

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENEOSCOPY, INC.,
Petitioner,

v.

EXACT SCIENCES CORPORATION,
Patent Owner.

Case No: IPR2024-00459
U.S. Patent 11,634,781

DECLARATION OF PETER WOOD

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1. I, Peter Wood, have personal knowledge of the following facts or believe them to be accurate based upon information provided to me by others and a reasonable investigation. If called upon, I would testify that the below is true and correct to the best of my knowledge.

I. BACKGROUND

2. I have been employed by Exact Sciences Corporation (“Exact Sciences”) since May of 2012. When I first joined Exact Sciences in 2012, I was hired as the Director of Global Product Marketing. Since then I have had roles in Cologuard® sales, sales management, new business development, and pipeline product development. Currently, I am Vice President of Screening Portfolio Strategy, a position I have held since August 2023. In this role, I support the delivery of Exact Sciences’ screening product portfolio to customers (patients, physicians, and researchers from both private medicine and academia), and coordinate all of the functions (e.g., research and development, operations and manufacturing, market access, regulatory affairs, etc.) related to the successful delivery of Exact Sciences’ colorectal cancer (“CRC”) screening business, including the breakthrough Cologuard products for non-invasive CRC screening. I work regularly with other teams within Exact Sciences, including with those responsible for Exact Sciences’ Cologuard products, their clinical validation, commercialization, financials, and strategy and execution of bringing non-invasive CRC screening products to

customers (patients, physicians, and researchers from both private medicine and academia).

3. I am knowledgeable about the development, clinical validation, marketing, and sales of Cologuard products. I am also knowledgeable about trends in demand for non-invasive CRC screening tests, and the factors that impact that demand. I am knowledgeable about industry trends in general but also specifically about the non-invasive CRC screening market.

4. On May 3, 2024, Geneoscopy obtained FDA approval for ColoSense™, which is a non-invasive CRC screening test that is positioned to directly compete with Exact Sciences' Cologuard products. The FDA's approval notification to Geneoscopy is available on the FDA's website at the below link and a true and correct copy is marked as Exhibit 2030:

https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230001A.pdf.

II. COLOGUARD PRODUCTS

5. Exact Sciences is a diagnostics company that was founded in 1995 and today specializes in cancer screening, detection, and treatment guidance. It was founded to develop a non-invasive screening test for CRC and in 2014 launched Cologuard, which was the world's first FDA-approved non-invasive stool-based CRC screening test that detects blood and nucleic acid biomarkers. Cologuard is a stool DNA (sDNA) informed CRC screening test that uses a biomarker panel which

analyzes a person's stool sample for 10 DNA biomarkers, as well as for blood in the stool. Exact Sciences co-developed Cologuard with the Mayo Clinic, and following the FDA's approval of Cologuard, the Mayo Clinic was the first health system to offer Cologuard.

6. Cologuard's multi-marker approach to CRC screening is one of its main distinguishing features. Before Cologuard, there were no FDA-approved non-invasive nucleic acid diagnostic CRC screening tests at all. With Cologuard, Exact Sciences delivered a revolutionary product that addressed a major unmet need for a CRC screening test that was more convenient than colonoscopy and offered improved performance compared to the other available non-invasive CRC screening options – fecal immunochemical test (FIT) and guaiac-based fecal occult blood test (gFOBT). From the time of its launch in 2014 through the beginning of 2024, Cologuard was the only FDA-approved non-invasive stool-based blood and nucleic acid CRC screening test available in the United States.

7. Cologuard was developed to provide a convenient and accurate, non-invasive home testing option for those at average risk of CRC. It solved at least two problems, both of which often prevented or discouraged people from participating in CRC screening. First, it is essentially a laboratory in a box that enables a patient to collect a sample without medical supervision, thereby avoiding the need for the patient to visit the doctor's office to provide a sample. The ease of use of Cologuard

helped to increase the number of patients who screen for CRC. Second, it preserves the integrity of genetic material as well as blood protein in the stool sample, without requiring conventional freezing processes, for a sufficient amount of time for the patient sample to be shipped to a laboratory via common mail carrier. This avoids the breakdown of nucleic acids and blood protein so that testing can be successfully performed several days after the sample is collected.

