

**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

**DEFENDANT NEOGENOMICS LABORATORIES, INC.'S OPPOSITION AND
CONDITIONAL CONSENT TO NATERA'S MOTION FOR LEAVE TO FILE
FIRST AMENDED COMPLAINT**

The Court's September 24, 2024 Order requires that Natera base any proposed amendment to its complaint at least in-part on information learned after September 12, 2024. (Dkt. 330 at 3.) Natera fails to meet this requirement.

Natera argues that since September 12, it has learned new evidence demonstrating that (1) "RaDaR 1.1 uses biological samples obtained from a subject at different time points," and (2) "that an SNV mutation present in less than 0.015% of the cell-free DNA having the SNV locus is detected from the sequence reads in RaDaR 1.1." (Dkt. 339 at 7.) RaDaR 1.1, however, does not differ from RaDaR 1.0 in either respect. There is no reason Natera could not have asserted the '596 Patent against RaDaR 1.0 at the beginning of this lawsuit.

Moreover, Natera's brief and amended complaint are noticeably devoid of any evidence or argument supporting its contention that documents produced by NeoGenomics

on October 31, 2024 “contained new information regarding aspects of the RaDaR 1.1 assay that serve as the basis for Natera’s [new] infringement claims.” (Dkt. 339 at 11.) Permitting Natera to add the ’596 patent at this juncture will prejudice NeoGenomics; it will expand the parties’ discovery obligations and risk delay to the current schedule, a central term in the parties’ partial settlement agreement. Natera’s motion to amend should therefore be denied according to the terms of the Court’s order.

Nevertheless, despite Natera’s inability to make the showing required by the Court’s order, NeoGenomics is eager to clear RaDaR 1.1 from Natera’s unfounded patent claims. NeoGenomics therefore does not oppose Natera’s proposed amendment provided that the prejudice to NeoGenomics caused by this late amendment is mitigated through the following measures:

- First, that the current trial date, October 13-17, 2025, be maintained subject to the Court’s availability and criminal docket. (Dkt. 330.) A principal term of the parties’ partial settlement agreement is that the parties would propose a case schedule that allows for trial within 6-8 months from the Notice required under the current schedule. (See Dkt. 324 at 10.)
- Second, prompt disclosure of Natera’s infringement contentions for its new patent, including a reasonable limit on the number of claims asserted in both patents.¹ Natera’s current proposal would delay infringement contentions

¹ NeoGenomics suggests no more than four claims per patent. In exchange, NeoGenomics could agree to limit its preliminary invalidity contentions under 35 U.S.C. § 102 and 103 to three combinations of up to three prior art references per claim.

until two days after the Court rules on its request for leave. Natera should provide its infringement contentions now and should meaningfully narrow its asserted claims across both patents now.

- Third, allowance for new discovery targeted at factual issues implicated by Natera's new infringement allegations.²

Incorporating these guidelines, NeoGenomics proposes the following schedule:

Event	Date
Natera serves preliminary infringement contentions for the '596 Patent and preliminary infringement contentions for the '454 Patent, limited to no more than 4 claims per patent	<i>*Within two business days of NeoGenomics' Opposition and Conditional Consent filing³</i>
NeoGenomics serves preliminary invalidity contentions, limited to no more than 3 combinations of 3 references per claim.	<i>December 11, 2024</i>
Parties exchange proposed claim construction terms	<i>December 20, 2024</i>
Parties exchange preliminary constructions and intrinsic evidence	<i>January 6, 2025</i>
Parties file Joint Claim Construction Statement	<i>January 13, 2025</i>
Parties file Opening Claim Construction briefs	<i>January 20, 2025</i>
Parties file Responsive Claim Construction briefs	<i>February 3, 2025</i>
Claim Construction Hearing	<i>At the court's convenience and discretion</i>

² NeoGenomics anticipates some of this discovery will occur abroad and may not be obtainable before the current close of fact discovery on April 4, 2025. NeoGenomics' proposal is contingent on allowing such evidence to be used at trial with sufficient disclosure before the Pretrial conference. A full schedule consistent with NeoGenomics' proposal is attached as Exhibit A.

³ This is the only date for which Natera proposes a different date (within two days of the Court's ruling on Natera's motion). Other dates indicated in italics are jointly proposed by the parties.

