

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CAREDX, INC.,

Plaintiff,

Civil Action No. 19-662-CFC

v.

NATERA, INC.,

Defendant.

Brian E. Farnan and Michael J. Farnan, FARNAN LLP, Wilmington, Delaware;
Edward R. Reines and Derek C. Walter, WEIL, GOTSHAL & MANGES LLP,
Redwood Shores, California; Randi Singer and Elizabeth McLean, WEIL,
GOTSHAL & MANGES LLP, New York, New York

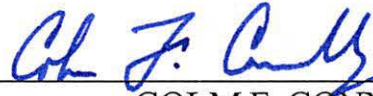
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Counsel for Defendant

MEMORANDUM OPINION

July 17, 2023
Wilmington, Delaware



COLM F. CONNOLLY
CHIEF JUDGE

Plaintiff CareDx, Inc. and Defendant Natera, Inc. make and sell competing diagnostic tests used to help treat kidney transplant patients. CareDx's test is called AlloSure. Natera's test is called Prospera. Both tests rely on technology that measures donor-derived cell-free DNA in the transplant patient's bloodstream.

Natera launched a marketing campaign in which it claimed that Prospera was superior in various ways to AlloSure. It based these claims of superiority on results from the so-called Sigdel Study, a retrospective study of blood samples from kidney transplant patients.

CareDx sued Natera for false advertising. In a trial held last year, it asked the jury to find that ten specific advertisements in Natera's marketing campaign were false and that Natera was liable for: (1) false advertising under the Lanham Act, 15 U.S.C. § 1125(a); (2) false advertising under the Delaware Deceptive Trade Practices Act (DTPA), 6 Del. C. § 2532; and (3) unfair competition under Delaware common law. The jury found that CareDx proved by a preponderance of the evidence at trial that: (a) nine of the ten alleged false advertisements were false; (b) Natera intentionally and willfully engaged in false advertising; (c) Natera was liable for false advertising under the DTPA; (d) Natera was liable for unfair

competition; and (e) Natera intentionally or recklessly engaged in unfair competition. The jury also found that CareDx was entitled to \$21.2 million in actual damages “attributable to Natera’s false advertising and/or unfair competition,” D.I. 329 at 17, and that CareDx was entitled to \$23.7 million in punitive damages “for Natera’s unfair competition,” D.I. 329 at 18.

Pending before me is Natera’s Motion for Judgment as a Matter of Law Pursuant to Federal Rule of Civil Procedure 50(b), New Trial pursuant to Federal Rule of Civil Procedure 59, or Remittitur (D.I. 339).

I. Legal Standards

A. Judgment as a Matter of Law

“If the court does not grant a motion for judgment as a matter of law made under Rule 50(a), . . . the movant may file a renewed motion for judgment as a matter of law [under Rule 50(b)] and may include an alternative or joint request for a new trial under Rule 59.” Fed. R. Civ. P. 50(b). Upon a Rule 50(b) motion, a jury verdict should be overturned “only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability.” *Fultz v. Dunn*, 165 F.3d 215, 218 (3d Cir. 1998) (internal quotation marks and citation omitted).

B. New Trial

Rule 59(a) permits a district court judge, “on motion,” to grant a new trial “for any reason for which a new trial has heretofore been granted in an action at law in federal court.” Fed. R. Civ. P. 59(a). A new trial may be granted when the verdict is contrary to the evidence, where a miscarriage of justice would result if the jury’s verdict were to stand, or when the court believes the verdict results from confusion. *Brown v. Nutrition Mgmt. Servs. Co.*, 370 F. App’x 267, 270 (3d Cir. 2010); *see also Nissho-Iwai Co. v. Occidental Crude Sales, Inc.*, 729 F.2d 1530, 1538 (5th Cir. 1984) (“A trial judge may order a new trial if he suspects that the jury verdict reflects confusion.”).

II. The Lanham Act, the Actual Deception Element, and the Parties’ Stipulation

The Lanham Act “provide[s] a remedy by way of civil damages or injunction against anyone who[] in connection with goods or services in commerce uses a false designation of origin [or] any false description or representation.”

