

**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-CCE-JLW

**NEOGENOMICS LABORATORIES, INC.'S
FIRST SET OF REQUESTS FOR ADMISSION (NOS. 1-24)**

Pursuant to Rules 26 and 36 of the Federal Rules of Civil Procedure, Defendant, NeoGenomics Laboratories, Inc. (“NeoGenomics” or “Defendant”) hereby requests that Plaintiff Natera, Inc. (“Natera” or “Plaintiff”) serve written responses to the following requests for admission (“Requests”) on NeoGenomics’ counsel of record within thirty (30) days.

DEFINITIONS

1. “Natera” or “Plaintiff” mean Natera, Inc. and includes each of its officers, directors, members, managers, agents, consultants, contractors, employees, attorneys, accountants, partners, corporate parents, subsidiaries, affiliates, divisions, predecessors-in-interest (including but not limited to Gene Security Network), or successors-in-interest, and any person or entity, past or present, who acts on Natera, Inc.’s behalf or purports to act on Natera, Inc.’s behalf.

2. “NeoGenomics” or “Defendant” means NeoGenomics Laboratories, Inc.

3. “‘454 Patent” means U.S. Patent No. 11,530,454, entitled “Detecting Mutations and Ploidy in Chromosomal Segments.”

4. “‘035 Patent” means U.S. Patent No. 11,519,035, entitled “Methods for Simultaneous Amplification of Target Loci.”

5. “Asserted Patents” means the ‘454 Patent and the ‘035 Patent, individually and collectively.

6. “Asserted Claims” means the claims of the Patents-In-Suit that Natera asserts NeoGenomics has infringed.

7. “Related Patent” or “Related Patents” means any U.S. patent, non-U.S. patent, U.S. patent application, including provisionals, or non-U.S. patent application, including provisionals, that claims priority to or from, shares a common claim of priority with, or shares all or substantially all of its specification with the Asserted Patents.

8. “Accused Products” means RaDaR, and any other products, devices, tools, or tests that Natera alleges infringe any asserted claim of the Asserted Patents that NeoGenomics has allegedly made, used, sold, offered for sale in the United States, or imported into the United States.

9. “Lawsuit” means the case styled *Natera, Inc. v. NeoGenomics Laboratories, Inc.*, C.A. No. 1-23-cv-629, pending in the United States District Court for the Middle District of North Carolina.

10. “Prior Art” has the same meaning as used in 35 U.S.C. §§ 102 and 103, and includes any patent, printed publication, prior knowledge, prior use, prior sale or offer for sale, or other act, event, or document defined in 35 U.S.C. §§ 102 and 103, taken singularly or in combination.

11. “MRD” means Minimal Residual Disease.

12. “Tumor Informed Assay” means a minimal residual disease assay that uses a tissue sample from a patient to generate a personalized panel or tumor “fingerprint.”

13. “Tumor Naïve Assay” means a minimal residual disease assay that uses a

standardized ctDNA panel, and that does not require a tissue sample from a patient to generate a personalized panel or tumor “fingerprint.”

14. “Molecular Diagnostic Services Program” or “MolDX®” means the Centers for Medicare and Medicaid Services’ program administered by Palmetto GBA to review all new test/assay clinical information to determine if a test meets Medicare’s reasonable and necessary requirement.

15. “Signatera” means Natera’s MRD assay launched in 2017, and all subsequent versions and updates thereto.

16. “RaDaR” means NeoGenomics’ RaDaR assay, and all subsequent versions and updates thereto.

INSTRUCTIONS

1. Natera must respond to these Requests in accordance and compliance with Federal Rules of Civil Procedure 26 and 36 and any other applicable rule or order.