I. LEGAL STANDARD

Because a scheduling order has already been entered, the Court should modify that order “only for good cause.” FED. R. CIV. P. 16(b)(4). “[D]iligence” is the “touchstone” of good cause under Rule 16(b). *Faulconer v. Centra Health, Inc.*, 808 F. App’x 148, 152 (4th Cir. 2020) (unpublished). When a moving party knew of the underlying conduct giving rise to the claim but did not promptly raise that conduct, “then the party cannot establish good cause under Rule 16.” *Id.* at 152 & n.1 (collecting cases). Indeed, the Court’s September 24, 2024 Order recognizes “the prejudice to NeoGenomics from an amendment filed now which could have been filed in August or early September” and accordingly states that “the need for the amendment must be based, at least in part, on information Natera learned or learns after September 12, 2024.” (Dkt. 330 at 3.)

II. FACTUAL BACKGROUND

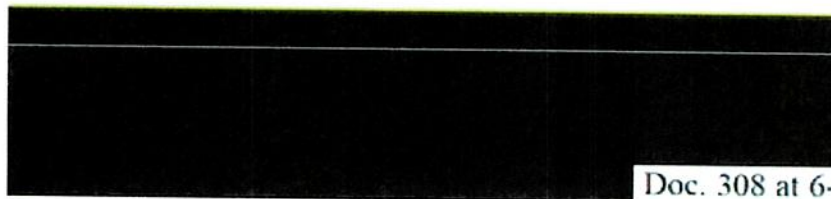
By late June 2024, NeoGenomics’ research and development had shown that the RaDaR 1.1 assay would work as intended. On June 21, NeoGenomics produced more than 3,700 documents describing the RaDaR 1.1 workflow and experiments. (See Dkt. 307 at 11.) The documents within this production included results from NeoGenomics’ feasibility experiments, including JIRA tickets showing internal discussion of those experiments. (Dkt. 313 ¶ 39.) NeoGenomics’ production also included a presentation with an overview of the new wet lab steps in RaDaR 1.1, a description of the initial feasibility experiments (including *sensitivity*), a diagram and list of the workflow adjustments that would have to be made to accommodate the new molecular biology steps, and proposed plans for

development of the commercial assay. (*Id.*) NeoGenomics has promptly produced the SOPs and documentation related to RaDaR 1.1 as it has become available. (*See* Dkts. 339-4, 339-6.) Most important to this motion, however, is that nothing produced after September 12, 2024 comprised truly *new information* regarding the two claim elements that Natera now contends it was not able to establish prior to receiving documents produced by NeoGenomics' on October 31, 2024.

III. ARGUMENT

A. NATERA CANNOT SHOW GOOD CAUSE BECAUSE ITS AMENDED ALLEGATIONS ARE BASED ON INFORMATION KNOWN WELL BEFORE SEPTEMBER 12, 2024

Natera's brief and amended complaint are devoid of any evidence or argument supporting its vague contention that documents produced by NeoGenomics on October 31, 2024 "contained new information regarding aspects of the RaDaR 1.1 assay that serve as the basis for Natera's [new] infringement claims." (Dkt. 339, at 11.) As Natera's Motion correctly acknowledges, RaDaR 1.0 and 1.1 differ in that:

 Doc. 308 at 6-7.

Dkt. 339 at 10. However, the two limitations of the '596 patent for which Natera argues it learned new information are completely different: "including at least that RaDaR 1.1 uses biological samples obtained from a subject at different time points and that an SNV mutation present in less than 0.015% of the cell-free DNA having the SNV locus is detected

from the sequence reads in RaDaR 1.1, which are relevant to Claim 1 of the '596 Patent.” (Dkt. 339 at 7.) Natera’s Amended Complaint shows that it had the information it relies on to allege infringement of these two limitations long before September 12, 2024.

First, the 0.015% sensitivity limitation in the '596 Patent is nearly *identical* to asserted claim 14 in the already-asserted '454 Patent (“wherein the 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”). The allegations on sensitivity in the amended complaint are that “RaDaR 1.1 is an updated version of RaDaR [1.0]” (Dkt. 339-1 at 420), and that the level of detection of RaDaR 1.1 is “equivalent to RaDaR 1.0” (*i.e.*, less than 0.015%). (*Id.* at 420-23.) The remainder of Natera’s allegations of RaDaR 1.1’s sensitivity are that RaDaR 1.0 meets the sensitivity limitations of the '596 patent. Natera has had the evidence underpinning its allegations for months.

