IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

NATERA, INC., Plaintiff, v. NEOGENOMICS LABORATORIES, INC, Defendant.	)	C.A. No. 1:23-cv-629 **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Natera, Inc. ("Natera") submits this Complaint against Defendant NeoGenomics Laboratories, Inc. ("NeoGenomics Laboratories"), and alleges as follows:

OVERVIEW OF THE ACTION

1. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*, from Defendant's infringement of Natera's U.S. Patent Nos. 11,530,454 (the "'454 Patent") and 11,519,035 (the "'035 Patent") (collectively, "Asserted Patents").

THE PARTIES

2. Plaintiff Natera is a corporation organized and existing under the laws of the state of Delaware.

3. Founded in 2004, Natera (f.k.a. Gene Security Network) is a pioneering genetics and bioinformatics company with industry-leading healthcare products. Natera is dedicated to improving disease management for oncology, reproductive health, and organ transplantation. For well over a decade, Natera has been researching and developing non-

invasive methods for analyzing DNA in order to help patients and doctors manage diseases. These ongoing efforts have given rise to a number of novel and proprietary genetic testing services to assist with life-saving health management.

4. Natera's pioneering and ongoing innovation is especially evident in the area of cell-free DNA ("cfDNA")-based testing. In the cfDNA field, Natera has developed unique and highly optimized cfDNA-based processes that can be used to test non-invasively for a range of conditions. Natera created an industry-leading cfDNA test, Panorama, which showcases Natera's mastery of cfDNA in the field of non-invasive prenatal testing. Natera has also applied its cfDNA testing platform to the challenge of assessing cancer. Natera has developed its cfDNA technology for approval in the clinical setting in order to provide patients with tools for early, clinically meaningful cancer assessment. Natera was awarded approval for coverage by Medicare for multiple indications.

5. In detecting and monitoring cancer, the use of non-invasive, blood-based tests offers significant advantages over older methods, such as invasive tumor biopsy. But the significant technological challenge is that such blood-based testing requires the measurement of very small amounts of relevant genetic material—circulating-tumor DNA ("ctDNA")—within a much larger blood sample. Natera's approach combines proprietary molecular biology and computational techniques to measure genomic variations in tiny amounts of DNA, representing a fundamental advance in molecular biology.

6. Natera's cfDNA platform is the product of well over a decade of hard work and investment of, on average, more than fifty million dollars per year in research and development. Natera has expended substantial resources researching and developing its technologies and establishing its reputation among physicians, insurers, and regulators as a company committed to sound science and consistently accurate, reliable results. This research, and the technological innovations resulting therefrom, are protected by a substantial patent portfolio, with over 330 patents issued or pending worldwide, including greater than 60 in the field of oncology.

7. Among these patented inventions include the '454 Patent and the '035 Patent, each of which Defendant infringes. Defendant has used Natera's patented cfDNA technology without permission and in violation of the patent laws.

8. Defendant NeoGenomics Laboratories, Inc. is a corporation organized and existing under the laws of the State of Florida. Upon information and belief, NeoGenomics Laboratories, Inc. operates laboratories throughout the United States, including in Durham, North Carolina.

9. Upon information and belief, Defendant NeoGenomics Laboratories, Inc. is a corporate affiliate of both Inivata, Inc. and Inivata Ltd. (collectively, "Inivata"). Defendant NeoGenomics Laboratories, Inivata Inc., and Inivata Ltd. are each wholly-owned subsidiaries of parent corporation NeoGenomics, Inc.

10. Defendant operates under and identifies with the trade name "NeoGenomics" and "NeoGenomics Laboratories." Upon information and belief, Defendant directly or

indirectly makes, uses, offers to sell and/or sells in the United States an assay that infringes at least one valid claim of each of the Asserted Patents, including in the State of North Carolina and in this District, and otherwise purposefully directs activities to the same.

11. Instead of developing its own science for its cancer detection and monitoring products, Defendant has unlawfully used Natera's patented technology, including in connection with the RaDaR™ Minimum Residual Disease Assay and any other products or assays that use the same or similar technology (collectively, "RaDaR" or "Accused Assay").

