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

PLAINTIFF NATERA'S REPLY IN SUPPORT OF ITS MOTION FOR A PRELIMINARY INJUNCTION PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 65(A) AND 35 U.S.C. § 283

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I. NATERA IS LIKELY TO PREVAIL ON THE MERITS

A. '454 Patent Infringement

NeoGenomics raises two non-infringement arguments: (1) RaDaR purportedly does not "sequenc[e] the amplicons" (Opp. 3-6); and (2) [redacted] (Opp. 6). Each fails.

1. "Sequencing the Amplicons"

NeoGenomics argues that "sequencing the amplicons" excludes additional amplification steps. But claims, like Claim 1, with "comprising" language can include unrecited steps precisely to avoid such "gotcha" theories of noninfringement. *Cias, Inc. v. All. Gaming Corp.*, 504 F.3d 1356, 1360 (Fed.Cir.2007). All Claim 1 requires is "sequencing the amplicons." RaDaR *does* obtain sequence reads of the amplicons generated via targeted multiplex amplification, as required by this "sequencing" step. Metzker.Decl., § IX.A, ¶270.

NeoGenomics' contrary argument (a disguised claim construction) is that "amplicons"[1] from targeted amplification must be "directly" sequenced without a modifying intervening step. Van-Ness.Decl[2], ¶78; Van-Ness.Tr,[3]. 236:21-22. But

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[1] NeoGenomics never proposed—therefore waived—a construction for this term. *Adv. Commc'n Design, Inc. v. Premier Retail Networks*, 46 F.App'x 964, 980 (Fed.Cir.2002).

[2] Dkt. 116.

[3] *See* Metzker.Decl., Ex. 1.

accepting this requires improperly reading the term "direct" into Claim 1, and disregarding controlling precedent, established claim construction canons, and the '454 Patent's teachings. Metzker.Decl., § IX.A, ¶¶271-272.

For example, asserted Claim 11, which depends from Claim 1, introduces an additional step of "barcoding PCR prior to the sequencing." Metzker.Decl., ¶¶273-274. Under the doctrine of claim differentiation, Claim 1's scope is broader than Claim 11—thus additional PCR steps are permitted, though not required. *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1242 (Fed.Cir.2003). NeoGenomics' Opposition fails to address Claim 11.

The '454 specification teaches additional amplifications following targeted amplification, (*e.g.*, Example 7), and sequencing using Illumina's system, which involves adding universal sequencing adapters by PCR, (Metzker.Decl., ¶274). NeoGenomics' interpretation excludes these necessary steps and reads out preferred embodiments which is "rarely, if ever, correct." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

NeoGenomics' reading also contradicts the meaning of "amplicons." PCR-related terms such as "amplicons" and "primers" refer to functional units of DNA involved in the PCR process—molecules containing the same characteristic sequence, which can be modified as needed. Contrary to NeoGenomics' characterization[4], when a similar argument arose in *ArcherDx*, the Court—and jury—rejected requiring identity between "a universal

[4] Dkt. 107 at 3.

primer" and "the universal primer" in a claim. That the same *sequence* was present in the two was sufficient for infringement.

NeoGenomics cites supposed "admissions" made during prosecution of a different patent, U.S. 11,486,008. Opp. 4-5. But absent allegation that a patentee acted as his own lexicographer (here there is none), claim scope can only be surrendered where there is a disavowal in the specification or during prosecution, and NeoGenomics does not argue one occurred. *AstraZeneca LP v. Breath Ltd.*, 542 F. App'x 971, 975-76 (Fed.Cir.2013) (disclaimer must be "clear and unmistakable"); Metzker.Decl., §IX.A.iii, ¶292. Moreover, because the '454 and '008 claims have materially different language[5] and the PTO found them patentable based on different arguments, statements in the '008 prosecution do not limit the '454 claims. *Invitrogen v. Clontech Labs.*, 429 F.3d 1052, 1078 (Fed.Cir.2005); *ResQNet.com v. Lansa*, 346 F.3d 1374, 1383 (Fed.Cir.2003).[6]

Even if NeoGenomics' construction were adopted, RaDaR would still infringe under doctrine of equivalents. *Spectrum Pharm. v. Sandoz*, 802 F.3d 1326, 1337

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[5] The '008 claims as issued recite sequencing "the amplicons obtained in the multiplex targeted amplification reaction," language which does not appear in any '454 claim. Metzker.Decl., ¶.