8. Cologuard's launch was preceded by and built upon many years of research and development. After more than a decade of research and investment, in April 2014 Exact Sciences published results from the DeeP-C Study in the *New England Journal of Medicine*, which reported on clinical outcomes of Cologuard across 90 sites and 10,000 patients. The head-to-head DeeP-C study compared the performance of Cologuard against an independent FIT test in order to demonstrate the safety, efficacy, and superiority of Cologuard, which created a new market segment/category of CRC screening tests. The results of the DeeP-C study were reported by Imperiale *et al* in an article published in the New England Journal of Medicine in 2014. *See Multitarget Stool DNA Testing for Colorectal-Cancer Screening*, 370(14) N. Eng. J. Med., 1287, 1287–1297 (2014) (Ex. 2008). Based on the results of the DeeP-C Study, the FDA approved Cologuard in August 2014 for individuals aged 50 and over with a healthcare provider's recommendation. The results of the DeeP-C study enabled Exact Sciences to obtain coverage for

Cologuard, and also contributed to convincing physicians to switch from FITs to the superior Cologuard test. In September 2019, the original PMA was reconsidered by the FDA, which resulted in amended approval for Cologuard for individuals aged 45 or older.

9. Exact Sciences' sales and marketing of the Cologuard test focuses on the two critical elements of efficacy and ease of use. Both are necessary for this diagnostic screening test that requires a physician prescription and at-home compliance by the user. Exact Sciences' focus is highlighted by its educational marketing materials which both discuss studies showing diagnostic accuracy of the test and describe ease of use. The Cologuard Patient Guide, Patient Brochure and Physician Brochure also describe and emphasize the ease of at-home collection and the efficacy of the Cologuard test. These documents are part of the Cologuard product information and earlier versions of these documents are accessible on the FDA website at https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130017c.pdf. A true and correct copy of the Cologuard product information downloaded from https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130017c.pdf is submitted herewith as Exhibit 2032.

10. Colonoscopy, Cologuard, and FIT are all guideline recommended by the United States Preventive Services Task Force ("USPSTF"). Cologuard is intended as a screening test. If a patient receives a positive (abnormal) Cologuard result, the

patient should follow up with a diagnostic colonoscopy to complete the screening process. Colonoscopy is an invasive procedure that requires diet changes and colon cleansing prior to execution, sedation during execution, and that must be performed in a healthcare facility. The burdens associated with colonoscopy often cause patients who are recommended to conduct CRC screening to avoid actually doing so. Cologuard is a non-invasive CRC screening test that does not require any dietary changes or colon cleansing and can be performed at home by the patient. Thus, Cologuard provides an easier, yet highly effective, screening option for patients that increases the likelihood that patients will follow screening recommendations.

11. Cologuard also offers several advantages over FIT, which is the other major non-invasive screening option. In particular, Exact Sciences demonstrated through its head-to-head study that Cologuard has superior sensitivity as compared to FIT. Moreover, Cologuard is recommended every three years, whereas FIT is recommended annually. Thus, relative to FIT, Cologuard requires less frequent testing for patients and patients are more likely to comply with testing recommendations.

12. Since 2014, Cologuard's prognostic and predictive qualities have been validated repeatedly in clinical studies, with over 90 peer-reviewed publications on Cologuard and many more studies in the clinical pipeline. This growing clinical

evidence supports the strong utility of non-invasive molecular diagnostic CRC screening tests in clinical practice and in clinical research.

A. Exact Sciences' Investments In Cologuard Products

13. Even after obtaining FDA approval for Cologuard, it took many years to gain widespread recognition and adoption of Cologuard among the relevant community. Exact Sciences has dedicated substantial resources to successfully establish Cologuard as the market leader in non-invasive CRC screening. For instance, between 2009 and the end of 2023 Exact Sciences spent over \$3.6 billion to develop, test, validate, obtain regulatory approval, obtain insurance coverage, market, and/or commercialize Cologuard and its new Cologuard Plus product. This investment includes over \$290 million in research and development and over \$3 billion in sales and marketing, which costs have included extensive education efforts concerning the need for CRC screening generally as well as the advantages and availability of the Cologuard test in particular as a new option for CRC screening as discussed below.