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331 and 1338(a).

13. NeoGenomics Laboratories is subject to this Court's personal jurisdiction at least because it directs the operations of a CAP/CLIA-certified laboratory located in Durham, North Carolina. In addition, NeoGenomics Laboratories is subject to this Court's personal jurisdiction because, on information and belief, Defendant, directly or indirectly, designs, develops, makes, uses, offers for sale, and/or sells the Accused Assay throughout the United States and within this District. Defendant has infringed and continues to infringe Natera's patents in this District by, among other things, engaging in infringing conduct within and directed at or from this District and purposely and voluntarily placing its infringing assay into the stream of commerce with the expectation that the infringing assay will be used in this District.

14. Upon information and belief, venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, among other things, NeoGenomics Laboratories has a regular and established place of business in this District at its CAP/CLIA-certified laboratory located in Durham, North Carolina and has committed acts of infringement at this same location.

BACKGROUND

15. Since 2004, Natera has been a global leader in genetic testing, including cfDNA testing. Natera's mission is to improve the management of disease worldwide, and it focuses on reproductive health, oncology, and organ transplantation. To improve the management of these conditions, Natera has developed novel technologies to make significant and accurate clinical assessments from the miniscule amounts of cfDNA present in a single blood sample. These technologies include methods to manipulate cfDNA in nonconventional ways in order to capture information about genetic variations in cfDNA and usefully transform that information for noninvasive testing. Natera develops and commercializes innovative, non-traditional methods for manipulating and analyzing cfDNA, and offers a host of proprietary cfDNA genetic testing services to the public to assist patients and doctors in evaluating and tracking critical health concerns.

16. Since its founding, Natera has researched, developed, and released ten molecular tests with applications in prenatal, cancer, and organ transplants, many of which are available through major health plans, or covered by Medicare or Medicaid, and therefore available to most patients in need of those tests. Natera's tests have helped more

than four million individuals to date. Natera's robust laboratory now processes over 130,000 tests per month in the United States and internationally, improving the ability of physicians to monitor and manage crucial health issues and patients to prosper around the world.

17. Building on these innovations, in 2017, Natera launched its cfDNA test to detect and monitor cancer, called Signatera®. Signatera is a personalized ctDNA surveillance tool that detects molecular residual disease ("MRD") when assessing disease recurrence or treatment response in solid tumors. Signatera is designed to screen for multiple tumor-derived targets with each assay. It is optimized to detect extremely low quantities of ctDNA and provides early knowledge of disease recurrence with a >99.5% clinical test specificity.

18. MRD assessment has become a standard of care in the management of patients with hematological malignancies, but until recently it has not been possible in solid cancers due to technical limitations. Accurate MRD testing and molecular monitoring offers the potential for physicians to change or escalate treatment in patients who are MRD-positive, and to de-escalate or avoid unnecessary treatment in patients who are MRD-negative. It also holds potential as a surrogate endpoint in clinical trials.

19. Natera's technology has been validated in multiple clinical studies. In Cancer Research UK/University College London's Tracking Cancer Evolution through Therapy ("TRACERx"), Natera's technology was used for the multi-year monitoring of patient-specific single-nucleotide variants (SNVs) in plasma, to understand the evolution

of cancer mutations over time, and to monitor patients for disease recurrence. Results from the first 100 early-stage lung cancer patients analyzed as part of the study were featured on the cover of the May 2017 issue of Nature and showed that an early prototype version of Signatera identified 43% more ctDNA-positive early-stage lung cancer cases than a generic lung cancer panel and demonstrated its potential to detect residual disease, measure treatment response, and identify recurrence up to 11 months earlier than the standard of care, with a sensitivity of 93% at time of relapse.

20. The U.S. Food and Drug Administration ("FDA") recognized the importance of Natera's Signatera and has granted it three "Breakthrough Device" designations ("BDDs") for multiple cancer types. The first BDD was awarded on May 6, 2019 to help accelerate FDA assessment and review of Signatera as an *in vitro* companion diagnostic to a certain cancer therapy. In 2021, the FDA granted two additional BDDs covering new intended uses of the Signatera test to support its development through Phase III clinical trials as a companion diagnostic to different cancer therapies.

