

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

NATERA, INC.,

Plaintiff,

v.

INIVATA, INC. and INIVATA LTD.,

Defendants.

C.A. No. 21-56

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MEMORANDUM OPINION

March 14, 2022
Wilmington, Delaware



STARK, U.S. District Judge:

Pending before the Court is Defendants Inivata, Inc. and Inivata Ltd.’s (“Defendants” or “Inivata”) motion to dismiss Plaintiff Natera, Inc.’s (“Plaintiff” or “Natera”) first amended complaint (D.I. 13), filed pursuant to Federal Rule of Civil Procedure 12(b)(6). (D.I. 16) The Court has reviewed the parties’ briefs and other submissions. (*See, e.g.*, D.I. 17-20) For the reasons set forth below, the Court will deny Defendants’ motion to dismiss.

I. BACKGROUND

Natera filed its complaint in this case on January 20, 2021, alleging that Defendants have infringed U.S. Patent Nos. 10,262,755 (the “’755 patent”) and 10,597,709 (the “’709 patent”). (D.I. 1 ¶ 1; *see also* D.I. 13 ¶ 1) The ’755 patent claims “methods for detecting genetic mutations, including aneuploidy, in tumor DNA.” (D.I. 13 ¶ 28) The ’709 patent claims “methods for simultaneously amplifying multiple nucleic acid regions of interest in a reaction mixture.” (*Id.* ¶ 30) The complaint alleges that Defendants have “unlawfully used Natera’s patented technology, including in connection with Inivata’s InVisionFirst-Lung cancer diagnostic test (‘InVisionFirst-Lung’) and any other products that use the same or similar technology.” (*Id.* ¶ 13)

Defendants initially moved to dismiss in April 2021 (D.I. 10), to which Natera responded by filing the first amended complaint in May 2021 (D.I. 13). On June 1, 2021, Defendants filed the pending motion to dismiss. (D.I. 16)

II. LEGAL STANDARDS

Evaluating a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) requires the Court to accept as true all material allegations of the complaint. *See Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004). “The issue is not whether a plaintiff will ultimately prevail but

whether the claimant is entitled to offer evidence to support the claims.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotation marks omitted).

Thus, the Court may grant such a motion to dismiss only if, after “accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief.” *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (internal quotation marks omitted).

However, “[t]o survive a motion to dismiss, a civil plaintiff must allege facts that ‘raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).’” *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). A claim is facially plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). At bottom, “[t]he complaint must state enough facts to raise a reasonable expectation that discovery will reveal evidence of [each] necessary element” of a plaintiff’s claim. *Wilkerson v. New Media Tech. Charter School Inc.*, 522 F.3d 315, 321 (3d Cir. 2008) (internal quotation marks omitted).

The Court is not obligated to accept as true “bald assertions,” *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (internal quotation marks omitted), “unsupported conclusions and unwarranted inferences,” *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997), or allegations that are “self-evidently false,” *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996).

III. DISCUSSION

A. '755 Patent

Defendants first contend that Natera fails to plausibly allege that the accused products perform the claim limitation “amplifying at least 1000 polymorphic loci relating to cancer-associated aneuploidy.” (’755 patent at 197:37-38) Natera alleges that the accused assay, as described in Defendants’ Gale publication, targets “hotspots and entire coding regions” from 35 genes, for amplification and analysis, including four genes tested for copy number variants (“CNVs”), a cancer-associated aneuploidy. (D.I. 13 Ex. 3 at 14) Natera alleges the “entire coding regions” of the four genes contain more than 1000 polymorphic loci and, in this way, the claim limitation is satisfied. (*See id.* at 19-21) Defendants insist that Natera has “misinterpreted the Gale publication,” which, in Defendants’ view, discloses that only “hotspots” – but not “entire coding regions” – are amplified for the genes tested for CNVs. (*See* D.I. 17 at 5-8) In the present procedural posture, the Court will not dismiss a patent infringement claim based on Defendants’ contested reading of the Gale publication. (*See generally* D.I. 18 at 7-13) At this early stage, it appears that both parties are able to identify disclosures in the Gale publication (and the accompanying supplemental materials) that plausibly support their competing inferences. (*See* D.I. 17 at 6-7; D.I. 18 at 8-13; D.I. 19 at 2-6) In evaluating the pending motion to dismiss, the Court must resolve competing inferences in Natera’s favor. *See In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1340 (Fed. Cir. 2012).¹

