

Exhibit 2

**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

**HIGHLY CONFIDENTIAL –
OUTSIDE ATTORNEYS’ EYES
ONLY INFORMATION**

**PLAINTIFF NATERA, INC.’S DISCLOSURE OF ASSERTED CLAIMS AND
PRELIMINARY INFRINGEMENT CONTENTIONS**

Pursuant to Local Patent Rule 103.1, Natera, Inc. (“Natera”) provides its preliminary infringement contentions relating to NeoGenomics Laboratories, Inc.’s (“Defendant” or “NeoGenomics”) infringement of the Asserted Claims of U.S. Patent Nos. 11,319,596 (“the ’596 Patent”) and 11,530,454 (“the ’454 Patent”) (“the Asserted Patents”). Natera’s preliminary infringement contentions apply to at least the following products: RaDaR 1.1, and all other products, devices, tools, or tests using the same or similar technology that NeoGenomics has made, used, sold, or offered for sale in the United States, or imported into the United States (herein, the “Accused Products”). Exhibits 1-2 attached hereto are claim charts illustrating how the Accused Products embody each element of the Asserted Claims of the ’596 and ’454 Patents, respectively.

1. Asserted Claims (LPR 103.1(a))

For the reasons set forth below, Natera asserts that NeoGenomics infringes at least the following claims (“Asserted Claims”):

- '596 Patent: Claims 1, 5, 10-16, 18
- '454 Patent: Claims 1, 3, 8, 10, 12-15, 22, 24, 26-28

With respect to the '454 Patent, Natera asserts that the Accused Products (as defined below) infringe Claims 1, 3, 8, 10, 12-15, 22, 24, and 26-28 for at least the reasons set forth in Natera's Motion for a Preliminary Injunction (Doc. 6), Reply in Support Thereof (Doc. 144), Opening Expert Declaration (Doc. 17), Reply Expert Declaration (Doc. 145), expert testimony during the November 27, 2023 Preliminary Injunction Hearing, Natera's claim construction briefing (Docs. 262, 272) and supporting evidence (Docs. 263, 273), the Court's claim construction ruling (Doc. 280), Natera's Memorandum in Support of Motion for Leave to File First Amended Complaint (Doc. 337), the attached claim charts, and based on the information currently available to Natera. Natera thus reserves its rights to amend these Asserted Claims.

With respect to the '596 Patent, Natera asserts that the Accused Products (as defined below) infringe Claims 1, 5, 10-16, and 18 for at least the reasons set forth in Natera's Memorandum in Support of Motion for Leave to File First Amended Complaint (Doc. 337), the attached claim charts, and based on the information currently available to it. This identification is given without the benefit of any claim construction order by the Court that may issue in this case and Natera reserves its rights to amend these Asserted Claims.

2. Accused Products (LPR 103.1(b))

For all of the Asserted Claims of the '596 and '454 Patents, the Accused Products are RaDaR 1.1, and all other products, devices, tools, or tests using the same or similar technology that NeoGenomics has made, used, sold, offered for sale, imported into the

United States or intends to make, use, sell, offer for sale in the United States, or import into the United States. Natera's preliminary infringement contentions are based on these product lines, and Natera reserves the right to supplement, modify or amend these claim charts to incorporate additional product lines or specific variants within each product line as necessary and appropriate.

3. Infringement Claim Charts (LPR 103.1(c)-(d))

A chart identifying specifically where each element of the Asserted Claims of the '596 Patent may be found in the Accused Products is attached hereto as Exhibit 1. Pursuant to LPR 103.1(d), Exhibit 1 also identifies whether each element of each asserted claim is alleged to be present literally or under the doctrine of equivalents. Plaintiff reserves the right to amend these contentions to supplement its allegations under the doctrine of equivalents, particularly should the Court construe any claim terms of the Asserted Patents.

A chart identifying specifically where each element of the Asserted Claims of the '454 Patent may be found in the Accused Products is attached hereto as Exhibit 2. Pursuant to LPR 103.1(d), Exhibit 2 also identifies whether each element of each asserted claim is alleged to be present literally or under the doctrine of equivalents. Plaintiff reserves the right to amend these contentions to supplement its allegations under the doctrine of equivalents, particularly should the Court construe any claim terms of the Asserted Patents.