21. Natera not only developed the pivotal technology for personalized MRD testing, but has also invested considerable time and resources into developing the personalized cancer monitoring market. It has lobbied and convinced physicians, researchers, regulatory authorities and private payors on the feasibility of this new personalized cancer monitoring technology through extensive studies, which led Medicare to issue a draft Local Coverage Determination ("LCD") for Signatera in March 2019. In its draft LCD, Medicare determined that "[t]he analytical validity and clinical validity of

minimal residual disease testing using cell-free DNA, and Signatera in particular, appears to be well established based on available information for the test."

22. In addition, Signatera® achieved its first commercial policy coverage by Blue Cross and Blue Shield of Louisiana, effective January 1, 2023, which covers Signatera testing for plan members diagnosed with colorectal and muscle invasive bladder cancer and for pan-cancer immunotherapy monitoring. Additionally, effective March 1, 2023, Blue Shield of California, allows tumor-informed ctDNA testing with Signatera for patients with stage I-IV cancer to provide information for performing targeted therapy and/or monitoring for relapse or progression.

23. The clinical significance of Signatera has been acknowledged in over 40 peer-reviewed publications, including validation across multiple cancer types to detect recurrence earlier compared to standard diagnostic tools.[1] At the American Society of Clinical Oncology (ASCO) Annual Meeting held from June 2–6, 2023, Natera announced its new data on Signatera across a wide variety of cancers, including colorectal (CRC), lung, bladder, esophageal, pancreatic, melanoma, sarcoma and cholangiocarcinoma. The results highlight the signficance of Signatera among the oncology commnity as a platform to effectively use ctDNA to predict patient outcomes and assess treatment response for both common and rare cancers.

[1] Reinert T, et al. *Analysis of plasma cell-free DNA by ultradeep sequencing in patients with stages I to III colorectal cancer*. JAMA Oncol. 2019;5(8):1124–1131; Coombes RC, et al. *Personalized detection of circulating tumor DNA antedates breast cancer metastatic recurrence*. Clin Cancer Res. 2019;25(14):4255-4263.

24. Natera continues to be a global leader in cell-free DNA testing and was recognized among the top 10 most innovative health companies of 2022 for its development of Signatera.[2] Signatera was also a finalist of the Fierce Life Science Innovation Awards for Medical Device Innovation in 2021.[3] Signatera also won the 2021 MedTech Breakthrough Award for "Best New Technology Solution – Biopsy" in the medical device catetory.[4]

25. The Asserted Patents resulted from Natera's years-long research in developing innovative new methods for amplifying and sequencing cell-free DNA.

General Background of the Inventions

A. The '454 Patent

26. The '454 Patent, attached hereto as Exhibit 1, is entitled "Detecting Mutations and Ploidy in Chromosomal Segments" and issued from the USPTO on December 20, 2022. Natera owns the '454 Patent, including the right to enforce it and seek damages for infringement.

27. The '454 Patent claims methods for preparing plasma samples to detect ploidy of chromosome segments and single nucleotide variant ("SNV") mutations. The claimed methods perform whole genome sequencing of tumor samples and multiplex amplication of cfDNA isolated from plasma samples in order to detect SNV mutations. Independent claim 1 of the '454 Patent recites:

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[2] *See* Exhibit 27 at 2.
[3] *See* Exhibit 28 at 2.
[4] *See* Exhibit 29 at 5.

A method for preparing a plasma sample of a subject having cancer or suspected of having cancer or useful for detecting one or more single nucleotide variant (SNV) mutations in the plasma sample, the method comprising:

performing whole exome sequencing or whole genome sequencing on a tumor sample of the subject to identify a plurality of tumor-specific SNV mutations;

performing targeted multiplex amplification to amplify 10 to 500 target loci each encompassing a different tumor-specific SNV mutation from cell-free DNA isolated from a plasma sample of the subject or DNA derived therefrom to obtain amplicons having a length of 50-150 bases, wherein the target loci are amplified together in the same reaction volume; and

sequencing the amplicons to obtain sequence reads, and detecting one or more of the tumor-specific SNV mutations present in the cell-free DNA from the sequence reads, wherein the sequencing has a depth of read of at least 50,000 per target locus.

