S. Preventive Services Task Force 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 Cologuard for CRC screening.

44. In 2019, the FDA further expanded its approval of Exact Sciences' Cologuard test to include individuals age 45 to 49. The Cologuard test is currently approved for CRC screening in average risk adults 45 years of age and older. Nearly a decade after its initial FDA approval, the Cologuard test remains 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, 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, Exact Sciences presented data from the 26,000-plus-participant BLUE-C study, in which the next-generation Cologuard test met all study endpoints, demonstrating a 94% sensitivity for CRC at 91% specificity.[14] Exact Sciences plans to complete its application for FDA approval of the next-generation Cologuard test in the coming months.

EXACT SCIENCES' ASSERTED '781 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 '781 Patent asserted here.

[14] https://www.exactsciences.com/newsroom/press-releases/next-generation-cologuard-test-demonstrates-high-sensitivity-and-specificity-in-pivotal-blue-c-stud.

47. On April 25, 2023, the USPTO issued the '781 Patent, entitled "Fecal Sample Processing and Analysis Comprising Detection of Blood." A true and correct copy of the '781 Patent is attached as **Exhibit A**.

48. Exact Sciences is the owner of the '781 Patent. Exact Sciences acquired all rights to the patent filings that led to the '781 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 '781 Patent and related patent applications from MDXHealth SA, then operating as Oncomethylome Sciences, S.A. Exact Sciences has the right to enforce the '781 Patent and seek damages for Geneoscopy's infringement.

49. The '781 Patent, which was filed on September 28, 2022 and claims priority to February 3, 2009, was issued only after its underlying application, and its parent applications, were thoroughly vetted against the prior art during prosecution by the USPTO. This was confirmed by a reexamination request made by Geneoscopy.

50. Specifically, on May 22, 2023, Geneoscopy filed an *Ex Parte* Reexamination Request against 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 (attached as **Exhibit C**), confirming the patentability of ***all*** the claims in the '781 Patent. Thus, Geneoscopy has already tried and failed to demonstrate unpatentability of the claims of the '781 Patent.

51. Independent claim 1 of the '781 Patent reads:

> A method of processing a freshly-collected fecal sample without freezing, the method comprising:
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> a) collecting a fecal sample from a human subject, wherein the fecal sample is collected at home by the human subject by defecation directly into a sealable collection vessel;

b) removing a portion of the fecal sample to a separate sealable container to produce a removed portion and a remaining portion of the fecal sample;

c) combining the removed portion of the fecal sample in the separate sealable container with a buffer that prevents denaturation or degradation of blood proteins found in a fecal sample, and sealing the sealable container; and

d) combining the remaining portion of the fecal sample in the sealable collection vessel with a stabilizing buffer, and sealing the sealable collection vessel.

52. Claim 3 of the '781 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 container containing a removed portion of a fecal sample and a buffer; and
ii) a sealed sealable collection vessel containing a remaining portion of a fecal sample and a stabilizing buffer,
the pair of portions obtained by the method of claim 1;

b) testing the removed portion of the fecal sample for an amount of a blood protein present in the removed portion;

c) extracting nucleic acid from the remaining portion of the fecal sample; and

d) testing the nucleic acid for an amount of a human nucleic acid.

53. The '781 Patent is directed to clinically important methods of processing fecal samples that enable, among other things, "mass screening of asymptomatic patients" for CRC.[15] 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 analysis of the biomarkers in a laboratory.[16] The fecal sample is collected in two portions, a first

[15] '781 Patent (**Exhibit A**) at 1:51-55.

[16] *See, e.g.*, *id.* at 17:22-18:67.

portion removed to a sealable container containing a buffer that prevents denaturation or degradation of blood proteins, and a second portion combined with a stabilization buffer in a sealable collection vessel.[17]

54. 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.

55. The claims of the '781 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 '781 Patent claims, 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.

56. As referenced above, Exact Sciences' Cologuard test practices the '781 Patent 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).

