

**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

JOINT CLAIM CONSTRUCTION STATEMENT

Pursuant to Local Patent Rule 104.3 and the Court’s Scheduling Order (Doc. 213), Plaintiff Natera, Inc. (“Natera”) and Defendant NeoGenomics Laboratories, Inc. (“NeoGenomics”) (collectively, “the Parties”) hereby submit their Joint Claim Construction Statement with respect to the asserted claims of U.S. Patent Nos. 11,519,035 (the “’035 Patent”), and 11,530,454 (the “’454 Patent”).

I. L.P.R. 104.3 (A) – CONSTRUCTIONS OF CLAIMS, TERMS, PHRASES, OR CLAUSES ON WHICH THE PARTIES AGREE

The Parties have met-and-conferred and exchanged email correspondence in an effort to reduce the number of terms to be construed and to identify, narrow, and focus any areas of dispute. Natera and NeoGenomics have each withdrawn multiple terms for construction that were previously disclosed in the Parties’ respective Preliminary Identifications of Claim Terms served on March 1, 2024. The Parties may continue to meet and confer regarding the Parties’ claim constructions.

The Parties expressly reserve the right to rely on any evidence identified by the other party, and any evidence obtained, or that may be obtained, through claim construction discovery. The Parties expressly reserve the right to amend, correct, or supplement their claim construction positions and supporting or rebuttal evidence in response to any change of position by the other party, information received during claim construction discovery, supplementation to contentions (*e.g.*, infringement, invalidity) or for other good cause.

II. L.P.R. 104.3(B) – PROPOSED CONSTRUCTIONS OF EACH DISPUTED CLAIM TERM, PHRASE, OR CLAUSE, TOGETHER WITH AN IDENTIFICATION OF SUPPORTING INTRINSIC AND EXTRINSIC EVIDENCE

Natera’s and NeoGenomics’ proposed construction for each disputed claim term, phrase, or clause, along with citations to the intrinsic and extrinsic evidence each Party intends to rely upon is attached as Exhibit A.

III. L.P.R. 104.3(C) – THE ANTICIPATED LENGTH OF TIME NECESSARY FOR THE CLAIM CONSTRUCTION HEARING

A. Joint Agreement by the Parties

If the Court is to hold a Claim Construction Hearing, the Parties anticipate that a hearing will take no more than 3 hours, with the time divided equally per side. Subject to the Court’s preference, the Parties agree to present the disputed claim terms on a term-by-term basis. The Parties further agree that each Party may reserve time for rebuttal related to each term.

B. Natera's Position

Subject to the Court's preference, for each disputed term, Natera, as the patentee, proposes that it will present its position first, followed by NeoGenomics.

C. NeoGenomics' Position

Because NeoGenomics bears the burden of proof on indefiniteness, NeoGenomics proposes presenting its position first with respect to the terms it asserts are indefinite. NeoGenomics agrees with Natera's proposal for Natera to present its position first regarding the remaining terms.

IV. L.P.R. 104.3(D) – IDENTIFICATION OF WITNESSES AND SUMMARY OF OPINIONS

A. Natera's Position

(1) *Claim Construction Hearing*

Natera may offer live witness testimony at the hearing from Natera's technical expert, Dr. Michael Metzker, to explain, or respond to and rebut the opinions offered by Dr. Smith and evidence cited by NeoGenomics, regarding the constructions of any of the claim terms proposed for construction. Natera also may offer live testimony from Dr. Metzker regarding definiteness of the following claim terms from the '454 Patent: "clonal" (claims 3,5,17,19); "subclonal" (claims 4,5,18,19); "present in less than or equal to 0.015% of the cell-free DNA comprising the SNV locus" (claim 14); and "present in 0.005% to 0.015% of the cell-free DNA comprising the SNV locus" (claim 28). Natera further may offer Dr. Metzker to testify at the hearing in support of a plain and ordinary construction for each of the claim terms NeoGenomics argues are indefinite.

(2) *Claim Construction Briefing*

In support of its claim construction briefing, Natera may rely upon prior percipient and expert testimony offered during the Preliminary Injunction phase of this case, consistent with the identification of such testimony as set forth in Exhibit A.

Natera may also rely upon additional written and/or deposition testimony from Dr. Metzker offered as part of claim construction discovery consistent with the identification of such testimony as set forth in Exhibit A and as explained herein. Dr. Metzker may provide testimony in support of Natera's constructions for the claim terms at issue for both the '035 Patent and the '454 Patent. Dr. Metzker also may testify to rebut the constructions advanced by NeoGenomics and any opinions provided by its expert witness(es).