28. The claims of the ’454 Patent are not directed to an abstract idea, natural law, or natural phenomenon. Rather, they are directed to an innovative method of sample preparation comprising both sequencing a tumor sample and amplifying nucleic acid samples obtained from blood plasma using synthetic primers and amplification products to provide a novel, innovative, and personalized solution to issues peculiar to the particular problem of detecting ploidy of chromosome segments and SNVs in patients with cancer. The claims of the ’454 Patent cover methods of preparation of an unnatural preparation.

29. The ’454 Patent claims are directed to specific, nonconventional, non-routine methods for overcoming previously unresolved problems in this area. For example, as of the date of the invention, it would not have been routine or conventional to perform the claimed techniques either individually or in combination, including: performing whole

exome sequencing or whole genome sequencing on a turmor sample to identify a plurality of tumor-specific SNV mutations, performing targeted multiplex amplication to amplify 10 to 500 target loci each encompassing a different tumor-specific SNV mutation from cfDNA to obtain amplicons having a length of 50-150 bases, wherein the target loci are amplified together in the same reaction, and sequencing the amplicons to obtain sequence reads, wherein the sequencing has a depth of read of at least 50,000 per target locus.

B. The ’035 Patent

30. The ’035 Patent, attached hereto as Exhibit 2, is entitled “Methods for Simultaneous Amplification of Target Loci” and issued from the USPTO on December 6, 2022. Natera owns the ’035 Patent, including the right to enforce it and seek damages for infringement.

31. The ’035 Patent claims methods for amplifying and sequencing multiple nucleic acid regions of interest in one reaction volume. The claimed methods include targeted amplification of a plurality of single nucleotide polymorphism (SNP) loci associated with cancer on cell-free DNA in a single reaction volume and sequencing the plurality of SNP loci by conducting massively parallel sequencing. Independent claim 1 of the ’035 Patent recites:

> A method for amplifying and sequencing DNA, comprising:
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> tagging isolated cell free DNA with one or more universal tail adaptors to generate tagged products, wherein the isolated cell-free DNA is isolated from a blood sample collected from a subject who is not a pregnant women;

amplifying the tagged products one or more times to generate final amplification products, wherein one of the amplification steps comprises targeted amplification of a plurality of single nucleotide polymorphism (SNP) loci in a single reaction volume, wherein one of the amplifying steps introduces a barcode and one or more sequencing tags; and

sequencing the plurality of SNP loci on the cell free DNA by conducting massively parallel sequencing on the final amplification products, wherein the plurality of SNP loci comprises 25-2,000 loci associated with cancer.

32. The claims of the ’035 Patent are not directed to an abstract idea, natural law, or natural phenomenon. Rather, they are directed to a novel and innovative laboratory method comprising tagging cfDNA with universal tail adaptors, amplifying the tagged cfDNA including targeted amplification of 25-2,000 SNP loci associated with cancer in a single reaction volume, and sequencing the plurality of SNP loci by conducting massively parallel sequencing.

33. The ’035 Patent claims are directed to specific, nonconventional, non-routine methods for overcoming previously unresolved problems in this area. For example, as of the date of the invention, it would not have been routine or conventional to perform the claimed techniques either individually or in combination, including: tagging isolated cfDNA with one or more universal tail adaptors to generate tagged products; amplifying the tagged products one or more times to generate final amplification products, wherein one of the amplification steps comprises targeted amplification of a plurality of SNP loci in a single reaction volume, wherein one of the amplifying steps introduces a barcode and one or more sequencing tags; and sequencing the plurality of SNP loci on the cfDNA by

conducting massively parallel sequencing on the final amplification products, wherein the plurality of SNP loci comprises 25-2,000 loci associated with cancer.