¹ Despite their contentions, Defendants have not identified “irreconcilable internal inconsistencies” in the first amended complaint. (D.I. 17 at 7) Nor does the first amended complaint “affirmatively show no infringement.” (*Id.*)

Defendants next contend that Natera fails to plausibly allege that the accused products perform the claim limitation of “using the nucleic acid sequence data to generate phased allelic data.” (’755 patent at 197:45-46) Relying on Defendants’ Forshew and Gale publications, the first amended complaint alleges that the accused products “use the nucleic acid sequence data to generate phased allelic data for the set of polymorphic loci on each of the plurality of chromosomes or chromosome segment.” (D.I. 13 Ex. 3 at 22, 25) Defendants counter that the terms “phasing” and “phasing data” require “determining the ‘haplotype’ for an individual,” and that the publications Natera relies upon have “nothing to do with the claim limitation at issue.” (D.I. 17 at 8) This contention implicates a claim construction dispute, which the Court will not resolve in connection with a motion to dismiss. *See Nalco Co. v. Chem-Mod LLC*, 883 F.3d 1337, 1349 (Fed. Cir. 2018); *see also* D.I. 18 at 13-16) Additionally, whether the assay described in the Forshew and Gale publications performs this claim limitation under Defendants’ construction presents an issue of fact. Defendants’ argument, thus, does not provide a basis for dismissing Natera’s infringement claim.

Accordingly, the Court will deny Defendants’ motion to dismiss the claims that their accused products infringe the ’755 patent.

B. ’709 Patent

Defendants contend that the first amended complaint fails to plausibly allege that the accused products perform the claim limitation requiring amplifying “at least 50 target loci.” (’709 patent at 237:39-40) For this contention, Defendants point to the figure that Natera relies on for its infringement allegations, which discloses “markers from 37 genes,” arguing that “Natera’s extrapolation of 37 genes into over 50 loci, as the claims recite, is unfounded.” (D.I. 17 at 11-12) The first amended complaint alleges that “[e]ach of the 37 genes analyzed in the

Accused Products comprises hundreds to thousands of variants . . . , the accused products amplify at least 50 of these variants as target loci.” (D.I. 13 Ex. 4 at 4) At this stage, the Court has no basis not to credit as plausible the allegation that these 37 genes may plausibly comprise over 50 target loci.

Defendants also contend that Natera’s reliance on the Forshew publication, to allege that the “melting temperature” limitation of the ’709 patent is met, renders the ’709 patent “necessarily invalid since the Forshew publication predates the ’709 patent’s earliest possible priority date.” (D.I. 17 at 13) A patent is invalid as anticipated if “a single prior art reference discloses each and every limitation of the claimed invention.” *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). Natera’s first amended complaint does not allege that the Forshew publication discloses each and every limitation of the method claimed in the ’709 patent. Nor does the allegation that the accused products utilize the eTam-Seq method that was “described” in the Forshew publication necessarily indicate that the Forshew publication discloses each and every limitation of the method claimed in the ’709 patent. (See D.I. 18 at 18-19) Defendants’ invalidity theory may be the subject of evidentiary proceedings as this case moves forward but it does not provide a meritorious basis on which to dismiss Natera’s claims of infringement.²

Accordingly, the Court will deny Defendants’ motion to dismiss the claims that their accused products infringe the ’709 patent.

² Defendants’ indefiniteness-related and claim construction arguments (*see, e.g.*, D.I. 17 at 2) likewise provide no basis for the relief they seek in their motion. (*See also* C.A. No. 20-125 D.I. 243 at 10-12) (rejecting, in related litigation, indefiniteness argument)

IV. CONCLUSION

For the foregoing reasons, the Court will deny Defendants' motion to dismiss (D.I. 16).

An appropriate order follows.