57. By providing a sensitive, specific, and non-invasive screening option that implements the '781 Patent's technology for collecting samples for two separate testing methods

[17] *See, e.g.*, *id*.

in a reliable fashion, the Cologuard test has helped many of its millions of users avoid the devastating impact of CRC.

GENEOSCOPY'S INFRINGING ACTS

A. Geneoscopy developed CRC screening products designed to infringe the '781 Patent

58. Geneoscopy was founded in 2015, 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 in 2014.

59. 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"). 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.

60. 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 '781 Patent. Geneoscopy's ColoSense uses an RNA (nucleic acid) biomarker panel, along with a test component that detects the presence or absence of blood protein in the stool, similar to the DNA biomarker-based Cologuard test.

61. On information and belief, Geneoscopy has infringed, continues to infringe, and will infringe the '781 Patent, directly or indirectly, by developing, making, using, marketing, offering for sale, selling, or importing Geneoscopy's CRC screening products and/or services in

the United States, and/or contributing to and/or inducing others to use the same in an infringing manner in the United States, as illustrated below.

62. On information and belief, Geneoscopy has commercially marketed, used, offered for sale, and sold the ColoSense test as a commercial laboratory developed test, or LDT, in or around July 2023. In particular, at that time, Geneoscopy made a dedicated product webpage for its at-home CRC screening test under the commercial name "ColoSense."[18] This webpage advertised that "ColoSense is indicated for individuals 45 years and older, at average risk for colorectal cancer." The webpage also stated that ColoSense was available in 49 states (NY state lab certification pending). The webpage included a link to download an order form for the ColoSense test, titled "CRC Screening Test Requisition Form." The order form was available as recently as November 16, 2023, offering to commercially sell the ColoSense test.[19]

63. Geneoscopy has continued its infringement of the '781 Patent at least through its widespread commercial marketing and promotion of ColoSense, including its commercial offer for sale of the ColoSense test through, for example, the ColoSense order form posted on its company website. The order form for ColoSense does not include any statement that the test has not been cleared or approved by FDA. The order form collects patient information, provider information, and patient insurance information, and also requests patient authorization to bill their insurance for Geneoscopy's ColoSense test. In addition, although the doctor's information and signature are required, the order form appears to be directed to patients, as it is to be completed and signed by the patient.

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

[19] https://www.geneoscopy.com/wp-content/uploads/Test-Requisition-Form-LBL-TD-0007v1.pdf, attached hereto as **Exhibit G**.

64. In addition to these past and ongoing infringing activities, Geneoscopy will infringe the '781 Patent by commercially marketing, manufacturing, using, offering for sale, and selling its ColoSense test to the general public upon FDA approval in the imminent future. In recent public announcements, Geneoscopy disclosed its intention and meaningful preparations to commercially launch the ColoSense test widely to millions of patients immediately upon FDA approval. These public announcements and preparations for large-scale commercial launch of ColoSense came on the heel of the recent publication of Geneoscopy's clinical study on ColoSense in October 2023.

65. 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.[20] This clinical trial is also known as the CRC-PREVENT trial. On January 24, 2023, Geneoscopy announced that it submitted a PMA application to the FDA "for its noninvasive, stool-based, at-home screening test to detect colorectal cancer (CRC) and advanced adenomas (AA) in average-risk individuals."[21]

66. Also, 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."[22] This unique Z-code for ColoSense paved the path for Geneoscopy to commercially market, offer for sale, and sell its test 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

[20] https://clinicaltrials.gov/study/NCT04739722?term=colosense&rank=1.

[21] https://www.geneoscopy.com/geneoscopy-submits-premarket-approval-application-to-fda-for-its-noninvasive-colorectal-cancer-rna-biomarker-screening-test/.

[22] https://www.geneoscopy.com/geneoscopy-receives-z-code-from-palmetto-gba-for-its-noninvasive-multi-target-stool-rna-colorectal-cancer-screening-test/.

> 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.

67. On October 23, 2023, Geneoscopy published results from its CRC-PREVENT clinical trial on ColoSense in *JAMA*.[23] A true and correct copy of the *JAMA* paper is attached hereto as **Exhibit D**. A true and correct copy of the *JAMA* paper supplemental content is attached hereto as **Exhibit E**.

