

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

NATERA, INC.,

Plaintiff,

V.

INIVATA, INC. and INIVATA, LTD.,

Defendants.

Case No. 21-56-LPS

JURY TRIAL DEMANDED

**DEFENDANTS' OPENING BRIEF IN SUPPORT OF MOTION TO DISMISS FOR
FAILURE TO STATE A CLAIM**

Dated: April 12, 2021

OF COUNSEL:

Edward R. Reines

Derek C. Walter

Kaitlin Paulson

WEIL, GOTSHAL & MANGES LLP

201 Redwood Shores Parkway

Redwood Shores, CA 94065

Tel: (650) 802-3000

Fax: (650) 802-3100

edward.reines@weil.com

derek.walter@weil.com

kaitlin.paulson@weil.com

Brian E. Farnan (#4089)

Michael J. Farnan (#5165)

FARNAN LLP

919 North Market Street, 12th Floor

Wilmington, DE 19801

(302) 777-0300

bfarnan@farnanlaw.com

mfarnan@farnanlaw.com

Attorneys for Defendants

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I. NATURE AND STAGE OF THE PROCEEDINGS

On January 1, 2021, Plaintiff Natera, Inc. (“Natera”) filed its complaint against Inivata, Inc. and Inivata, Ltd. (collectively “Defendants”) accusing Defendants’ InVisionFirst-Lung cancer diagnostic test of infringing U.S. Patent No. 10,262,755 (“the ’755 patent”) and U.S. Patent No. 10,597,709 (“the ’709 patent”). D.I. 1. Defendants now move to dismiss Natera’s complaint for failure to state a claim.

II. SUMMARY OF ARGUMENT

Natera’s allegations of infringement based on the ’755 and ’709 patents are implausible on their face and should be dismissed. Indeed, Natera’s pleadings firmly establish that it cannot possibly be entitled to relief.

For the ’755 patent, all claims require the amplification of at least, 1,000 genetic loci. To allege infringement, Natera relies on a publication by Defendants that it contends shows the amplification of 4,320 genetic loci. As shown herein, however, Natera’s reading of Defendants’ publication is way off. The publication cited by Natera shows the amplification of only 32 loci, a number well below the 1,000 loci threshold required to infringe the ’755 patent. Natera’s pleadings are based on an erroneous and haphazard review of a technical publication and do not satisfy the plausibility threshold of Rule 8.

As to the ’709 patent, all claims require the amplification of at least 50 loci and the use of an “annealing temperature” that exceeds a “melting temperature.” To allege infringement, Natera relies on the same publication it relies upon for the ’709 patent, which shows 32 loci, not 50 or more. What’s worse, Natera alleges in its complaint that the accused products are based on a technique that was published in 2012, which is roughly two years before Natera’s earliest possible priority date of 2014. The allegations in Natera’s pleadings, which must be accepted as true for the purposes of this motion, thus establish that the ’709 patent is invalid.

Because Natera's complaint alleges facts establishing that it is not entitled to relief, Natera's allegations do not satisfy the Rule 8 plausibility standard and should be dismissed.

III. STATEMENT OF FACTS

Relevant facts are stated in the Argument section below as appropriate.

IV. ARGUMENT

To survive a motion to dismiss under Rule 12(b)(6), a complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.*

"A complaint is subject to dismissal for failure to state a claim if the allegations, taken as true, show the plaintiff is not entitled to relief." *Jones v. Bock*, 549 U.S. 199, 215, 127 S. Ct. 910, 920, 166 L. Ed. 2d 798 (2007). "Litigants may plead themselves out of court by alleging facts that establish defendants' entitlement to prevail." *Bennett v. Schmidt*, 153 F.3d 516, 519 (7th Cir. 1998).

As documented below, this is precisely what has happened here.

A. Natera's Allegations Based On The '755 Patent Are Implausible

All claims of Natera's '755 patent require "amplifying at least 1000 polymorphic loci relating to cancer-associated aneuploidy" from a plurality of chromosomes or chromosome segments of circulating tumor DNA. To the extent Natera's pleadings include any allegations directed to this claim element, they establish that Defendants do not infringe because they do not amplify at least 1,000 loci.