[6] NeoGenomics' cited cases are inapposite. (Opp. 5) *Elkay Mfg. Co. v. Ebco Mfg. Co.*, involved two sets of claims the applicant "affirmatively linked" during prosecution, and the issued claim language was identical but for one term. 192 F.3d 973, 980 (Fed. Cir. 1999). *Juniper Networks, Inc. v. Palo Alto Networks, Inc.*, addressed doctrine of equivalents where (unlike here) the asserted patent was a direct continuation of the earlier patent, and the Examiner allowed the claims for "substantially similar reasons," linking them. 15 F. Supp. 3d 499 (D. Del. 2014). The '454 and '008 Patent claims differ in materials ways (not by a mere word) and were never expressly linked.

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(Fed.Cir.2015). Sequencing the targeted PCR amplicons, as modified by universal PCR for sequencing, performs the same function (to obtain sequencing reads) in substantially the same way (by sequencing the amplified DNA) to produce substantially the same result (sequence reads that include the target loci). Metzker.Decl.,§IX.A.v. NeoGenomics' expert makes passing reference to "disclaimer" (Ex. 116, 30) but as discussed above, no disclaimer was made for the '454 Patent.

[redacted]

[redacted]

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[redacted]

B. ’035 Patent Infringement

Regarding Claim 1, NeoGenomics argues—incorrectly—that RaDaR does not perform targeted amplification of tagged products. Opp, 6-7. RaDaR allegedly does not infringe because, while it uses targeted PCR to generate tagged products, it does not perform a subsequent targeted PCR to separately amplify those tagged products. Opp. 7. Claim 1, however, does not require two separate targeted PCRs for “tagging” and “amplifying.” Metzker.Decl., §IX.B., ¶297.

PCR involves of a series of amplification “cycles,” each involving a separate and new amplification of what was produced in prior cycles. Van-Ness.Tr. 220:1-16; Metzker.Decl., §V.B.ii-iii. RaDaR’s targeted PCR involves 15 cycles. Metzker.Decl., ¶295; Van-Ness Tr. 228:17-19. The first cycle(s) of RaDaR’s targeted PCR introduces universal tags, one on each strand of the resulting product (“tagging” step). Metzker.Decl., ¶296. NeoGenomics argues that the initial tagging occurs over two cycles, (Opp. 7), but even if true, that would be irrelevant. All agree at least one tag is added at the first cycle, the dual-tagged products are formed by at least the second cycle’s end, and tagged products

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are thereafter amplified by targeted amplification numerous times in the remaining cycles of PCR ("amplifying" step). Metzker.Decl., §IX.B; Van-Ness.Tr. 228:20-232:25.

C. NeoGenomics Has Not Raised A Substantial Question Of Invalidity

1. Obviousness

NeoGenomics does not argue the Natera claims lack novelty. NeoGenomics argues they are obvious. Opp. 8-11. Obviousness, however, requires (1) motivation to combine and (2) reasonable expectation of success. *Regents Univ. Cal. v. Broad Inst.*, 903 F.3d 1286, 1291 (Fed.Cir.2018). NeoGenomics makes neither showing.

NeoGenomics and its expert identify no evidence of motivation to combine. *See generally* Van-Ness.Decl., §X; Metzker.Decl, ¶75. That alone defeats NeoGenomics' arguments. *In re Rouffet*, 149 F.3d 1350, 1358 (Fed.Cir.1998).

NeoGenomics also fails to grapple with unpredictability of the art, particularly well-known obstacles to the use of cell-free DNA ("cfDNA"), which is challenging to manipulate even with known methods. Metzker.Decl., §II.A; Van-Ness.Tr., 109:25-110:7, 116:19-117:21. In combining disparate teachings, Dr. Van Ness fails to address—even acknowledge—difficulties in identifying genetic variants in low-abundance, unpredictable cancer-associated cfDNA ("ctDNA"). Askilled artisan would not be motivated to modify the prior art to achieve the claimed methods or reasonably expect success doing so. NeoGenomics' obviousness combinations all fail. 903 F.3d at 1291.

NeoGenomics' technical arguments also lack merit. ***First***, the '454 claims are not obvious over Forshew (Opp. 10), as the Examiner recognized during prosecution.