68. In an October 23, 2023 press release about the *JAMA* publication, Geneoscopy claimed that its ColoSense test has the "highest sensitivity" for detecting CRC among available noninvasive screening tests.[24] Then, in a November 2023 interview, Geneoscopy's Chief Science Officer, Erica Barnell, disclosed that Geneoscopy has submitted CRC-PREVENT study results to the FDA to support its PMA application for ColoSense, and it expected a decision from the FDA in the imminent future.[25]

69. In this November 2023 interview, Geneoscopy's CSO, Erica Barnell, "described the multitarget stool RNA 'ColoSense' test and the CRC-PREVENT study."[26] Dr. Barnell stated:

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[23] https://www.geneoscopy.com/gastrointestinal-health/colorectal-cancer-screening/.

[24] 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/.

[25] https://www.geneoscopy.com/noninvasive-multitarget-stool-rna-test-proves-sensitive-for-colorectal-cancer-advanced-adenomas/.

[26] https://www.geneoscopy.com/noninvasive-multitarget-stool-rna-test-proves-sensitive-for-colorectal-cancer-advanced-adenomas/.

> **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 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.

70. Most recently, 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. 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."[27] In the press release, Geneoscopy's Chief Commercial Officer 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.

71. On November 15, 2023, Medical Device Network published an online news article regarding the multi-year agreement between Geneoscopy and LabCorp.[28] 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.

72. 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, shows that Geneoscopy has purchased products such as "Salesforce Health Cloud, Salesforce Maps with Territory Planning, Salesforce Marketing Cloud, Salesforce Experience

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[27] https://www.geneoscopy.com/geneoscopy-signs-multi-year-agreement-with-labcorp-to-distribute-noninvasive-multi-target-stool-rna-mt-srna-colorectal-cancer-screening-test/.

[28] https://www.medicaldevice-network.com/news/geneoscopy-labcorp-colorectal-cancer-test/?cf-view.

Cloud, Salesforce Shield, Conga, and Integration."[29] Geneoscopy hired Copper Hill Consulting because "Geneoscopy is 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."[30]

73. Additionally, in a job posting Geneoscopy is currently advertising, it seeks 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 "leads execution of detailed new product launch plans."[31]

74. These public announcements regarding, and extensive and meaningful preparations for, post-FDA commercial launch demonstrate that (1) Geneoscopy has submitted the recently published data from the CRC-PREVENT study to the FDA to support its pending PMA application for ColoSense; (2) Geneoscopy is expecting a decision from the FDA imminently within the next three months; (3) Geneoscopy has engaged consulting firms such as Copper Hill Consulting to prepare for commercial sale of its ColoSense test; (4) Geneoscopy has signed a multi-year deal with LabCorp that will allow Geneoscopy to widely distribute and commercialize ColoSense to reach hundreds of millions of patients in the United States immediately upon FDA approval; (5) Geneoscopy plans to commercially launch ColoSense at a large scale upon imminent FDA approval to directly compete with Exact Sciences' Cologuard test; and (6) Geneoscopy has already

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29 https://www.copperhillconsulting.com/2023/08/09/customer-story-geneoscopy.

30 *Id.*

31 https://geneoscopy.isolvedhire.com/jobs/1016799 (job posting also available on LinkedIn).

begun recruiting new hires for the specific purpose of rolling out the commercial marketing and sale of ColoSense.

75. Geneoscopy has its own CLIA-certified laboratory in the United States that has performed or will perform one or more of the Accused Products.[32] As noted on its company website, Geneoscopy's laboratory is CLIA accredited and CAP certified. Geneoscopy also holds several state licenses.

76. Upon receiving FDA approval, Geneoscopy will commercially market its infringing non-invasive stool sample-based test for CRC screening.

77. Geneoscopy has been, and will be, a direct competitor of Exact Sciences in the market for non-invasive stool sample-based test for CRC screening.