Regarding the '454 Patent claim terms that NeoGenomics alleges are indefinite and not amenable to construction, Dr. Metzker may opine that a person of ordinary skill in the art in could determine with reasonable certainty the meaning of the terms "clonal", "subclonal", "present in less than or equal to 0.015% of the cell-free DNA comprising the SNV locus", "present in 0.005% to 0.015% of the cell-free DNA comprising the SNV locus" based on the context provided by the surrounding claim language, the descriptions provided in the '454 Patent specifications, and the knowledge of a person of ordinary skill in the art. Dr. Metzker may further opine that, in light of the surrounding claim language and the specification of the '454 Patent, the aforementioned claim terms should each be construed according to their plain and ordinary meaning.

Dr. Metzker may modify his opinions, as well as the bases for his opinions, based upon the nature and content of the information that NeoGenomics or its expert witness(es) may produce or disclose.

B. NeoGenomics' Position

NeoGenomics intends to present written testimony from Dr. David I. Smith to show that the '454 Patent, read in light of the specification and the prosecution history, fails to inform those skilled in the art with reasonable certainty about the scope of the following claim terms: “clonal” (claims 3,5,17,19); “subclonal” (claims 4,5,18,19); “present in less than or equal to 0.015% of the cell-free DNA comprising the SNV locus” (claim 14); and “present in 0.005% to 0.015% of the cell-free DNA comprising the SNV locus” (claim 28). As an example, NeoGenomics intends to present written testimony from Dr. Smith that a person of ordinary skill in the art would not be able to determine whether a particular SNV mutation is “clonal” or “subclonal” with reasonable certainty. As another example, NeoGenomics intends to present written testimony from Dr. Smith that a person of ordinary skill in the art would not know with reasonable certainty which of multiple possible ways to use in order to determine whether a method is “capable of detecting an SNV mutation that is present in less than or equal to 0.015% of the cell-free DNA comprising the SNV locus” or “capable of detecting an SNV mutation that is present in 0.005% to 0.015% of the cell-free DNA comprising the SNV locus.”

NeoGenomics further reserves the right to rely on additional written or live testimony of David I. Smith to rebut any claim construction, or the testimony of any expert in support thereof, offered by Natera.

March 15, 2024

/s/ Robert C. Van Arnam

WILLIAMS MULLEN, LLP
Robert C. Van Arnam (N.C. Bar No. 28838)
Andrew R. Shores (N.C. Bar No. 46600)
P.O. Drawer 1000
Raleigh, NC 27602-1000
Telephone: (919) 981-4015
Fax: (919) 981-4300

QUINN EMANUEL URQUHART
& SULLIVAN, LLP
Kevin P.B. Johnson*
Victoria F. Maroulis*
555 Twin Dolphin Shores, 5th Floor
Redwood Shores, CA 94065
(650) 801-5000

Andrew Bramhall*
Kevin Smith*
Tara Srinivasan, Ph.D.*
50 California Street, 22nd Floor
San Francisco, CA 94111
(415) 875-6600

/s/ John F. Morrow

WOMBLE BOND DICKINSON (US) LLP
John F. Morrow, Jr. (Bar No. 23382)
One West Fourth Street
Winston-Salem, NC 27101
Telephone: 336.721.3584
Facsimile: 336.733.8429

MORRISON & FOERSTER, LLP
Matt I. Kreeger*
425 Market Street
San Francisco, CA 94105
(415)268-7000

Aaron G. Fountain*
300 Colorado St. Ste 1800
Austin, TX 78701
(512) 617-0650

*Attorneys for Defendant NeoGenomics
Laboratories, Inc.*

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

Sandra Haberny, Ph.D.*
865 South Figueroa Street, 10th Floor
Los Angeles, CA 90017
(213) 443-3000

Attorneys for Plaintiff Natera, Inc.

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

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: March 15, 2024

/s/ Robert C. Van Arnam

Robert C. Van Arnam (N.C. Bar No.
28838)

Andrew R. Shores (N.C. Bar No. 46600)

WILLIAMS MULLEN, LLP

P.O. Drawer 1000

Raleigh, NC 27602-1000

Telephone: (919) 981-4015

Fax: (919) 981-4300

rvanarnam@williamsmullen.com

ashores@williamsmullen.com