DEFENDANT'S INFRINGING ACTS

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

35. The infringing products include, but are not limited to, RaDaR, and any other infringing method, product, device, or test developed by Defendant that apply Natera's patented methods for preparing, amplifying, sequencing, and analyzing cfDNA to detect and monitor genes and genetic mutations associated with a patient's cancer.

36. As provided in more detail below, each element of at least one claim of the '454 Patent is literally present in RaDaR or is literally practiced by the processes through which RaDaR is 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.

37. As provided in more detail below, each element of at least one claim of the '035 Patent is literally present in RaDaR or is literally practiced by the processes through which RaDaR is 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.

38. Attached as Exhibits 3-4 are preliminary and exemplary claim charts describing infringement of claim 1 of the ’454 Patent and claim 1 of the ’035 Patent, respectively. Exhibits 5-16 are documents referenced in Exhibits 3 and 4, which demonstrate examples of infringement. The claim charts are not intended to limit Natera’s right to modify the charts or allege that other products or activities of Defendant infringe the identified claims or any other claims of the Asserted Patents or any other patents. Defendant infringes more than one claim of the ’454 Patent and infringes more than one claim of the ’035 Patent.

39. Exhibits 3-4 are hereby incorporated by reference in their entirety. Each claim element in Exhibit 3 that is mapped to the Accused Assay shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure, and therefore a response to each claim element is required. Each claim element in Exhibit 4 that is mapped to the Accused Assay shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure, and therefore a response to each claim element is required.

40. Upon information and belief, NeoGenomics Laboratories designs, develops, makes and uses, or directs or controls the design, development, make and use of, the RaDaR assay by purposefully directing the activities at its CAP/CLIA-certified laboratory in the Research Triangle Park (RTP) located at 8 Davis Drive, Durham, North Carolina.[5] According to the CAP and CLIA certificates (attached hereto as Exhibits 18-19, respectively), this laboratory is registered to Inivata, Inc., a corporate affiliate of

[5] *See* Exhibit 17 at 2.

NeoGenomics Laboratories, and the director of this laboratory is Dr. Siby Sebastian, Ph.D.[6] On its website, NeoGenomics Laboratoris acknowledges that Dr. Siby Sebastian is also "the Director of the NeoGenomics CAP/CLIA Clinical Laboratory at the Research Triangle Park (RTP), North Carolina."[7] Moreover, according to its 2022 Annual Report to shareholders (attached hereto as Exhibit 21), NeoGenomics Laboratories stated that "[w]e have a renewed focus on next-generation sequencing (NGS), minimal residual disease (MRD) technology such as RaDaR . . . By centralizing the R&D function and integrating Inivata, we believe we are now well-positioned to capitalize on the innovation of Inivata while enhancing the development process for new product."[8]

41. Upon information and belief, NeoGenomics Laboratories performs, or directs or controls the performance of, the RaDaR assay. In its published guide for patients, NeoGenomics Laboratories states that RaDaR testing is "conducted on [a] blood sample in our lab."[9]

42. Upon information and belief, NeoGenomics Laboratories also offers for sale and sells, or directs or controls the offer for sale and sale of, the Accused Assay. On March 16, 2023, NeoGenomics began selling and offering to sell RaDaR in the United States.[10] In its 2022 Annual Report to shareholders, NeoGenomics Laboratories stated that "[w]e

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6 *See* Exhibits 18-19.
7 *See* Exhibit 20.
8 *See* Exhibit 21 at 7.
9 *See* Exhibit 22 at 2.
10 *See* Exhibit 23 at 1.

believe NeoGenomics is well-positioned to gain market share with our . . . RaDaR® assay liquid biopsy test for MRD."[11]

43. Upon information and belief, NeoGenomics Laboratories induces Inivata to perform any RaDaR tests that NeoGenomics is not performing itself. While RaDaR is ordered through NeoGenomics Laboratories, its insurance reimbursement certifications and approvals, including MolDX, list Inivata as authorized to perform RaDaR tests.[12] In addition, the request forms for the RaDaR test report that RaDaR may be performed by Inivata.[13]