Parkway Baking Co. v. Freihofer Baking Co., 255 F.2d 641, 648 (3d Cir. 1958).

To establish liability for a false advertising claim under the Lanham Act, a plaintiff must prove five elements:

- 1) that the defendant has made false or misleading statements as to his own product [or another’s];
- 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience;
- 3) that the deception is material in that it is likely to influence

purchasing decisions; 4) that the advertised goods traveled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc.

Pernod Ricard USA, LLC v. Bacardi U.S.A., Inc., 653 F.3d 241, 248 (3d Cir. 2011)

(alterations in the original) (citation omitted). The second element—actual deception—is presumed and need not be proven for liability purposes if a plaintiff “proves that an advertisement is unambiguous and literally false.” *Id.* But under Third Circuit law, if a plaintiff alleges that an advertisement is misleading—as opposed to unambiguous and literally false—then the plaintiff must prove customer deception in order to establish liability under the Lanham Act.

Actual deception, however, must still be proven to establish damages for a Lanham Act violation, even if based on an unambiguous and literally false advertisement. *See Parkway Baking Co.*, 255 F.2d at 648 (“[A] plaintiff in order to make out a cause of action for damages under [the Lanham Act] must show not only that the defendant’s advertisement is false but also that this falsification actually deceives a portion of the buying public.”); *id.* (“[T]here must be a showing of some customer reliance on the false advertisement” to establish damages under the Lanham Act.); *TRUSTID, Inc. v. Next Caller, Inc.*, 2023 WL 2298748, at *3 (Fed. Cir. Mar. 1, 2023) (“[T]he seminal Lanham Act case in the Third Circuit, *Parkway Baking v. Freihofers Baking Co.*, 255 F.2d 641 (3d Cir. 1958)[,] holds

that, for cases involving monetary damages, ‘there must be a showing of some customer reliance on the false advertisement.’”).

Although CareDx alleged in its Amended Complaint that Natera’s advertisements were false and misleading, the parties stipulated on the eve of trial that CareDx was not asserting “a claim that any advertising is misleading” and that “Natera will not use testimony, evidence, or argument about whether CareDx has proven ‘actual deception’ . . . to argue, suggest, or imply that CareDx cannot prove that Natera is liable for false advertising.” D.I. 301-1 at 113. The parties further stipulated that “[b]oth parties can use testimony, evidence, or argument about whether the other party can prove ‘actual deception’ for other purposes, including for whether damages have been proven.” D.I. 301-1 at 13.

III. Judgment as a Matter of Law

Natera argues that it is entitled to a judgment as a matter of law “because CareDx did not present evidence of actual deception and customer reliance, which precludes an award of damages, nor did it present evidence sufficient for a reasonable jury to find any of the advertisements literally false.” D.I. 340 at 4. Natera also argues that CareDx failed to establish common-law unfair competition and a DTPA violation and that Natera is entitled to a judgment as a matter of law on these claims. D.I. 340 at 18–20. I address these arguments in the order Natera presented them in its briefing.

A. Damages

1. Lanham Act

The parties agreed at trial and the jury was instructed that

to recover damages under the Lanham Act, the plaintiff must prove by a preponderance of the evidence that, one, the defendant's false advertising actually deceived a portion of the purchasing public in that customers relied on the false advertising in making a purchasing decision. There's no presumption here for the damages question. The burden rests on the plaintiff to prove that by a preponderance of the evidence.

All right. And then the second thing that the plaintiff must prove by a preponderance of the evidence is that, as a result of the false advertising, the plaintiff sustained injury. If you find that CareDx proved these things, then you consider what amount of money to award to CareDx as damages.

3/14 Tr. 1462:14–1463:2.

Natera argues, and I agree, that CareDx adduced at trial no evidence that any person was deceived by or relied on any of the nine advertisements found by the jury to be false. CareDx insists otherwise, but the evidence it points to does not establish directly or even circumstantially that a person was in fact deceived by or relied on Natera's advertisements.