14. Following the FDA's approval of Cologuard, the Centers for Medicare & Medicaid Services ("CMS") issued a National Coverage Determination ("NCD") for Cologuard in October 2014. Cologuard was the first medical device to receive FDA approval and a final NCD as part of a parallel review process. The NCD for Cologuard established a new category of CRC screening tests for screening stool or

fecal DNA and provided that Medicare insurance would cover Cologuard once every three years for eligible patients. Obtaining coverage for a new type of CRC screening product was a monumental endeavor and involved great efforts to obtain certain needed recognition and recommendations for the new class of device that Cologuard represented.

15. In 2016, as a direct result of Exact Sciences' efforts, the USPSTF recognized "stool DNA test with fecal immunochemical test" in its Grade A recommendation for adults aged 50 to 75, and its Grade B recommendation for adults aged 45-49. Because Cologuard was an entirely new type of CRC screening test, it was a significant undertaking for Exact Sciences to generate the data that USPSTF used to inform these new recommendations. Indeed, it was a several-years-long effort for Exact Sciences to prepare the results that led to the USPSTF's recognition of "stool DNA test with fecal immunochemical test" in its recommendations. Today, Cologuard is covered by all major commercial insurers.

16. In order to combat low patient adherence to CRC screening, Exact Sciences has also developed and employs a bespoke customer care team to actively engage both providers and patients using various communications media to ensure patients carry out provider-ordered Cologuard screenings. There is a growing importance for such patient navigation services given the other CRC screening options available to patients. These services are included in the price of Cologuard,

and Exact Sciences imposes no additional charges for providing these services to patients. We also undertake substantial efforts on a daily basis to educate providers and patients about the differences between CRC screening options and the specific benefits of Cologuard products, which we believe to be critical to furthering adherence to CRC screening recommendations.

17. Because of the extensive investments and the proprietary technology obtained during the course of development, Exact Sciences has become the leader in the U.S. non-invasive CRC testing space. Cologuard use grew from approximately 4 thousand tests in 2014, to over 4 million tests in 2023. Exact Sciences has also assembled a sales force of over 1,000 individuals who are focused exclusively on Cologuard products.

18. To protect its significant investment in its innovative products, Exact Sciences has sought and obtained many patents protecting Cologuard, including the '781 patent at issue in this case.

B. Industry Praise for Exact Sciences and the Cologuard Product

19. Exact Sciences has received numerous awards for the innovative work on Cologuard. These awards have included the *Everyday Health Award for Innovation*, the *Wisconsin Innovation Award*, and the *Prix Galien Award* for the best medical technology product discussed below.

20. Exact Sciences has issued press releases upon receipt of industry awards. True and accurate copies of those press releases are available at the Exact Sciences website and true and correct copies have been downloaded and submitted in connection with Exact Sciences' Patent Owner response as discussed below.

21. By press release dated October 28, 2016, Exact Sciences announced receipt of the prestigious Prix Galien USA Award for best medical technology product in 2016. That press release is available at <https://www.exactsciences.com/newsroom/press-releases/exact-sciences-cologuard-wins-prestigious-prix-galien-award>. A true and correct copy of that press release is submitted herewith as Exhibit 2042.

22. In addition, in 2014, the year Cologuard received FDA approval, the Cologuard test won a "Best of What's New" award from Popular Science. Exact Sciences announced receipt of that reward on its website, available at <https://www.exactsciences.com/newsroom/press-releases/cologuard-wins-popular-science-magazines-2014-best-of-whats-new-award>. A true and correct copy of that press release is submitted herewith as Exhibit 2043.

23. In January of 2015, the Cologuard test won an Everyday Health Award for Innovation as set forth in a press release by Everyday Health, Inc. that is available at <https://www.prnewswire.com/news-releases/everyday-health-awards-for->

[innovation-winners-announced-at-2015-international-ces-300017454.html](https://www.exactsciences.com/newsroom/press-releases/wisconsin-innovation-winners-announced-at-2015-international-ces-300017454.html). A true and correct copy of that announcement is submitted herewith as Exhibit 2044.

24. As further recognition, the Cologuard test was also awarded a Wisconsin Innovation Award (WIA) in the “Healthcare/Health IT” category in 2015. *Id.* Exact Sciences’ announcement of that award is available on its website at <https://www.exactsciences.com/newsroom/press-releases/wisconsin-innovation-award-2015>. A true and correct copy of that announcement is submitted herewith as Exhibit 2045.