78. Geneoscopy's past, ongoing, and imminent future post-FDA approval commercial infringing activities are unrelated 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 '781 Patent and that its conduct infringed the '781 Patent

79. Geneoscopy knew or should have known of the inventions claimed in the '781 Patent since the issuance of the '781 Patent on April 25, 2023.

80. Geneoscopy has had actual knowledge of the '781 Patent since at least May 1, 2023. Geneoscopy has also known that its commercial activities relating to ColoSense have infringed, are infringing, and will infringe one or more claims of the '781 Patent, directly or indirectly, at least since May 1, 2023. Geneoscopy has acted with a specific intent to induce others to infringe the '781 Patent at least since May 1, 2023.

[32] https://www.geneoscopy.com/about-us/our-lab-and-our-credentials/.

81. On May 1, 2023, Exact Sciences sent a notice letter by email to Geneoscopy's CEO, Andrew Barnell, identifying Geneoscopy's ColoSense test as infringing multiple claims of the '781 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.

82. Rather than respecting Exact Sciences' patent rights, three weeks later, Geneoscopy immediately requested *ex parte* reexamination of the '781 Patent at the USPTO on May 22, 2023, based on numerous combinations of ten 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.

83. 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 asserts that Geneoscopy disagrees with Exact Sciences' accusation of infringement, it provides no basis for that assertion. The letter also does not dispute Geneoscopy's "commercial and non-exempt research use" of ColoSense. The response letter contends 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.

84. 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 C**.

85. 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.

86. 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, repeating 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—asserting 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.

C. Geneoscopy's Accused Products, including ColoSense

87. 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, or (2) induce others to apply, Exact Sciences' patented methods for processing a stool or fecal sample, 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.

88. Geneoscopy's Accused Products use stool samples that are collected applying the methods claimed in the '781 Patent (*e.g.*, claim 1 and 2). Geneoscopy's Accused Products process such stool samples applying the methods claimed in the '781 Patent (*e.g.*, claim 3 and its dependent claims).

89. As provided in more detail below, each element of at least one claim of the '781 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.

90. 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 has infringed, continues to infringe, and will infringe claims 1 and 2, directly and indirectly

91. Geneoscopy has directly infringed, and/or induced others to infringe, and/or contributed to the infringement of, claims 1 and 2 of the '781 Patent, literally or under the doctrine of equivalents. For example, Geneoscopy provides instructions to users of its Accused Products to carry out the steps of claims 1 and 2 in the United States. Geneoscopy also makes, uses, sells, offers for sale, or imports 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 has infringed, continues to infringe, and will infringe claims 1 and 2 of the '781 Patent, directly and indirectly.

92. As discussed *supra*, Geneoscopy has had actual knowledge of the '781 Patent since at least May 1, 2023. As also discussed *supra*, Geneoscopy had known and specifically intended that its actions, including providing instructions to users of its Accused Products or to others, induce actual infringement of the '781 Patent, since at least May 1, 2023.

93. Geneoscopy's knowledge of the '781 Patent and its infringement of that patent, as discussed *supra*, also demonstrate 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 '781 Patent and are not staple articles or commodities of commerce suitable for substantial non-infringing use.

94. For example, Section 5 of the *JAMA* paper supplemental content (**Exhibit E**) 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").

95. On information and belief, Geneoscopy has provided and is providing the same or substantially the same instructions as those described Section 5 of the *JAMA* paper supplemental content, to users of its ColoSense test, including the ColoSense test that Geneoscopy has marketed, used, offered for sale, and sold as a commercial LDT in 2023.

96. On information and belief, Geneoscopy will provide the same or substantially the same instructions as those described Section 5 of the *JAMA* paper supplemental content, to users of its ColoSense test upon FDA approval of the ColoSense test in the imminent future. Geneoscopy has applied for FDA regulatory approval of its ColoSense test based on the clinical trial described in the *JAMA* paper that was conducted using the testing protocol described in Section 5 of the *JAMA* paper supplemental content.