44. NeoGenomics Laboratories is a direct competitor of Natera in the market for personalized, tumor-informed recurrence monitoring specifically. In promoting its infringing RaDaR assay, NeoGenomics Laboratories repeatedly undermined Signatera and Natera to investors, including at the Goldman Sachs 44th Annual Global Healthcare Conference held on June 13, 2023. NeoGenomics Laboratories touted its infringing and competing RaDaR assay to investors as being "about 10x more sensitive than the other product that's really commercially available in the market,"[14] which is Signatera, even though there is no clinical evidence or head-to-head study to substantiate this claim. On information and belief, representatives of NeoGenomics Laboratories have repeated

[11] *See* Exhibit 21 at 9.
[12] *See* Exhibit 24.
[13] *See* Exhibit 25 at 2.
[14] *See* Exhibit 26 at 1.

similar misleading claims to potential customers, including current Signatera customers, in promoting the infringing RaDaR assay.

45. On July 27, 2023, NeoGenomics Laboratories announced that RaDaR obtained Medicare coverage for cancer recurrence detection and monitoring in patients with breast cancer.[15]

46. NeoGenomics Laboratories has actual knowledge of the '454 Patent since at least as early as December 20, 2022, when Natera filed an infringement lawsuit in the District of Delware asserting the '454 Patent against two corporate affiliates of NeoGenomics Laboratories: Inivata, Inc., and Inivata, Ltd.[16]

47. NeoGenomics Laboratories has actual knowledge of the '035 Patent since at least as early as the date of this Complaint.

48. NeoGenomics Laboratories has thus made extensive unauthorized use of Natera's patented technology, including the technology described and claimed in the Asserted Patents, causing Natera to suffer immediate and irreparable harm. Natera brings this action to enforce its patents rights. Natera thus requests that this Court award it damages sufficient to compensate for NeoGenomics Laboratories' infringement of the Asserted Patents, find this case exceptional, award Natera its attorneys' fees and costs, and

[15] *See* Exhibit 30 at 1.

[16] *See Natera, Inc. v. Inivata, Inc. et al,* Case No. 1:22-cv-01609-UNA, Dkt. No. 1 (D. Del. Dec. 20, 2022); *see also* Exhibit 12 at 115 (In its 2022 Annual Report, NeoGenomics Laboratories acknowledged that Natera "filed a second patent infringement complaint on December 20, 2022 against Inivata Limited and Inivata Inc. alleging that RaDaR® minimal residual disease test infringes one patent.")

grant an injunction against NeoGenomics Laboratories to prevent any further infringement of the Asserted Patents.

COUNT I: DIRECT INFRINGEMENT OF U.S. PATENT NO. 11,530,454

49. Natera incorporates by reference and re-alleges the foregoing paragraphs as if fully set forth herein.

50. Natera is the owner of the ’454 Patent, which was duly and legally issued by the USPTO on December 20, 2022.

51. Defendant has infringed and continues to infringe at least one claim of the ’454 Patent pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by performing, or directing or controlling the performance of, the Accused Assay within the United States and without authority.

52. Defendant’s infringement has damaged and will continue to damage Natera, which is entitled to recover the damages resulting from Defendant’s wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

53. Moreover, Defendant’s infringement has caused, and will continue to cause, irreparable injury to Natera, for which damages are an inadequate remedy, unless Defendant, including its corporate affiliates and subsidiaries, is enjoined from any and all activities that would infringe the claims of the ’454 Patent.

COUNT II: DIRECT INFRINGEMENT OF U.S. PATENT NO. 11,519,035

54. Natera incorporates by reference and re-alleges the foregoing paragraphs as if fully set forth herein.

55. Natera is the owner of the ’035 Patent, which was duly and legally issued by the USPTO on December 6, 2022.

56. Defendant has infringed and continues to infringe at least one claim of the ’035 Patent pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by performing, or directing or controlling the performance of, the Accused Assay within the United States and without authority.

57. Defendant’s infringement has damaged and will continue to damage Natera, which is entitled to recover the damages resulting from Defendant’s wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

58. Moreover, Defendant’s infringement has caused, and will continue to cause, irreparable injury to Natera, for which damages are an inadequate remedy, unless Defendant, including its corporate affiliates and subsidiaries, is enjoined from any and all activities that would infringe the claims of the ’035 Patent.