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Metzker.Decl., §VI.A.i.a.C. Sequencing each SNV locus 50,000 times or more—which Forshew does not teach, *id.*— would not reasonably be expected to identify rare variants in low-abundance ctDNA above the background "noise" from sequencing-related error rates. *Id.* §VI.A.i.a.B.

Second, it would not have been obvious to modify Bashashati[8] to amplify multiple cfDNA loci in one reaction volume. (Opp. 10). Doing so could generate unwanted byproducts and hamper the method's success. Metzker.Decl., §VI.A.ii.a; Van-Ness.Tr. 132:13-133:3.

Third, the '035 Patent is not obvious over Kaper's Access Array system (Opp. 10). Metzker.Decl., §VI.B.i. The '035 Patent *teaches away* from using Access Array, disparaging it as "problematic for samples with a limited amount of DNA"—*e.g.*, ctDNA. *Id.* §VI.B.i.a.

Finally, NeoGenomics' reliance on ARM-PCR fails to teach cfDNA or targeted amplification of SNP loci in one reaction volume. *Id.* §§VI.B.ii.a-b.

2. Written Description

Contrary to NeoGenomics' argument (Opp. 11-12), the '454 specification describes whole genome sequencing ("WGS") explicitly and in terminology a skilled artisan would recognize—e.g., "long read sequencing" and "phasing." Metzker.Decl., §VIII.A; *Ariad*

[8] Dkt. 118-14 ('454 Patent, p.8).

Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1352 (Fed.Cir.2010) (written description "does not demand any particular form of disclosure").

NeoGenomics' other conclusory arguments (Opp. 12) lack merit because the patents show possession of the inventions and provide examples. Metzker.Decl., §VIII.B. The patents teach the claimed methods could be performed without selecting primers to avoid "primer dimer" formation. *Id.* §VIII.B.i.

3. Inventorship

NeoGenomics' inventorship argument (opp. at 11-14) is a red herring. NeoGenomics cannot overcome the presumption that inventorship is accurate. *Hess v. Adv. Cardiovascular Sys.*, 106 F.3d 976, 980 (Fed.Cir.1997). There is no evidence any allegedly omitted inventor contributed to ***conception*** of the '454 claims. *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460-61 (Fed.Cir.1998). At most, NeoGenomics suggests Dr. Jamal-Hanjani articulated the state of the prior art regarding "whole exome sequencing" (WES) to Natera, but that is not enough to be an inventor. *See id.*, *Eli Lilly and Co. v. Aradign Corp.*, 376 F.3d 1352, 1359 (Fed. Cir. 2004); Van-Ness.Tr 22:17-24:1. [redacted] And Natera already conceived of using WES in the context of the '454 claims by June 2014, months before meeting Dr. Jamal-Hanjani. Ex. 1 (NAT-NEO-00884450); Ex. 2 (NAT-NEO-00574120-22); Ex. 3 (NAT-NEO-00774814, -21, -25); Ex. 4 (Zimmermann.Tr) 109:24-113:19; 100:24-104:8, 105:16-109:13.

Improper inventorship is rarely grounds for denying a preliminary injunction; it can be corrected any time—including during litigation and without explanation—without affecting validity. Stoll.Decl., §VI.D; *Egenera v. Cisco Sys.*, 972 F.3d 1367, 1376 (Fed.Cir.2020); *Canon Computer Sys. v. Nu-Kote Int'l*, 134 F.3d 1085, 1088 (Fed.Cir.1998). Natera did so during prosecution of the '035 Patent,[9] and during litigation asserting its ancestor '220 Patent, which was upheld in *Natera v. ArcherDx* despite the same inventorship challenge. Dkt. 109-1 at 10-11.

4. Section 101

Natera's response to NeoGenomics' motion to dismiss (Dkt. 131), incorporated by reference, explains why the Natera Patent claims are patent-eligible. *See also* Metzker.Decl., §VII.