In its complaint, Natera cites to the Gale publication as allegedly showing Defendants' infringement. Specifically, Natera states that "Inivata's Gale publication, in Supporting

Information, at S5 Table, shows 4,320 loci amplified and analyzed. Gale, Exhibit 7, at p. 15; S5 Table, Exhibit 7A, at p. 106.” D.I. 1-1, Ex. 3 at 12. Page 15 of Gale cites to Table S5 as providing a “[l]isting of the variants” analyzed in the Gale publication. Table S5 is a spreadsheet that indeed lists those variants. Page 106 of the table is the last page of the spreadsheet, which shows that there are 4,320 rows. D.I. 1-1, Ex. 7A at 106. From this number of rows, Natera concludes that 4,320 variants were analyzed in the Gale publication. *See id.* Natera is wrong.

In fact, there are only 32 variants in Table S5. If one compares Row 1 of Table S5 to row 33 of Table S5, for instance, one immediately sees that both rows pertain to the same locus (i.e., `mis_chr10_121520163_G_C`). *See* D.I. 1-1, Ex. 7A. The same is true of rows 2 and 34, rows 3 and 35, rows 4 and 36, and so on. *Id.* In fact, the exact same 32 loci are repeated in Table S5 of Gale 135 times, representing 135 different sets of experimental conditions. *Id.*¹ Nowhere does the Gale publication include any evidence of amplification of more than 1,000 loci, as the claims recite. As documented above, Gale includes *fewer* than 1,000 loci. The content of Natera’s pleadings is thus directly contrary to the claim requirements. In such circumstances, dismissal is appropriate.

This Court, for instance, has dismissed a complaint in circumstances very similar to those at issue here. In *Cumberland Pharm. Inc. v. Sagent Agila LLC*, “every claim of the '356 patent

¹ Importantly, the Court is permitted to consider the content of Gale in connection with the instant motion to dismiss because Natera attached Gale to its complaint. *See, e.g., Anderson v. Loc. 435 Union*, No. CV 12-1119-LPS, 2014 WL 4955611, at *1 (D. Del. Sept. 30, 2014) (“The Court may consider documents attached to the complaint in ruling on a motion to dismiss under Rule 12(b)(6).”). In fact, to the extent there is any conflict between Natera’s allegations based on Gale and the content of Gale itself, it is the actual content of Gale that controls. *See, e.g., ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 n.8 (3d Cir. 1994) (“Where there is a disparity between a written instrument annexed to a pleading and an allegation in the pleading based thereon, the written instrument will control.”).

expressly require[d] a formulation that is ‘free of a chelating agent’ or ‘free from a chelating agent.’” No. CV 12-825-LPS, 2013 WL 5913742, at *2 (D. Del. Nov. 1, 2013). The Plaintiffs’ pleading, however, admitted that “that EDTA is a chelating agent,” and that the accused product “includes EDTA.” *Id.* Even to the extent the complaint satisfied the notice pleading requirement, the Court held that this “does not preclude dismissal, given the Complaint’s failure (nonetheless) to state a claim for which relief may be granted.” *Id.*

Indeed, courts routinely dismiss complaints such as the one at issue here, where the allegations are inconsistent with the claim language and hence establish that the plaintiff is not entitled to relief. *See, e.g., Mosaic Brands, Inc. v. The Ridge Wallet LLC*, No. 220-CV-04556-ABJCX, 2020 WL 5640233, at *4 (C.D. Cal. Sept. 3, 2020) (dismissing complaint where “Plaintiff alleges that Defendant’s product ‘meets all of the elements of Claim 1, as shown further element-by-element’ in a claim chart attached to the FAC....But the claim chart contradicts this summary allegation.”); *Qwikcash, LLC v. Blackhawk Network Holdings, Inc.*, No. 4:19-CV-876-SDJ, 2020 WL 6781566, at *4 (E.D. Tex. Nov. 17, 2020) (The “pleading defect identified by Blackhawk is not that Qwikcash has failed to allege enough or sufficiently specific facts to survive a Rule 12(b)(6) motion to dismiss, but rather that—given irreconcilable internal inconsistencies on the face of its pleading—Qwikcash’s claim of direct infringement is patently implausible.”); *Howard v. Ford Motor Co.*, No. 1:16CV127-LG-RHW, 2016 WL 4077260, at *5 (S.D. Miss. July 29, 2016) (where defendant argued that “complaint and its attachments affirmatively show no infringement” making “patent infringement implausible,” dismissing complaint with prejudice and explaining that “[a]ccording to the pleadings, these limitations are absent from Ford’s MyKey system”); *Metricolor LLC v. L’Oreal S.A.*, 791 F. App’x 183, 188 (Fed. Cir. 2019) (“As the district court correctly found, nothing in the complaint shows that the Accused Products contain the ‘air-