COUNT III: INDIRECT INFRINGEMENT OF U.S. PATENT NO. 11,530,454

59. Natera incorporates by reference and re-alleges the foregoing paragraphs as if fully set forth herein.

60. NeoGenomics Laboratories has indirectly infringed and continues to indirectly infringe at least one claim of the ’454 Patent pursuant to 35 U.S.C. § 271(b), literally or under the doctrine of equivalents, by inducing its corporate affiliate Inivata to perform the Accused Assay within the United States without authority. NeoGenomics Laboratories engaged in such inducement having knowledge of the ’454 Patent at least as

of December 20, 2022 when Natera filed a lawsuit alleging infringement of the '454 Patent by Inivata in the District of Delaware.[17] Furthermore, NeoGenomics Laboratories knew or should have known that its actions of selling or offering to sell the Accused Assay would induce direct infringement by Inivata and intended that its actions would induce direct infringement by Inivata. NeoGenomics Laboratories offers for sale the Accused Assay via its website specifically intending that Inivata perform the Accused Assay in NeoGenomics Laboratories' CAP/CLIA-certified laboratory in Durham, NC upon purchase by a customer.

61. As a direct and proximate result of NeoGenomics Laboratories' indirect infringement by inducement of the '454 Patent, Natera has been and continues to be damaged. Thus, Natera is entitled to recover the damages resulting from NeoGenomics Laboratories' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

62. Moreover, Defendant's infringement has caused, and will continue to cause, irreparable injury to Natera, for which damages are an inadequate remedy, unless NeoGenomics Laboratories is enjoined from any and all activities that would infringe the claims of the '454 Patent.

[17] *Natera, Inc. v. Inivata, Inc. et al.*, Case No. 22-cv-1609-GBW, Dkt. No. 1 (D. Del. Dec. 20, 2022).

COUNT IV: INDIRECT INFRINGEMENT OF U.S. PATENT NO. 11,519,035

63. Natera incorporates by reference and re-alleges the foregoing paragraphs as if fully set forth herein.

64. NeoGenomics Laboratories has indirectly infringed and continues to indirectly infringe at least one claim of the '035 Patent pursuant to 35 U.S.C. § 271(b), literally or under the doctrine of equivalents, by inducing its corporate affiliate Inivata to perform the Accused Assay within the United States without authority. NeoGenomics Laboratories engaged in such inducement having knowledge of the '035 Patent, at least as of the service of the present Complaint. Furthermore, NeoGenomics Laboratories knew or should have known that its actions of selling or offering to sell the Accused Assay would induce direct infringement by Inivata and intended that its actions would induce direct infringement by Inivata. NeoGenomics Laboratories offers for sale the Accused Assay via its website specifically intending that Inivata perform the Accused Assay in NeoGenomics Laboratories' CAP/CLIA-certified laboratory in Durham, NC upon purchase by a customer.

65. As a direct and proximate result of NeoGenomics Laboratories' indirect infringement by inducement of the '035 Patent, Natera has been and continues to be damaged. Thus, Natera is entitled to recover the damages resulting from NeoGenomics Laboratories' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

66. Moreover, Defendant's infringement has caused, and will continue to cause, irreparable injury to Natera, for which damages are an inadequate remedy, unless NeoGenomics Laboratories is enjoined from any and all activities that would infringe the claims of the '035 Patent.