II. NATERA WILL SUFFER IRREPARABLE HARM

A. Natera Did Not Unreasonably Delay

NeoGenomics' "delay" argument (Opp. 15) fails. Delay does not bar an injunction where, as here, there is good cause. *Hybritech v. Abbott Labs.*, 849 F.2d 1446, 1457 (Fed.Cir.1988). Natera has been litigating to enforce its patents since 2020, and these asserted patents did not issue until December 2022. *See* D.Del. case nos. 20-cv-38, 20-cv-125, 21-cv-56. A patentee facing multiple infringers will often have "good cause for seeking relief against [a different infringer] first." *Hybritech*, 849 F.2d at 1457; *Polymer Techs. v. Bridwell*, 103 F.3d 970, 975-76 (Fed.Cir.1996).

[9] Stoll Decl. ¶¶54-56.

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Further, before July 2023, RaDaR lacked Medicare approval. NeoGenomics contends (Opp. 16) that Medicare approval does not drive sales, citing a survey. Dkt. 110-1. That survey found, however, that "reimbursement status" was an important factor influencing MRD-test-vendor choice, ranking higher than "cost," "report clarity/comprehensiveness," and "quality of customer support." *Id*., NEOGEN4241*; see* Ex. 5., Malackowski.Tr., 71 [redacted] NeoGenomics itself has made a point to publicly announce RaDaR's Medicare approval for RaDaR.[10]

B. Natera Will Lose Market Share, First-Mover Advantage, Clinical Opportunities, and Biopharmaceutical Partnerships

NeoGenomics' argument (Opp., 17) that there is no irreparable harm because of Natera's large market share is misplaced. A patentee's large market share weighs ***in favor*** of an injunction—not against—because the patentee has more to lose from infringement than the infringer has from injunction. *Metalcraft of Mayville v. Toro*, 2016 WL 4076894, *4 (E.D.Wis.2016) (granting PI to patentee with "about 100% of the market"); *Arlington Indus. v. Bridgeport Fittings*, 2011 WL 2927817, *10 (M.D.Pa. July 18, 2011) (similar). Even the report NeoGenomics cites predicts ***Natera will lose*** and ***NeoGenomics will gain*** market share. Dkt. 92-1, NEOGEN00004203. Further, NeoGenomics cites only data for

[10] Dkt. 1-30 at 2.

the overall MRD-test market, not the tumor-informed market, [redacted].[11]

NeoGenomics incorrectly contends that "Natera and NeoGenomics do not directly compete in the MRD market." Opp. 18. [redacted] Malackowski.Tr., 60-62, 71; Dkt. 12-23, 12. The implausibility of NeoGenomics' position is illustrated by its contentions that: (1) Natera will not be harmed because Signatera has "numerous competitors" (Ex. 6 at 3), and (2) [redacted]. Malackowski Tr., 73-76.[12]

Natera's CEO's statements that Guardant's ***tumor-naïve*** MRD test is Natera's largest competitor and new competitors have "got a very long way to go" (Opp., 18-19) reflect only that Natera holds the largest share of the ***overall*** MRD-test market. They do not suggest RaDaR's entrance into the tumor-***informed*** market will not harm Natera.

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[11] NeoGenomics' contention (Opp., 24) that injunction "would change the status quo, not preserve it" because RaDaR will lose ill-gotten market share is contrary to law. *Atlas Powder v. Ireco Chems.*, 773 F.2d 1230, 1231 (Fed.Cir.1985).

[12] That the parties are the only two significant players in the tumor-informed market is alone sufficient for irreparable harm. *Douglas Dynamics v. Buyers Prods.*, 717 F.3d 1336, 1345 (Fed.Cir.2013); *Robert Bosch v. Pylon Mfg.*, 659 F.3d 1142, 1151 (Fed.Cir.2011).

Nor does the law require specific lost contracts.[13] Notwithstanding, [redacted] (Sikri.Tr., 134) and Natera identified a lost contract with Moderna. Dkt. 6, 18. NeoGenomics ignores that: (1) Moderna partnered with NeoGenomics to use its tumor-informed MRD test, RaDaR; (2) [redacted] (Malackowski.Tr., 60); and (3) because of RaDaR, Moderna no longer needed Natera.