CareDx cites, for example, testimony from a Natera employee and Natera's expert that Natera internally characterized a PowerPoint slide that contained at least one of the false advertisements as "the money slide." D.I. 348 at 2. But that

testimony is not probative of actual customer behavior. CareDx also insists that financial statements it introduced at trial “show significant growth [of Prospera sales] from the start of [Natera’s] marketing campaign in early 2020 to the end of 2021.” D.I. 348 at 2. But it fails to identify any evidence adduced at trial that linked those increased sales to customers’ actual deception or reliance on Natera’s advertisements. CareDx’s reliance on Natera’s marketing plans and its training of marketing personnel, *see* D.I. 348 at 3–4, similarly fails. Proof of what Natera intended to accomplish or thought it could achieve with its marketing plans and training efforts in no way establishes that those plans and efforts succeeded.

CareDx says that Dr. Maag and Ms. King’s testimony at trial “confirmed [that] Natera’s false advertisements led to confusion among customers.” D.I. 348 at 2. But here is the testimony of Dr. Maag cited by CareDx:

Q. Okay. All right.

And did this concern you, that they were marketing that their specificity was better in the Sigdel study than in the Bloom study?

A. You [i.e., counsel] kind of mentioned how many phone calls I got from the University of Pennsylvania, from Cleveland Clinic, from all around the country about their claiming superiority based on what, they have a better assay. So this caused a lot of confusion internally and externally with our customers.

3/7 Tr. 212:4–12. And here is the testimony of Ms. King cited by CareDx:

A. So the Brave Heart team was a group of our executives who were meeting to respond to these kind of messages that were coming from Natera. So we would talk about things like – you know, we would review messaging that we were seeing out in the field, we would review centers that we were hearing were coming back and getting messages, these kind of superiority claim messages from Natera, that sort of thing.

Q. And were you included in the Brave Heart team?

A. Yes, I was.

* * * *

Q. So does it matter whether the other party is claiming superiority or not?

A. Absolutely.

Q. Isn't it true that CareDx is going to respond?

A. Oh, we respond on a very different level if somebody is coming out and claiming superiority in an inappropriate way when they're basing these two publications as the basis for these claims.

You know, these two publications are ones that are not apples to apples, and they're going around as if they are and confusing clinicians, confusing patients. And that is why we have to have, you know, a much bigger response to that than what we have with a company, a competitor, that's coming in and messaging their data appropriately.

3/8 Tr. 364:23–365:7, 378:15–379:4. No rational juror could conclude from this vague, conclusory, and hearsay-riddled testimony that customers were deceived by or relied on false advertisements published by Natera.

Finally, CareDx argues that “[c]ourts routinely recognize that deliberately false advertising campaigns, in which substantial resources are devoted, support a reasonable inference that customers were actually deceived.” D.I. 348 at 4. But the cases it cites in support of this assertion are decisions issued in three circuits that have held that actual deception may be presumed from evidence of deliberate engagement in false advertising. See D.I. 348 at 4–5 (citing *U-Haul Int’l., Inc. v. Jartran, Inc.*, 793 F.2d 1034, 1041 (9th Cir. 1986); *Resource Dev. V. Statue of Liberty-Ellis Island*, 926 F.2d 134, 140 (2d Cir. 1991); *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 42 (D.C. Cir. 1985)). In the Third Circuit, evidence of an intent to mislead does not warrant a presumption of actual deception. *Johnson & Johnson-Merck Consumer Pharms. Co. v. Rhone-Poulenc Rorer Pharms., Inc.*, 19 F.3d 125, 132 (3d Cir. 1994); see also *TRUSTID, Inc. v. Next Caller, Inc.*, 2022 WL 318299, at *9 (D. Del. Jan. 5, 2022) (“[T]he Third Circuit held [in *Johnson*] that an intent to mislead alone cannot create a presumption of actual deception[.]” (citing *Johnson*, 19 F.3d at 132)), *aff’d*, 2023 WL 2298748 (Fed. Cir. Mar. 1, 2023).

For these reasons, I will grant Natera’s request for judgment as a matter of law of no damages under the Lanham Act.