97. Attached as **Exhibit F** is a preliminary and exemplary claim chart describing Geneoscopy's direct or indirect infringement of claim 1 of the '781 Patent. The claim chart is not intended to limit Exact Science' 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 '781 Patent or any other patents. Geneoscopy infringes, and will imminently infringe, more than one claim of the '781 Patent. **Exhibit F** is hereby incorporated by reference in its entirety.

98. As described *supra*, Geneoscopy knows that the practice of the ColoSense product technology, as described in the instructions to patients and other users, infringes the claims of the '781 Patent. The text of the instructions, which follow the methods steps of the '781 Patent claims, demonstrates that Geneoscopy has both knowledge and specific intent that the patients and other users infringe the claims of the '781 Patent.

99. It is also expected that discovery will likely reveal additional evidentiary support that Geneoscopy performs, and/or induces others to perform, and/or contributes to the performance of, the limitations of claims 1 and 2 of the '781 Patent.

100. As discussed *supra*, Geneoscopy's actions are egregious and beyond typical infringement. Geneoscopy could not have reasonably or subjectively believed that its actions did not constitute infringement of the '781 Patent, particularly in light of the notice provided by Exact Sciences and Geneoscopy's failed reexamination challenge. Nor could Geneoscopy reasonably or subjectively believe that the '781 Patent is invalid.

101. By its actions, Geneoscopy's infringement of the '781 Patent has irreparably harmed Exact Sciences. Unless Geneoscopy's infringing acts are enjoined by this Court, Exact Sciences will continue to suffer additional irreparable injury. Exact Sciences has no adequate remedy at law.

102. By its actions, Geneoscopy's infringement of the '781 Patent has damaged and continues to 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 has infringed, continues to infringe, and will infringe claim 3 and its dependent claims, directly and indirectly

103. Geneoscopy has directly infringed, and/or induced others to infringe, and/or contributed to the infringement of, at least claims 3-4 and 12-19 of the '781 Patent, literally or under the doctrine of equivalents. For example, Geneoscopy performs, and/or instructs others to perform, the methods of the '781 Patent in the United States. Geneoscopy also makes, uses, sells, offers for sale, and/or imports kits or 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 has infringed, continues to infringe, and will infringe at least claims 3-4 and 12-19 of the '781 Patent, directly and indirectly.

104. As discussed *supra*, Geneoscopy has had actual knowledge of the '781 Patent since at least May 1, 2023 and has known and specifically intended that its actions, including providing instructions to others, induce actual infringement of the '781 Patent, since at least May 1, 2023.

105. Geneoscopy's knowledge of the '781 Patent and its infringement of that patent, as discussed *supra*, also demonstrate 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 '781 Patent and are not staple articles or commodities of commerce suitable for substantial non-infringing use.

106. On information and belief, Geneoscopy has used and is using the same or substantially the same protocols as those described Section 5 of the *JAMA* paper supplemental content, to process and analyze stool samples for its ColoSense test, including the ColoSense test that Geneoscopy has marketed, used, offered for sale, and sold as a commercial LDT in 2023.

107. On information and belief, Geneoscopy will use the same or substantially the same protocols as those described Section 5 of the *JAMA* paper supplemental content, to process and analyze stool samples for its ColoSense test upon FDA approval of the ColoSense test in the imminent future. Geneoscopy has applied for FDA regulatory approval of its ColoSense test based on the clinical trial described in the *JAMA* paper that was conducted using the testing protocol described in Section 5 of the *JAMA* paper supplemental content.

108. Attached hereto as **Exhibit F** is a preliminary and exemplary claim chart describing Geneoscopy's direct or indirect infringement of claim 3 of the '781 Patent. The claim chart is not

intended to limit Exact Science' 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 '781 Patent or any other patents. Geneoscopy has infringed, and will imminently infringe, more than one claim of the '781 Patent. **Exhibit F** is hereby incorporated by reference in its entirety.

109. As described *supra*, Geneoscopy knows about the '781 Patent and knows that the practice of the ColoSense product technology, as described in the *JAMA* paper supplemental content, infringes the claims of the '781 Patent, directly or indirectly.