COUNT V: WILLFUL INFRINGEMENT OF U.S. PATENT NO. 11,530,454

67. Natera incorporates by reference and re-alleges the foregoing paragraphs as if fully set forth herein.

68. NeoGenomics Laboratories has acted willfully and egregiously in performing the acts of infringement identified in this Complaint. NeoGenomics Laboratories' infringement of the '454 Patent has been and is deliberate and willful and constitutes egregious misconduct. NeoGenomics Laboratories engaged in such conduct having knowledge of the '454 Patent at least as of December 20, 2022 when Natera filed a lawsuit alleging infringement of the '454 Patent by Inivata in the District of Delaware.[18] Furthermore, NeoGenomics Laboratories knew or should have known that its actions of selling or offering to sell the Accused Assay would induce direct infringement by Inivata and intended that its actions would induce direct infringement by Inivata. NeoGenomics Laboratories offers for sale the Accused Assay via its website specifically intending that Inivata perform the Accused Assay in NeoGenomics Laboratories' CAP/CLIA-certified laboratory in Durham, NC upon purchase by a customer. In performing the acts of

[18] *Natera, Inc. v. Inivata, Inc. et al.*, Case No. 22-cv-1609-GBW, Dkt. No. 1 (D. Del. Dec. 20, 2022).

infringement identified in this Complaint, NeoGenomics Laboratories has been willfully blind to its ongoing infringement.

69. As a direct and proximate result of NeoGenomics Laboratories' willful infringement, Natera has been and continues to be damaged. Thus, Natera is entitled to recover the damages resulting from NeoGenomics Laboratories' wrongful acts in an amount to be determined at trial. Natera deserves treble damages and the reimbursement of its fees and costs as set forth in 35 U.S.C. §§ 284 and 285.

70. Moreover, Defendant's infringement has caused, and will continue to cause, irreparable injury to Natera, for which damages are an inadequate remedy, unless NeoGenomics Laboratories is enjoined from any and all activities that would infringe the claims of the '454 Patent.

COUNT VI: WILLFUL INFRINGEMENT OF U.S. PATENT NO. 11,519,035

71. Natera incorporates by reference and re-alleges the foregoing paragraphs as if fully set forth herein.

72. NeoGenomics Laboratories has acted willfully and egregiously in performing the acts of infringement identified in this Complaint. NeoGenomics Laboratories' infringement of the '035 Patent has been and is deliberate and willful and constitutes egregious misconduct. NeoGenomics Laboratories engaged in such conduct having knowledge of the '035 Patent, at least as of the service of the present Complaint. Furthermore, NeoGenomics Laboratories knew or should have known that its actions of selling or offering to sell the Accused Assay would induce direct infringement by Inivata

and intended that its actions would induce direct infringement by Inivata. NeoGenomics Laboratories offers for sale the Accused Assay via its website specifically intending that Inivata perform the Accused Assay in NeoGenomics Laboratories' CAP/CLIA-certified laboratory in Durham, NC upon purchase by a customer. In performing the acts of infringement identified in this Complaint, NeoGenomics Laboratories has been willfully blind to its ongoing infringement.

73. As a direct and proximate result of NeoGenomics Laboratories' willful infringement, Natera has been and continues to be damaged. Thus, Natera is entitled to recover the damages resulting from NeoGenomics Laboratories' wrongful acts in an amount to be determined at trial. Natera deserves treble damages and the reimbursement of its fees and costs as set forth in 35 U.S.C. §§ 284 and 285.

74. Moreover, Defendant's infringement has caused, and will continue to cause, irreparable injury to Natera, for which damages are an inadequate remedy, unless NeoGenomics Laboratories is enjoined from any and all activities that would infringe the claims of the '035 Patent.

PRAYER FOR RELIEF

WHEREFORE, Natera respectfully requests the following relief:

1. A judgment that Defendant has infringed the '454 Patent and the'035 Patent literally or under the doctrine of equivalents;

2. An order enjoining Defendant and their respective 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 further infringement of the ’454 Patent and the’035 Patent;

3. An award of damages sufficient to compensate Natera for Defendant’s infringement under 35 U.S.C. § 284;

4. A declaration that Defendant’s infringement of ’454 Patent and the’035 Patent has been willful and deliberate, and an increase to the award of damages of three times the amount found or assessed by the Court, in accordance with 35 U.S.C. § 284;

5. A determination that this is an exceptional case under 35 U.S.C. § 285 and that Natera be awarded attorneys’ fees;

6. Costs and expenses in this action;

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

8. 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, Natera respectfully demands a trial by jury on all triable issues.

Dated: July 28, 2023

Resepctfully Submitted,

WILLIAMS MULLEN

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