Nor has Natera licensed the patents to Clarient. Opp. 21. That license expired in 2018, four years before the asserted patents issued. Even if that license included the patents, "the fact that a patentee has licensed others under its patents does not mean that unlicensed infringement must also be permitted while the patents are litigated." *Abbott Labs. v. Sandoz*, 544 F.3d 1341, 1361-62, (Fed.Cir.2008).[14]

C. Natera Will Suffer Reputational Harm

Rather than dispute it is harming Natera's reputation, NeoGenomics slings mud. Opp., 22. That third parties have injured Natera's reputation does not preclude further injury by NeoGenomics. Nor has NeoGenomics shown these third-party statements are independent of its own conduct because many of them occurred ***after*** NeoGenomics began

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[13] *See Apple v. Samsung Elecs.*, 2012 WL 2576136, at *5 (N.D.Cal. July 3, 2012) ("the Federal Circuit has not required proof of specific lost customers") (citing *i4i Ltd. P'ship v. Microsoft*, 598 F.3d 831, 862 (Fed. Cir. 2010)); *Canon v. Color Imaging*, 292 F.Supp.3d 1339, 1347 (N.D.Ga.2018).

[14] NeoGenomics cites *ActiveVideo Networks v. Verizon Communications*, 694 F.3d 1312, 1338 (Fed.Cir.2012), but those parties did not compete and the patentee tried to license the patent throughout the industry, including to the defendant.

infringing and disparaging Signatera. Infringement is also depriving Natera of opportunities to ***improve*** its reputation because [redacted] Malackowski.Tr., 121.

D. There Is Causal Nexus

NeoGenomics contends RaDaR's sales are driven by sensitivity and advanced bioinformatics, not Natera's patents. Opp. 24 (citing Dkt.115 ¶44). But the cited declaration paragraph simply opines RaDaR is sensitive, not that sensitivity drives demand. RaDaR's sensitivity is irrelevant because the law requires "only "some connection between the patented feature and demand for" RaDaR, not that "a patented feature is the one and only reason for consumer demand." *Apple v. Samsung Elecs.*, 735 F.3d 1352, 1364 (Fed.Cir.2013).

III. BALANCE OF HARMS

Contrary to NeoGenomics' contention (Opp., 24), the fact that an injunction may harm its market share or customer relationships is irrelevant. *See Pfizer v. Teva Pharms., USA*, 429 F.3d 1364, 1382 (Fed.Cir.2005); *Celsis In Vitro v. CellzDirect*, 664 F.3d 922, 931 (Fed.Cir.2012). NeoGenomics' expert and 30(b)(6) deponent [redacted]. Malackowski.Tr., 121-22. Nor does NeoGenomics' investment in purchasing Inivata (RaDaR's developer), [redacted] work in its favor. *i4i*, 598 F.3d at 863 (rejecting defendant's reliance on development costs); Malackowski Tr., 127.

IV. PUBLIC INTEREST

NeoGenomics does not dispute that Natera has capacity to meet increased demand, weighing in favor of an injunction. *Boehringer Ingelheim Vetmedica v. Schering-Plough,* 106 F.Supp.2d 696, 707 (D.N.J.2000). NeoGenomics' unproven claims that RaDaR has "high sensitivity" and is superior are undermined by its argument that RaDaR will not capture a large portion of the market. *Target Therapeutics v. SciMed Life Sys.,* 1996 WL 289034 (N.D.Cal.1996) (granting injunction despite argument that physicians preferred defendant's catheters; finding patentee's 85% market share undermined defendant's claim to product superiority), *vacated on other grounds* 113 F.3d 1256 (Fed.Cir.1997). Nor would an injunction "interfer[e] with prospective trials" or "hurt on-going cancer research" because of the carve-out in Natera's proposed injunction for existing patients. Dkt. 5-1 at 2.[15] NeoGenomics' declarant, Mr. Sikri, opines [redacted] (Dkt. 115 at ¶¶15, 31-34, 39, 43, 47), but its expert and 30(b)(6) deponent [redacted] (Malackowski.Tr., 136).

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[15] *Cordis Corp. v. Boston Scientific Corp.*, 99 F.App'x 928, 935 (Fed.Cir.2004), and *Hybritech*, 849 F.2d at 1458, are not contrary. *Hybritech* affirmed without explanation a record-specific finding. *Id*. In *Cordis*, the patentee could not satisfy demand and its product had "safety or efficacy concerns." 99 F.App'x at 935.

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CERTIFICATE OF WORD COUNT

The undersigned counsel hereby certifies that this brief complies with the 3,125-word count limitation of Local Rule 7.3(d).

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

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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 6, 2023

By: */s/ Robert C. Van Arman*

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