110. It is also expected that discovery will likely reveal additional evidentiary support that Geneoscopy performs, and/or induces others to perform, and/or contributes to the performance of, the limitations of at least claims 3-4 and 12-19 of the '781 Patent.

111. As discussed *supra*, Geneoscopy's actions are egregious and beyond typical infringement. Geneoscopy could not have reasonably or subjectively believed that its actions did not constitute infringement of the '781 Patent, particularly in light of the notice provided by Exact Sciences and Geneoscopy's failed reexamination challenge. Nor could Geneoscopy reasonably or subjectively believe that the '781 Patent is invalid.

112. By its actions, Geneoscopy's infringement of the '781 Patent has irreparably harmed Exact Sciences. Unless Geneoscopy's infringing acts are enjoined by this Court, Exact Sciences will continue to suffer additional irreparable injury. Exact Sciences has no adequate remedy at law.

113. By its actions, Geneoscopy's infringement of the '781 Patent has damaged and continues to 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: INFRINGEMENT OF U.S. PATENT NO. 11,634,781

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

115. Exact Sciences is the owner of the '781 Patent, which was duly and legally issued by the USPTO on April 25, 2023.

116. Geneoscopy has made, used, offered for sale, sold, and/or imported the Accused Products including its ColoSense product in the United States.

117. Geneoscopy continues to make, use, offer for sale, sell, and/or import the Accused Products including its ColoSense product in the United States.

118. Geneoscopy has infringed, and/or continues to infringe, at least one claim of the '781 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.

119. Geneoscopy has acted, and/or is acting, with the requisite knowledge and specific intent to induce others to infringe at least one claim of the '781 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.

120. Geneoscopy has acted, and/or is acting, with the requisite knowledge to contribute to the infringement of at least one claim of the '781 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 '781 Patent.

121. Geneoscopy's infringement has damaged and continues to 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.

122. Exact Sciences has suffered and continues to suffer irreparable harm with no adequate remedy at law unless this Court enjoins Geneoscopy from directly infringing, inducing infringement, and/or contributing to infringement of the '781 Patent.

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

124. Geneoscopy's infringement has been and continues to be deliberate, willful, and unlicensed, justifying an award of enhanced damages under 35 U.S.C. § 284.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,634,781

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

126. Geneoscopy's imminent offer for sale, sale, distribution, manufacture, use and/or importation in the United States of the Accused Products including its ColoSense product in the United States will infringe the '781 Patent under one or more subsections of 35 U.S.C. § 271 in the United States.

127. Geneoscopy will infringe at least one claim of the '781 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.

128. Geneoscopy will act with the requisite knowledge and specific intent to induce others to infringe at least one claim of the '781 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.

129. Geneoscopy will act with the requisite knowledge to contribute to the infringement of at least one claim of the '781 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 '781 Patent.

130. 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.

131. Exact Sciences will suffer irreparable harm with no adequate remedy at law unless this Court enjoins Geneoscopy from directly infringing, inducing infringement, and/or contributing to infringement of the '781 Patent.

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

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

134. 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 '781 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:

135. A judgment that Geneoscopy has infringed and is infringing the ’781 Patent;

136. A judgment that Geneoscopy has actively induced and contributed to infringement, and is actively inducing and contributing to infringement, of the ’781 Patent;

137. A judgment declaring that Geneoscopy’s manufacture, use, sale, offer for sale, or importation into the United States of the Accused Products upon FDA approval will infringe the ’781 Patent;

138. A judgment declaring that Geneoscopy’s manufacture, use, sale, offer for sale, or importation into the United States of the Accused Products upon FDA approval will actively induce and contribute to infringement of the ’781 Patent;

139. 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 ’781 Patent;

140. 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 ’781 Patent;

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

142. A determination that Geneoscopy’s infringement of the ’781 Patent has been willful;

143. An award of treble damages for Geneoscopy's willful infringement of the '781 Patent;

144. 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;

145. Costs and expenses that Exact Sciences incurred in this action;

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

147. 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

/s/ Jack B. Blumenfeld

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