**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| CAREDX, INC. and THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, | ) | |
| Plaintiffs, | ) | |
| v. | ) | Civil Action No. 19-567-CFC |
| NATERA, INC., | ) | |
| Defendant. | ) | |

## REPORT AND RECOMMENDATION

1. Presently pending before the Court in this patent infringement case is Defendant Natera, Inc.'s ("Defendant" or "Natera") motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6) (the "Motion"). (D.I. 9) In its Motion, Natera argues that: (1) the patents asserted by Plaintiffs CareDx, Inc. and The Board of Trustees of the Leland Stanford Junior University ("Plaintiffs" or "CareDx")—United States Patent Nos. 9,845,497 ("'497 patent") and 8,703,652 ("'652 patent")—are directed to patent-ineligible subject matter pursuant to 35 U.S.C. § 101; and (2) CareDx's allegations that Natera's Kidney Test infringes the '652 patent fail to meet the *Twombly/Iqbal* pleading standard.[1] This Report and Recommendation will address Natera's second argument only.[2] For the reasons that follow, the Court recommends that, as to that argument, the Motion should be DENIED.

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[1] The Motion has been referred to the Court for resolution, (D.I. 24), and was fully briefed on June 24, 2019, (D.I. 19).

[2] The Court will address Natera's arguments relating to Section 101 in a subsequent Report and Recommendation.

2. The standard of review here is the familiar two-part analysis applicable to motions made pursuant to Rule 12(b)(6). First, the court separates the factual and legal elements of a claim, accepting "all of the complaint's well-pleaded facts as true, but [disregarding] any legal conclusions." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009). Second, the court determines "whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). A plausible claim does more than merely allege entitlement to relief; it must also demonstrate the basis for that "entitlement with its facts." *Id.* Thus, a claimant's "obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do[.]" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation omitted). In assessing the plausibility of a claim, the court must "'construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.'" *Fowler*, 578 F.3d at 210 (quoting *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)).

3. Natera contends that CareDx has failed to allege facts sufficient to plausibly show that every limitation of claim 1 of the '652 patent (the sole independent claim) is contained in its accused Kidney Test. (D.I. 10 at 19-20) That claim recites, *inter alia*, a "method for detecting transplant rejection, graft dysfunction, or organ failure . . . wherein sensitivity of the method is greater than 56% compared to sensitivity of current surveillance methods for cardiac allograft vasculopathy (CAV)" (the "sensitivity limitation"). (D.I. 11, ex. B at cols. 27:39-28:40) Because CareDx's Complaint "does not allege any facts to show that the accused test's sensitivity is compared to that of then-current methods for surveillance of the specific CAV heart

condition recited in the claim[,]" Natera argues that CareDx's allegations of infringement with respect to claim 1 of the '652 patent are implausible. (D.I. 10 at 19 (emphasis omitted)) Implicit in Natera's argument is that the claim requires that the accused infringer performing the method *actually perform a comparison* between the accused test's sensitivity and the sensitivity of then-current surveillance methods for CAV—as opposed to simply requiring that the sensitivity of the accused method *is greater* than 56% as compared to the specified methods regarding CAV. (D.I. 10 at 20 (Defendant asserting that "Natera does not compare the sensitivity of its Kidney Test to *anything* when performing it") (certain emphasis in original); *see also* D.I. 15 at 20)

4. But to the extent CareDx's Complaint sets out a plausible allegation of infringement of the sensitivity limitation—even one that may not ultimately prevail after intrinsic and extrinsic evidence are weighed at the claim construction stage—then CareDx has met its burden at this stage of the case. (D.I. 15 at 20)[3] And CareDx has done so here. Its Complaint incorporates by reference a claim chart that cites to exemplary evidence that the sensitivity levels of Natera's Kidney Test range from 89% to 91.8%. (D.I. 1 at ¶ 37; *id.*, ex. 8 at 6-8) Moreover, the sensitivity limitation might easily be read to require only a showing that the accused product's sensitivity is greater than 56% compared to the specified methods (as opposed to

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[3] *See also Confluent Surgical, Inc. v. Hyperbranch Med. Tech., Inc.*, Civil Action No. 17-688-LPS-CJB, 2017 WL 4804264, at *2 (D. Del. Oct. 25, 2017) (denying a motion to dismiss allegations of direct infringement where the defendant asserted that plaintiffs did not plausibly allege infringement of one limitation of the asserted claims, because the motion to dismiss stage is not the appropriate time for claim construction and because plaintiffs' complaint included plausible allegations addressing each limitation of the asserted claims) (citing cases); *D&M Holdings Inc. v. Sonos, Inc.*, Civil Action No. 16-141-RGA, 2017 WL 1395603, at *11 (D. Del. Apr. 18, 2017) (same); *cf. Pragmatus AV, LLC v. Yahoo! Inc.*, Civil Action No. 11-902-LPS-CJB, 2012 WL 6044793, at *8 (D. Del. Nov. 13, 2012) (explaining that typically, "[t]o engage in the claim construction process upon review of a motion to dismiss would be to go beyond the scope of a court's traditional gatekeeping role in reviewing such a motion").

requiring the actual performance of a comparison by the accused infringer). (*See* D.I. 15 at 20) This could be said to be especially so as to a claim that speaks of the sensitivity limitation in a somewhat passive (not active) voice. (D.I. 11, ex. B at cols. 27:39-28:40 (the claim reading "wherein sensitivity of the method is greater than 56% compared to. . ." not "wherein a comparison of the sensitivity of the method demonstrates that . . .")[4] On the present record, then, there is a plausible reading of the sensitivity limitation that could allow for a finding of infringement.

5. For the foregoing reasons, the Court recommends that the Motion be DENIED.

6. This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006). The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Dated: November 25, 2019

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE

[4] The Court emphasizes that it has drawn no concrete conclusions as to what this limitation in fact requires and will consider any further evidence on this point at the appropriate future time (e.g. at a *Markman* hearing).