2. If a Request is not admitted, the answer must specifically deny it or state in detail why you cannot truthfully admit or deny it. A denial must fairly respond to the substance of the matter; and when good faith requires that you qualify an answer or deny only a part of a matter, the answer must specify the part admitted and qualify or deny the rest. *See Fed. R. Civ. P. 36(a)(4).*

3. Natera may assert lack of knowledge or information as a reason for failing to admit or deny only if you state that you have made reasonable inquiry and that the information you know or can readily obtain is insufficient to enable you to admit or deny. *See id.*

4. Unless otherwise specified, the relevant time period is up to and including the date upon which you respond.

5. These Requests are continuing in nature. Natera is required to timely supplement these responses with any information discovered or identified subsequent to the service of these Requests, within a reasonable period of time following such discovery, pursuant to Federal Rule of Civil Procedure 26(e).

REQUESTS

REQUEST NO. 1:

Tumor Informed Assays sometimes compete against Tumor Naïve Assays.

REQUEST NO. 2:

Tumor Informed Assays never compete against Tumor Naïve Assays.

REQUEST NO. 3:

Signatera sometimes competes against Tumor Naïve Assays.

REQUEST NO. 4:

Signatera never competes against Tumor Naïve Assays.

REQUEST NO. 5:

Natera has lost one or more sales of Signatera to a Tumor Naïve Assay.

REQUEST NO. 6:

Natera has never lost a sale of Signatera to a Tumor Naïve Assay.

REQUEST NO. 7:

Signatera sometimes competes against Guardant's Reveal™.

REQUEST NO. 8:

Signatera never competes against Guardant's Reveal™.

REQUEST NO. 9:

Signatera sometimes competes against Adaptive Technologies' ClonoSEQ™.

REQUEST NO. 10:

Signatera never competes against Adaptive Technologies' ClonoSEQ™.

REQUEST NO. 11:

Damages adequate to compensate Natera for NeoGenomics' alleged infringement can be calculated with reasonable certainty.

REQUEST NO. 12:

Damages adequate to compensate Natera for NeoGenomics' alleged infringement cannot be calculated with reasonable certainty.

REQUEST NO. 13:

Signatera has Medicare approval for adjuvant indications.

REQUEST NO. 14:

RaDaR does not have Medicare approval for adjuvant indications.

REQUEST NO. 15:

Natera has licensed Related Patents.

REQUEST NO. 16:

Natera has not licensed Related Patents.

REQUEST NO. 17:

The barcoding PCR in the RaDaR assay (Doc. 1-15 at FIG. 2A) does not perform targeted amplification.

REQUEST NO. 18:

The barcoding PCR in the RaDaR assay (Doc. 1-15 at FIG. 2A) performs targeted amplification.

REQUEST NO. 19:

The fixed primer panel of common population-specific SNPs in the RaDaR assay (Doc. 1-10 at 1187) does not target 25-2,000 loci associated with cancer.

REQUEST NO. 20:

The fixed primer panel of common population-specific SNPs in the RaDaR assay (Doc. 1-10 at 1187) targets 25-2,000 loci.

REQUEST NO. 21:

Forsheiw, T. et al., *Noninvasive Identification and Monitoring of Cancer Mutations by Targeted Deep Sequencing of Plasma DNA* 4(136):36RA68 (May 2012) (“Forsheiw”) at FIGs. 1, S1 and 1-2 teaches 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.

REQUEST NO. 22:

Forsheiw does not teach 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.

REQUEST NO. 23:

Forsheiw at FIGs. 1, S1 and 1-2 teaches 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, and wherein one of the amplifying steps introduces a barcode and one or more sequencing tags.

REQUEST NO. 24:

Forsheiw does not teach 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, and wherein one of the amplifying steps introduces a barcode and one or more sequencing tags.

June 18, 2024

/s/ Matthew I. Kreeger

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**Special Appearance under Local Civil Rule 83.1(d)*

Certificate of Service

I, the undersigned, hereby certify that on June 18, 2024, a true and correct copy of the foregoing **NEOGENOMICS LABORATORIES, INC.'S FIRST SET OF REQUESTS FOR ADMISSION** was served via electronic mail upon the following:

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