Further, Natera has known the facts underlying NeoGenomics’ sensitivity claims regarding RaDaR 1.0 since 2023 (Dkt. 339-1 at 425 (citing NEOGEN00000120)). Natera has known RaDaR 1.1 is an updated version of RaDaR 1.0 at least since July 1, 2024. (Dkt. 307 at 11.) More importantly, Natera has had the results of NeoGenomics’ experimentation concerning RaDaR 1.1’s sensitivity since at least August 5, 2024. (Dkt. 302-3 at 7) (showing [REDACTED]

[REDACTED] [REDACTED] [REDACTED]; (Dkt. 302-12 at 140-141 (Forsheew Jul. 19, 2024 30(b)(6) Dep. Tr. at 139:18-140:3)) (“[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]”).

In addition, Natera has similarly known for months that RaDaR 1.1 uses biological samples from multiple timepoints.⁴ Indeed, Natera’s amended complaint cites documents for this limitation of the ’596 Patent that were produced *before the preliminary injunction* and a version of NeoGenomics website that was “last accessed [on] January 30, 2024.” (Dkt. 339-1 at 400-402 (citing to NEOGEN00000116 and NeoGenomics’ website.)

Ignoring this evidence, Natera attempts to create doubt by arguing that documents produced by NeoGenomics on October 31, 2024 “contained new information regarding aspects of the RaDaR 1.1 assay that serve as the basis for Natera’s [new] infringement claims.” (Dkt. 339, at 11.) This is mere attorney argument. Nowhere in its brief or amended complaint does Natera: (a) point to any new document that establishes these two elements; or (b) demonstrate or otherwise explain how any new document contained any information different from the evidence discussed above that was produced long before September 12, 2024. (*Id.*) Natera’s showing thus does not approach “good cause” required for any amendment based on information learned *after* September 12, 2024. (Dkt. 330 at 3-4.)

B. NEOGENOMICS WILL BE PREJUDICED IF THE ADDITION OF THE ’596 PATENT DELAYS THE TRIAL DATE

As the Court has already recognized, Natera’s delayed efforts to add the ’596 patent

⁴ Monitoring patient samples from multiple timepoints is how MRD monitoring works.

results in prejudice to NeoGenomics. (Dkt. 330 at 3.) A central term of the parties' partial settlement agreement—agreeing on a case schedule that allows for trial within 6-8 months, which the Court set for October 2025. (See Dkts. 330; 324 at 10.) Natera's infringement allegations concerning the '596 Patent will require additional claim construction and fact discovery—at least from its inventors and *putative* inventors. Nevertheless, NeoGenomics believes that the schedule proposed by Natera is achievable with the following modifications—as long as the addition of the '596 patent and any additional discovery, claim construction, and other procedures do not cause the trial date to slip. Should that happen, the Court should sever the '596 patent to a separate case with a separate schedule.

First, Natera's proposal would delay infringement contentions until two days after the Court rules on its request for leave. There is no reason for this delay. Natera's exhibits to its proposed amended complaint already include an exemplary claim chart for the '596 Patent, and for months Natera has had NeoGenomics' preliminary invalidity contentions to the '454 Patent. Natera should provide its infringement contentions now and should meaningfully narrow its claims across both patents now to accommodate the compressed schedule.

Second, the insertion of a new patent to the suit necessarily brings with it added discovery obligations. For example, Natera attempts to minimize the additional discovery by arguing that amendment will not require deposing "any additional inventors" (Dkt. 339 at 12), overlooking that NeoGenomics may need to depose the same inventors a second time to ask questions specific to the '596 patent. Further, NeoGenomics will seek discovery from individuals at the University College of London to determine the

applicability of its improper inventorship claim to the '596 Patent and, given their location, will likely need to do so under the Hague Convention.

In the event Natera's proposed Amended Complaint results in a material change to the trial date, the Court should deny Natera's motion for leave now, or sever the '596 patent claims later, because Natera cannot show good cause for its amendment and the amendment would prejudice NeoGenomics.

IV. CONCLUSION

Natera has failed to meet the Court's requirement to show that its proposed amendment is based on information learned after September 12, 2024. Nevertheless, NeoGenomics will not oppose amendment provided that:

- the current trial date of October 13-17, 2025 can be maintained.
- Natera provides prompt disclosure of its infringement contentions for its new patent, including a reasonable limit on the number of claims asserted, within two business days of this Opposition and Conditional Consent filing.
- NeoGenomics may propound new discovery requests, including deposition notices, targeted at factual issues implicated by Natera's new infringement allegations, and may use any such evidence obtained internationally after the close of fact discovery.

This the 15th day of November, 2024

/s/ John F. Morrow Jr.

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

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on November 15, 2024, a true and correct copy of the foregoing document was served via electronic notice and electronic mail upon the following:

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