25. In 2016, Exact Sciences received the Business Intelligence Group’s 2016 Company of the Year BIG Award for Business in the Health Care category. The Exact Sciences announcement concerning that award is available at <https://www.exactsciences.com/newsroom/press-releases/2-years-since-cologuards-fda-approval-0>. A true and correct copy of that announcement is submitted herewith as Exhibit 2046.

26. I was employed by Exact Sciences when it received each of these awards and I was personally aware at the time of these awards. At the time that Exact Sciences received each of the awards that I discuss above, the Cologuard test was Exact Sciences’ only product.

III. THE NON-INVASIVE CRC SCREENING MARKET

27. The non-invasive CRC screening market is still growing and has massive potential. The unscreened market remains very large, with around 50% of the patient market—roughly 44 million people—remaining unscreened. Due to the size of the unscreened patient market, Cologuard competes with the “no screening” option just as much as it competes with other CRC screening tests on the market.

28. The CRC screening market is a highly complex and dynamic market, often characterized by uncertainty and unknowns.

29. Exact Sciences has learned that the available CRC screening tests compete on ease of use just as much as (or in some cases, more so than) they compete on accuracy and performance. Providers are highly influential in determining which CRC screening test a patient completes, or if they complete any test at all. Due in part to low patient compliance rates, provider dynamics are unique in the CRC screening market as they often favor convenience and likelihood of patient compliance over accuracy and performance. All else being equal, providers would rather have patients get screened in some way than not at all. That is, in the interest of convenience and certainty that the test will actually be performed, providers may suggest a test that is more likely to be completed even though it may not be as accurate as other options.

30. Adding another level of complexity to the CRC screening market, each healthcare provider has a unique understanding—and sometimes a substantial lack of understanding—of the accuracies and performance of the available test options and the differences between them. For example, patients and providers often lack depth of knowledge regarding how performance data was computed for each test, and likewise lack an appreciation for statistical quality differences that exist between clinical performance data across CRC screening methods. Consequently, a provider or patient may prefer one test over another based on that test having a higher reported performance measure in an area that is meaningful to the provider or patient. In making a selection among CRC screening tests, however, the provider or patient may not realize that the performance data reported for their selected test was actually based on different or less robust clinical data. Indeed, most healthcare providers prescribing CRC screening tests are primary care physicians—not gastroenterology specialists—and often lack the background and depth of product knowledge to appreciate the nuanced differences between products. Moreover, each provider may have individual relationships with phlebotomy labs, gastrointestinal physicians, and other resources that he or she has come to know and trust (or, in some cases, distrust), all of which influence which CRC screening method they suggest to patients. A provider’s understanding (or lack of understanding) of performance differences across products, coupled with the resources at the provider’s disposal, can heavily

influence demand for some tests over others, even if that demand is not warranted by legitimate performance differences. This is particularly true where differences between tests are not obvious to providers and comparisons of performance across CRC screening tests are not necessarily apples-to-apples. For example, some providers do not know the difference between Cologuard and standard FIT tests and may confuse one for the other as they are both “non-invasive stool tests.” Others still may have no awareness at all that the majority of Cologuard’s benefit to morbidity and mortality is from pre-cancer detection. Consequently, educating providers and patients about the differences between CRC screening options and the specific benefits of Cologuard has been and continues to be critical.

31. To this end, Exact Sciences has engaged in significant educational efforts, which make up a substantial portion of Exact Sciences’ sales and marketing. Furthermore, it is critical to build and maintain trust with the medical community, through robust clinical evidence and careful marketing claims supported by the evidence. Exact Sciences has been careful to build that trust, through strong evidence and cautious marketing claims about its product, including to distinguish Cologuard from less reliable tests on the market such as the FIT tests. Without these efforts, there is a considerable risk that patients and providers may make a CRC screening selection that later results in missed expectations and a loss of trust in a particular modality.

32. Exact Sciences expended significant effort and capital to complete the head-to-head DeeP-C study comparing Cologuard against FIT in order to demonstrate the superiority of Cologuard's performance. That seminal study helped to establish a new market segment for multitarget stool-based blood and nucleic acid CRC screening tests. Now that the market has been created and has begun to mature, new entrants such as Geneoscopy may more easily align themselves with Cologuard products and may take advantage of Exact Sciences' efforts to establish the market segment by positioning their product, such as ColoSense, as a direct alternative to Cologuard.