These are *initial* claim charts. Natera has therefore provided preliminary citations to evidence to show NeoGenomics' infringement. This is not intended to be an exhaustive

citation of all of the evidence of NeoGenomics' infringement. These initial claim charts are based on publicly available information and on NeoGenomics' limited document production in connection with RaDaR 1.1 to date and the Court's Order on Motions and Setting Schedule (Doc. 330). Natera reserves the right to supplement or modify the disclosures as additional information is obtained. Natera reserves all rights to amend and supplement these initial claim charts in accordance with the Court's orders, Local Rules, and the Federal Rules of Civil Procedure as appropriate. Discovery is currently ongoing, and additional facts, documents, things, and testimony, whether known or unknown to Natera, may become relevant. Natera reserves the right to amend, alter, or supplement these initial claim charts based on any further investigation, fact or expert discovery, and any contentions or positions taken by NeoGenomics and/or its designated experts.

By providing these preliminary infringement contentions and corresponding claim charts, Natera does not waive any right to introduce at trial any subsequently discovered or developed evidence or expert opinions. Natera reserves the right to refer to, conduct discovery with reference to, or offer into evidence at the time of trial, any and all facts, expert opinions, documents and things notwithstanding the statements in these initial claim charts. Natera further reserves its right to refer to, conduct discovery with reference to, or offer into evidence at the time of trial, any and all facts, documents and things that are not currently recalled but might be recalled at some time in the future. Natera may also rely on documents, testimony, and things produced in the course of fact and expert discovery, including those which have not yet been produced by NeoGenomics or which Natera has not yet identified or appreciated the significance of in the context of this litigation.

NeoGenomics' production of documents to date is deficient, as it omits core documents, including but not limited to documents detailing whether the SNV mutations selected in RaDaR 1.1 comprise clonal, subclonal, or a combination of clonal and subclonal variants and whether RaDaR 1.1 determines clonal heterogeneity as well as the specific details regarding the selection and quantification of tumor-specific SNVs, including documents sufficient to show the complete wet laboratory and bioinformatics workflows for the Accused Products. This is improper. *See, e.g., Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1381-82 (Fed. Cir. 2005) (explaining that operation of product prior to issuance of a patent is relevant to establishing post-issuance infringement). Thus, NeoGenomics' production is incomplete and Natera does not have full discovery into the technology of the Accused Products, and versions thereof. Natera accordingly reserves the right to supplement these initial claim charts when NeoGenomics produces additional documentation.

Based on Natera's investigation to date, Natera alleges that each element of the Asserted Claims is found literally in the Accused Products and/or methods that use the Accused Products as shown in the attached charts. To the extent that one or more elements of the Asserted Claims are not literally present or practiced in the Accused Products, Natera alleges that the Accused Products infringe under the doctrine of equivalents because the differences, if any, between the claim elements and the Accused Products are insubstantial and the Accused Products perform the same or substantially the same functions, in the same or substantially the same ways, to achieve the same or substantially the same results as such elements. Natera reserves the right to supplement, modify, and/or amend its

infringement theories under the doctrine of equivalents based upon information learned through discovery. Natera will provide such supplementations, modifications, and/or amendments, if necessary, as appropriate, including to address any claim construction ruling issued by the Court.

4. Infringing Activity

With respect to the '454 Patent, Natera asserts that the Accused Products infringe Claims 1, 3, 8, 10, 12-15, 22, 24, and 26-28 under at least 35 U.S.C. § 271 (a) and (b) for at least the reasons set forth in Natera's Motion for a Preliminary Injunction (Doc. 6), Reply in Support Thereof (Doc. 144), Opening Expert Declaration (Doc. 17), Reply Expert Declaration (Doc. 145), expert testimony during the November 27, 2023 Preliminary Injunction Hearing, Natera's claim construction briefing (Docs. 262, 272) and supporting evidence (Docs. 263, 273), the Court's claim construction ruling (Doc. 280), Natera's Memorandum in Support of Motion for Leave to File First Amended Complaint (Doc. 337), the attached claim charts, and based on the information currently available to Natera. Natera thus reserves its rights to amend these Asserted Claims.

