APPENDIX A

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

_____

Nos. 23-2427, 23-2428

_____

CAREDX, INC.,
Appellant

v.

NATERA, INC.

_____

CAREDX, INC.,

v.

NATERA, INC.,
Appellant

_____

On Appeal from the United States District Court
for the District of Delaware
(No. 1-19-cv-00662)
U.S. District Judge: Honorable Colm F. Connolly

_____

Submitted Under Third Circuit L.A.R. 34.1(a)
August 25, 2025

_____

Before: SHWARTZ, MATEY, and FISHER, Circuit Judges.

(Filed: August 28, 2025)

OPINION*

SHWARTZ, Circuit Judge.

Plaintiff CareDx sued Defendant Natera for violations of the Lanham Act and state law based on allegedly false claims Natera made about its organ transplant rejection detection product. A jury found for CareDx and awarded it damages. The District Court denied Natera's motion for judgment as a matter of law on liability but vacated the damages award. We agree with the District Court and will affirm.

I

CareDx and Natera make and sell competing tests that use DNA to detect whether a patient's body has rejected a transplanted kidney**,** called AlloSure and Prospera, respectively. CareDx asserts that Natera falsely claimed in marketing materials that its product was superior to CareDx's, for which CareDx sued Natera for false advertising under the Lanham Act, 15 U.S.C. § 1125(a), the Delaware Deceptive Trade Practices Act ("DTPA"), Del. Code Ann. tit. 6, § 2532, and Delaware common law prohibiting unfair competition. Natera's advertisements pointed to results from two studies—a Natera study on Prospera (the "Sigdel study") and a CareDx study on AlloSure (the "Bloom

* This disposition is not an opinion of the full court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

study")—to demonstrate Prospera's superiority. CareDx asserts that ten claims, which the parties call Claims A through J, in these advertisements are false.[1]

At trial, the parties offered evidence about the Sigdel and Bloom studies. Each study sought to determine how accurately AlloSure and Prospera detected whether a patient had rejected a kidney transplant. In the Bloom study, patients were identified across fourteen clinical sites, and then researchers collected blood samples and compared AlloSure's detection of kidney rejection against that of a biopsy. The results showed that AlloSure had a sensitivity of 59.3%,[2] specificity of 84.7%,[3] area under the curve

[1] Natera's advertising campaign included press releases, materials on its website, and presentations and brochures for physicians. See App. 2156 (website), 2168 (physician's brochure) (Claim A); App. 2169 (physician's brochure) (Claim B); App. 2200 (press release) (Claim C); App. 2209-10 (press release), 2220-23 (press release), 2225 (press release) (Claim D); App. 2163 (website) (Claim E); App. 2169 (physician's brochure) (Claim F); App. 2252 (presentation at organ transplant summit) (Claim G); App. 2169 (physician's brochure) (Claim H); App. 2249 (presentation at organ transplant summit), 2269 (presentation to physicians) (Claim J). The verdict form places each relevant advertising material that pertains to each claim on its own page.

[2] Sensitivity measures the likelihood of the test coming back positive if a rejection occurred, as opposed to resulting in a false negative. A false negative means that a patient rejected the transplant, but the test came back negative indicating that the patient did not reject the transplant. False negatives have serious consequences because they could result in the patient having a "more severe rejection requiring more treatment or even eventually los[ing] the kidney and go[ing] back on dialysis." App. 1283-84 (Dr. Phillipe Gauthier, senior medical director of Natera's organ health group).

[3] Specificity refers to the likelihood of the test coming back negative if a rejection has not occurred, as opposed to resulting in a false positive. A higher specificity means a higher chance of avoiding false positives, which occur when there was no rejection, but a test indicates that there was. False positives may lead patients to undergo additional testing, such as a biopsy.

("AUC") of 0.74,[4] and negative predictive value ("NPV") of 84%.[5] The Sigdel study took existing plasma samples, which had already been tested for rejection through biopsies, from a single site, and compared Prospera's ability to assess whether the transplanted kidney was rejected against that existing data. According to the Sigdel study, Prospera had a sensitivity of 88.7%, specificity of 72.6%, AUC of 0.87, and NPV of 95.1%.

Evidence at trial revealed differences in the studies' designs and methods. E.g., App. 955-56 (Dr. Minnie Sarwal, co-author of the Sigdel study, testifying that the studies were "different"). The Bloom study was multi-site, which meant that it could be generalized to the universal standard of care, while the Sigdel study was single-site, and thus "considerably less generalizable." App. 1338 (Dr. Steven Weisbord, CareDx's expert in nephrology, research study design and conduct, and medical publishing).[6] The Bloom study used a prospective methodology, which created a lower risk of selection bias because patients were first selected and then biopsied and tested to see how AlloSure performed. App. 957-58 (Dr. Sarwal testifying that an advantage of a prospective study is the "absence of any selection bias . . . based on patient demographics and patient

[4] AUC is a composite of sensitivity and specificity.

[5] NPV is the percentage of those without rejection who received a negative test result. A higher NPV means that the test misses fewer rejections and thus has fewer false negatives. .