2. State Law Claims

Natera argues, and I agree, that because CareDx failed to prove customer deception from and reliance on Natera's advertisements, CareDx failed to establish the causation and injury necessary to recover damages for CareDx's state law claims. D.I. 340 at 5, 9, 11, 19. CareDx does not dispute that proof of causation and injury is necessary to establish damages. On the contrary, it proposed, *see* D.I. 292 at 40, 46, and I read to the jury the following instructions:

Actual damages refers to the amount of money that will reasonably and fairly compensate the plaintiff *for any injury you find was caused by the other party's false advertising.*

* * * *

If you decide that Natera's . . . false advertising *caused [CareDx] harm* under Delaware common law for unfair competition, and if you award compensatory damages, then you must decide whether the conduct justifies an award of punitive damages.

3/14 Tr. 1463:4–7, 1464:12–16 (emphasis added). Having failed, for the reasons stated above, to establish customer deception or reliance on Natera's advertisements, CareDx also failed to establish the causation and injury required to sustain a damages award arising from its state law claims. I will therefore grant Natera's request for judgment as a matter of law of no damages.

B. Literal Falsity

As noted above, the jury found that nine of ten Natera advertising statements challenged by CareDx were literally false. Natera argues that “CareDx failed to adduce sufficient evidence of literal falsity” because “the challenged statements are ambiguous” and, “even assuming the statements were unambiguous, CareDx failed to show falsity.” D.I. 340 at 11–15 (some capitalization removed).

The first advertisement found by the jury to be false (*see* D.I. 329 at 4) refutes Natera’s contentions. In that advertisement, Natera stated, among other things, that Prospera is “[m]ore sensitive and specific than current assessment tools across all types of rejection.” JTX-7.2; *see also* JTX-5.3 (stating that Prospera is “more sensitive and specific than current assessment tools across all type of rejection”). Natera’s designated corporate representative admitted at trial, however, that both the Sigdel Study and CareDx’s Bloom study found that Prospera’s specificity was lower than AlloSure’s specificity and that AlloSure was a “current assessment tool[,]” as that phrase is used in the advertisement. 3/8 Tr. 440:14–441:15, 442:4–13, 444:13–445:1. Based on this testimony, a rational juror could conclude that the statement that Prospera was more sensitive *and* specific than the current assessment tools was unambiguous and false.

Natera adduced evidence at trial to support its contention that the phrase “sensitive and specific” “reasonably refers to ‘AUC’—a measure familiar to

physicians that combines both sensitivity and specificity.” D.I. 354 at 10. And it argues that “[s]ince a physician could reasonably interpret Natera’s advertisements either way [i.e., under either CareDx’s or Natera’s reading of ‘sensitivity and specificity’], the[] [advertisements] are ambiguous” and therefore cannot sustain a liability finding of literal falsity under the Lanham Act. D.I. 354 at 10.

Ambiguity, however, is a fact question for the jury. *See Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 199 (3d Cir. 2014) (reviewing “district court’s findings that an advertising claim is unambiguous and literally false for clear error”); *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 589 (3d Cir. 2002) (treating “ambiguity” finding under Lanham Act as fact question subject to clearly erroneous standard of review); *see also Wing Enterprises, Inc. v. Tricam Indus., Inc.*, 511 F. Supp. 3d 957, 968 (D. Minn. 2021) (noting that majority of circuits, including the Third Circuit, have treated ambiguity determination for literal falsity under Lanham Act as a fact question). And, as just noted, there was record evidence from which a rational juror could find that the “sensitivity and specificity” advertisement was unambiguous and literally false.

For these reasons, I will deny Natera’s motion insofar as it seeks a judgment as a matter of law of no liability on CareDx’s Lanham Act claim.

C. Unfair Competition

Under Delaware law, “[t]o state a claim for unfair competition, a plaintiff must [prove] a reasonable expectancy of entering a valid business relationship, with which the defendant wrongfully interferes, and thereby defeats the plaintiff’s legitimate expectancy and causes him harm.” *Agilent Techs., Inc. v. Kirkland*, 2009 WL 119865, at *5 (Del. Ch. Jan. 20, 2009) (internal quotation marks and citation omitted). Natera argues that it is entitled to judgment as a matter of law with respect to CareDx’s unfair competition claim because CareDx failed to adduce evidence of a reasonable expectation of entering into a business relationship, causation, and injury.