With respect to the '596 Patent, Natera asserts that the Accused Products infringe Claims 1, 5, 10-16, and 18 under at least 35 U.S.C. § 271 (a) and (b) for at least the reasons set forth in Natera's Memorandum in Support of Motion for Leave to File First Amended Complaint (Doc. 337), the attached claim charts, and based on the information currently available to it.

NeoGenomics has made the following admissions in its Second Amended Answer to Natera's Complaint (Doc. 128 at ECF 9-10, ¶¶ 40-43):

- “NeoGenomics admits that it ‘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.’ NeoGenomics further admits that ‘this laboratory is registered to Inivata, Inc., a corporate affiliate of NeoGenomics Laboratories.’ NeoGenomics admits that Dr. Siby Sebastian, Ph.D previously served as a director of this laboratory. NeoGenomics further admits that Dr. Siby Sebastian was ‘the Director of the NeoGenomics CAP/CLIA Clinical Laboratory at the Research Triangle Park (RTP), North Carolina.’” *Id.* at ¶ 40.
- “NeoGenomics admits that it performs, or directs or controls the performance of, the RaDaR assay. NeoGenomics further admits that, in its published guide for patients, NeoGenomics Laboratories states that RaDaR testing is ‘conducted on [a] blood sample in our lab.’” *Id.* at ¶ 41.
- “NeoGenomics admits that it had 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 Delaware asserting the ’454 Patent against two corporate affiliates of NeoGenomics Laboratories, Inc.: Inivata, Inc., and Inivata, Ltd.” *Id.* at ¶ 47.

Natera reserves the right to supplement, modify, and/or amend these assertions based upon information learned through discovery. If necessary, Natera will provide supplementations, modifications, and/or amendments as appropriate, including to address any claim construction ruling issued by the Court.

5. Priority Date of the Asserted Patents (LPR 103.1(e))

The '596 Patent issued from U.S. Patent App. 16/288,351, which was filed on February 28, 2019 as a continuation of U.S. Patent App. No. 16/014,961, filed on June 21, 2018, which is a continuation of U.S. Patent App. No. 14/692,703 ("the '703 Application"), filed on April 21, 2015, now Pat. No. 10,179,937. The '596 Patent claims priority to the '703 Application. Accordingly, the priority date of each of the Asserted Claims of the '596 Patent is no later than April 21, 2015.

The '454 Patent issued from U.S. Patent App. No. 17/738,354, which was filed on May 6, 2022 as a continuation of U.S. Patent App. No. 17/692,469, filed on Mar. 11, 2022, which is a continuation of U.S. Patent App. No. 15/898,145, filed on Feb. 15, 2018, now Pat. No. 11,319,595, which is a continuation of U.S. Patent App. No. 14/692,703 ("the '703 Application"), filed on Apr. 21, 2015, now Pat. No. 10,179,937. The '454 Patent claims priority to the '703 Application. Accordingly, the priority date of each of the Asserted Claims of the '454 Patent is no later than April 21, 2015.

6. Natera's Practicing Products (LPR 103.1(f))

For the reasons set forth in Natera's Opening Expert Declaration (Doc. 17) and Reply Expert Declaration (Doc. 145), Natera asserts that its Signatera product, a tumor-informed MRD assay, practices one or more of the Asserted Claims. Natera's investigation

is ongoing, and Natera reserves the right to supplement and/or amend its disclosures under LPR 103.1(f).

7. Document Production Accompanying Disclosure (LPR 103.2(a), (b), and (c))

During the course of fact discovery, Natera produced in excess of 58,000 documents, which include documents required under LPR 103.2(a), (b), and (c). Natera will make supplemental productions in connection with the '596 Patent on a rolling basis.

8. Conclusion

The preliminary infringement contentions provided herein are based on information obtained to date and may not be exhaustive. Natera's investigation of NeoGenomics' infringement is ongoing. Natera reserves the right to supplement and/or amend these contentions as more information is learned through discovery in this action, including, without limitation, to identify additional asserted claims, additional Accused Products, and to further identify where each element of each asserted claim is found in each Accused Product, either literally or under the doctrine of equivalents.

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CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing document to be served via electronic mail on all counsel of record for Defendant.

Dated: November 25, 2024

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