33. For example, on Geneoscopy's recent NephronNext investor presentation in April 2024, it provided graphics to try to demonstrate to listeners that ColoSense has comparable performance to Exact Sciences' new Cologuard Plus product, and also referenced Cologuard's year-over-year growth in discussing the market opportunity for Geneoscopy's ColoSense product. The Geneoscopy investor presentation was accessed by Exact Sciences' personnel at <https://nephronnext.open-exchange.net/stream/531120>, a password protected link, in connection with an April 10, 2024 investor conference that was not specific to Geneoscopy. Exhibit 2029 is a true and correct copy of that Geneoscopy investor presentation, with a caption header from the district court litigation between Exact Sciences' and Geneoscopy.

IV. EXACT SCIENCES' CRC SCREENING DEVELOPMENT AND COLOGUARD SALES

34. CRC screening volumes are the primary driver of Exact Sciences' annual revenues and have been since the introduction of the Cologuard test.

35. Exact Sciences' SEC filings, which can be accessed on the company website at <https://investor.exactsciences.com/investor-relations/financial-information/sec-filings/default.aspx>, reflect the importance of the Cologuard test as well as the continued, and increasing, success of the Cologuard test. Exhibits 2034 to 2040 are true and correct copies of Exact Sciences' form 10-Ks for the years 2004, 2008, 2014, 2016, 2018, 2021, and 2023, respectively.

36. Exact Sciences stated in its Form 10K for the year ending December 31, 2014, that for "the foreseeable future" Exact Sciences' "ability to generate revenue will depend entirely on the commercial success of Cologuard." Ex. 2036 at 15. The Cologuard test was Exact Sciences' only product at that time.

37. The Cologuard test remained Exact Sciences' only product for the years 2014 through 2018, and Exact Sciences' revenue for those years reflects the product's success: \$1,798,000 in 2014; \$39,437,000 in 2015; \$99,376,000 in 2016; \$265,989,000 in 2017; and \$454,462,000 in 2018. *See* Ex. 2038 at 16, 40. Although the Cologuard test is no longer Exact Sciences' only product, it remains the primary source of Exact Sciences' revenue. Based primarily on the success of the Cologuard

test, Exact Sciences' revenues have continued to grow from \$876,293,000 in 2019 to \$2,499,766,000 in 2023. *See* Ex. 2039 at 75; Ex. 2040 at 66.

38. Since Cologuard received FDA approval in 2014, Exact Sciences has successfully scaled up to support from just 4 thousand tests in 2014 to roughly 4 million tests in 2023. To date, Exact Sciences has fulfilled over 14 million orders for Cologuard screening tests. Exact Sciences' success with the Cologuard test is particularly noteworthy considering that, less than six years before FDA approval of the Cologuard test, Exact Sciences reported in its SEC form 10K that it was down to only four full-time employees. Ex. 2034 at 18.

39. In connection with use of the Cologuard test by patients, Exact Sciences, through a third-party vendor, sends a satisfaction survey to a randomized subset of patients who completed and returned their Cologuard test kit. One of the questions in the survey is "Have you screened for colon cancer in the past?" The results of the ongoing survey are kept in the regular course of business at Exact Sciences. I am familiar with how those results are kept. The survey consistently shows that approximately 40% of patients self-report that they had never screened for colon cancer prior to using the Cologuard test. For the twelve months from October 2023 through September 2024, 39.8 percent of reporting patients responded they had never screened for colon cancer in the past. A true and correct copy of a printout from the survey database showing the percent of "yes" and "no" patient responses is submitted

herewith as Exhibit 2041. Exact Sciences also includes information concerning these survey results in its SEC filings. For example, Exact Sciences' Form 10K for the year ending December 31, 2023 states that "[i]nternal studies have shown that approximately 40% of surveyed Cologuard users were previously unscreened for colorectal cancer." Ex. 2040 at 5.

40. Cologuard is undisputedly the leading product in the non-invasive CRC screening space, which is a testament to its significant clinical utility as well as to Exact Sciences' proficiency in scaling up complex diagnostics and laboratory testing as demand has increased over the years.

41. In signing this declaration, I recognize that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

42. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on the information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: 24 OCT 24



Peter Wood