CareDx’s unfair competition claim was based on its claims of false advertising. But, as I have already found, it failed to adduce record evidence that customers were deceived by or relied on Natera’s false advertisements, and therefore it did not provide an evidentiary basis for a rational juror to conclude that Natera caused CareDx any injury.

I also agree with Natera that CareDx failed to adduce any evidence that CareDx had a reasonable expectancy of entering into a valid business relationship that Natera interfered with. CareDx says that its evidence of lost sales is sufficient to show that CareDx had a reasonable expectation of entering into a valid business relationship. D.I. 348 at 21. That may be the case, but CareDx neither cited in its

briefing nor adduced at trial evidence to show that Natera interfered with (i.e., caused harm to) a valid business relationship.

Accordingly, I will grant Natera's motion insofar as it seeks a judgment as a matter of law of no liability on CareDx's unfair competition claim.¹

D. The DTPA

Natera argues that it is entitled to judgment as a matter of law on CareDx's DTPA claim because CareDx failed to establish causation and injury. But as CareDx notes, Natera misstates the law with respect to the DTPA, which expressly provides that for liability purposes "a complainant need not prove competition between the parties or actual confusion or misunderstanding." 6 Del. C. § 2532(b). Consistent with that express provision and at the request of both parties, I instructed the jury that CareDx "d[id] not need to prove . . . actual confusion or misunderstanding in order to prove a violation of the [DTPA]." 3/14 Tr. 1461:14–16.

For these reasons, I will deny Natera's motion insofar as it seeks judgment as a matter of law of no liability on CareDx's DTPA claim.

¹ CareDx's unfair competition claim is the only claim for which CareDx sought punitive damages. *See* D.I. 329 at 18. Accordingly, my granting Natera's motion for judgment as a matter of law of no liability on CareDx's unfair competition claim provides an independent reason to grant judgment as a matter of law of no punitive damages.

IV. Conditional Ruling on Motion for a New Trial

Under Rule 50(c), “[i]f the court grants a renewed motion for judgment as a matter of law, it must also conditionally rule on any motion for a new trial by determining whether a new trial should be granted if the judgment is later vacated or reversed.” Fed. R. Civ. P. 50(c). I believe a new trial would be warranted for the same reasons I will grant judgment as a matter of law of no damages for any claim and no liability for CareDx’s unfair competition claim—that is, the verdict is contrary to the evidence and, accordingly, a miscarriage of justice.

V. Remittitur

Because I will grant judgment as a matter of law of no damages, I need not and do not address Natera’s request for a remittitur.

VI. Conclusion

For the reasons discussed above, I will grant in part and deny in part Natera’s motion for judgment as a matter of law. I will grant the motion insofar as it seeks judgment as a matter of law of no damages for any claim and no liability for CareDx’s unfair competition claim. I will otherwise deny the motion.

The Court will issue an Order consistent with this Memorandum Opinion.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CAREDX, INC.,

Plaintiff,

v.

NATERA, INC.,

Defendant.

Civil Action No. 19-662-CFC

ORDER

At Wilmington this Seventeenth day of July in 2023:

For the reasons set forth in the Memorandum Opinion issued this day, it is **HEREBY ORDERED** that Defendant Natera, Inc.'s Motion for Judgment as a Matter of Law Pursuant to Fed. R. Civ. P. 50(b), New Trial Pursuant to Fed. R. Civ. P. 59, or Remittitur (D.I. 339) is **GRANTED IN PART** and **DENIED IN PART**. The motion is **GRANTED** insofar as it seeks judgment as a matter of law in Natera's favor with respect to liability on Plaintiff CareDx, Inc.'s unfair competition claim and with respect to damages for all claims. The motion is otherwise **DENIED**.

It is **FURTHER ORDERED** that the Parties shall submit no later than July

31, 2023 a proposed Judgment for the Court to sign and enter.

Cohn F. Connolly

CHIEF JUDGE