tight reclosing seal’ / ‘air-tight reclosable seal’ required by the independent claims.”); *Ottah v. Fiat Chrysler*, 884 F.3d 1135, 1142 (Fed. Cir. 2018) (where a complaint accused features inconsistent with the claim language, ruling “[w]e have liberally construed the pleadings, but have concluded that the Second Amended Complaint’s accusation of infringement lacks plausibility”).

B. Natera’s Allegations Based On The ’709 Patent Are Implausible

The claims of the ’709 patent are directed to techniques for copying DNA associated with more than 50 different “target loci” using two temperatures: an “annealing temperature” and a “melting temperature.” All claims of the ’709 patent require that “the annealing temperature for the reaction conditions is greater than a melting temperature of the at least 50 primers.” Natera again relies upon the Gale publication to plead infringement of this claim element. Again, the Gale publication undermines Natera’s pleadings.

As with the ’755 patent, Natera cites the S5 Table of the Gale publication to establish that there are more than 50 loci. *See, e.g.*, D.I. 1-1, Ex. 4 at 3 (“The primers targeting the 4320 target loci described in Gale comprise at least 50 primers....”). As explained above, however, the S5 Table of Gale includes only 32 loci. *See supra* Part IV.A. Natera’s pleading for the ’709 patent, as with the ’755 patent, is based on an erroneous reading of Gale and does not meet the threshold plausibility standard of Rule 8. This alone warrants dismissal.

Natera’s pleading with respect to the ’709 patent, however, suffers from yet another defect when one considers the ’709 patent’s earliest possible priority date, which is April 21, 2014. *See* D.I. 1-1, Ex. 2 at (60). To allege infringement of the “melting temperature” limitation of the ’709 patent, Natera points to Defendants’ use of a technology called “eTAm-Seq,” which was previously described in a publication by Forshew. As Natera alleges in its pleadings, the “Accused Products ‘us[e] eTAm-Seq technology,’ which ‘is based on methods previously described,’ with reference to Forshew....” D.I. 1-1, Ex. 5 at 3. Natera goes on to allege that

“Forshew further discloses that the annealing temperature of the reaction is 60°C, which, on information and belief, is greater than a melting temperature of at least 50 primers.” *Id.*

The problem with these allegations is that if, as Natera contends, the Accused Products utilize the approach described in Forshew, then the '709 patent is necessarily invalid because Forshew published in 2012, roughly two years before Natera's earliest possible 2014 priority date. *See Upsher-Smith Lab'ys, Inc. v. PamLab, L.L.C.*, 412 F.3d 1319, 1322 (Fed. Cir. 2005) (“That which infringes, if later, would anticipate, if earlier.”). Importantly, Natera cannot swear behind the Forshew reference because the '709 patent is a post-AIA patent. And, even if the '709 patent were a pre-AIA patent, Natera could not swear behind Forshew because it published more than a year before Natera's earliest filing date. *See* pre-AIA 35 U.S.C. § 102(b).

As the Supreme Court explained, a “complaint is subject to dismissal for failure to state a claim if the allegations, taken as true, show the plaintiff is not entitled to relief.” *Jones*, 549 U.S. at 215. Certainly, the notion that Natera could pursue a viable claim of infringement based on technology that was published two years before it filed for a patent is implausible under Rule 8, providing yet another basis for dismissal of Natera's allegations based on the '709 patent.

V. CONCLUSION

For the foregoing reasons, Natera's complaint should be dismissed.

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Respectfully submitted,

OF COUNSEL:

FARNAN LLP

Edward R. Reines
Derek C. Walter
Kaitlin Paulson
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
Tel: (650) 802-3000
Fax: (650) 802-3100
edward.reines@weil.com
derek.walter@weil.com
kaitlin.paulson@weil.com

/s/ Michael J. Farnan
Brian E. Farnan (#4089)
Michael J. Farnan (#5165)
919 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 777-0300
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Attorneys for Defendants