[6] See also App. 818 (Dr. Peter Maag, a board member and former CEO and Chair of CareDX, App. 797, testifying about the importance of studying the standard of care "in multiple centers to be reflective of what's happening in transplantation," as opposed to an "individual center"), 1066 (Dr. Paul Billings, former CMO at Natera and Natera's designated Rule 30(b)(6) witness for marketing topics, App. 1051-52, testifying that the Sigdel study was "a single site study").

selection material"), 1340 (Dr. Weisbord discussing that, in the Bloom study, "patients were recruited, and the patients underwent a biopsy and blood was collected to bank and to assess for the AlloSure assay"[7]). This prospective methodology sometimes resulted in ambiguous results, however, based on the reality that certain patients demonstrate partial rejection. App. 1005 (Sasha King, CareDx's Chief Marketing Officer, discussing the differences between prospective and retrospective studies). By contrast, the Sigdel study selected from already-existing patient samples that had been tested for organ rejection and were either "clearly not rejection [or] clearly rejection." App. 1005-06.

In light of these differences, witnesses from CareDx and Natera testified that the Bloom and Sigdel studies were not comparable. E.g., App. 1612-13 (Dr. Uwe Christians, Natera's expert in kidney transplantation and diagnostic testing, testifying that the studies did not allow for "head-to-head comparisons" between Prospera and AlloSure according to the regulatory definition of "head-to-head comparison"), 1085-86, 2302 (Dr. Billings acknowledging in an email that "apples to apples" comparisons in "these kinds of studies" are "not possible"),[8] 830-31 (Dr. Peter Maag, board member and former CareDx

[7] An assay is a test used in the analysis of a drug or product to determine the presence of particular characteristics. Assay, Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/assay (last visited Aug. 14, 2025). At trial, when witnesses referred to the assay or assays, they referred to the studies themselves or their results, such as the Bloom or Sigdel studies. E.g., App. 1086 (discussing the differences between the Bloom and Sigdel studies in terms of, among other things, having different "study design[s] in terms of the assays").

[8] At his deposition, Dr. Billings testified that he was unaware of any "reliable head-to-head comparisons between Prospera and AlloSure," and that any such comparisons would be "flawed." App. 1080-83. At trial, however, he denied that (1) the comparisons between AlloSure and Prospera were flawed and (2) there were no good head-to-head studies between AlloSure and Prospera. App. 1081-82.

Chief Executive Officer and Chairman, testifying that the studies were not comparable because of their differences), 1364-65 (Dr. Weisbord testifying that it would not be "appropriate" to compare the studies' results because of the "overlap in the [confidence] intervals," which means that the products' performance from the studies might not have been "statistically significantly different," and that one is not likely superior to the other), 955-56 (Dr. Sarwal testifying that she did not attempt to account for design differences when comparing the results of the Bloom and Sigdel studies).[9]

Based on this and other evidence, the jury found that CareDx proved by a preponderance of the evidence that (1) nine of Natera's challenged advertising claims were literally false under the Lanham Act and DTPA, (2) Natera intentionally and willfully engaged in false advertising, and (3) Natera was liable for unfair competition under Delaware state law. The jury awarded CareDx $21.2 million in actual damages "attributable to Natera's false advertising and/or unfair competition," App. 681, and $23.7 million in punitive damages "for Natera's unfair competition," App. 682.

Natera moved for judgment as a matter of law, or, in the alternative, a new trial or remittitur, arguing that the evidence did not permit a rational jury to find that (1) the nine advertisements were literally false, or (2) there was actual deception and reliance, thereby

[9] There was also testimony that the studies' differences did not impact the results, so the studies could be compared. E.g., App. 1031 (Dr. Felipe Acosta, lead data scientist at Natera, testifying that the results of the Bloom and Sigdel studies could be compared with respect to AUC), 1550 (Dr. Christians testifying that it was "scientifically reasonable to compare" the Sigdel study with Bloom and another study). Thus, the jury had conflicting evidence to weigh.

precluding damages on all claims.[10] The District Court found sufficient evidence of literal falsity as to Claims A, B, C, D, E, F, G, H, and J, and thus upheld the verdict finding Natera liable on CareDx's Lanham Act and DTPA false advertising claims. CaredDx, Inc. v. Natera, Inc., No. 19-cv-662, 2023 WL 4561059, at *5-6 (D. Del. July 17, 2023) ("CareDx I"); CareDx, Inc. v. Natera, Inc., No. 19-cv-662, 2024 WL 5201130, at *6 (D. Del. Dec. 23, 2024) ("CareDx III").[11] The Court, however, held that there was insufficient evidence to establish the actual deception and reliance elements necessary for CareDx to (1) recover damages under the Lanham Act, and in turn, establish the causation and harm elements necessary to recover damages under state law, CareDx I, 2023 WL 4561059, at *3-5; (2) prove wrongful interference with any business

[10] CareDx moved for judgment as a matter of law as to the jury's finding that Natera was not liable as to one claim, Claim I, which the District Court denied. CareDx presents no arguments challenging the order denying its motion for judgment as a matter of law, and so it failed to preserve any challenge to that order. In re Niaspan Antitrust Litig., 67 F.4th 118, 135 (3d Cir. 2023).

[11] The District Court initially ruled on the literal falsity of just one of Natera's advertisements (Claim A) without addressing the remaining eight advertisements (Claims B, C, D, E, F, G, H, J). CareDx I, 2023 WL 4561059, at *5. As a result, we remanded for the District Court to consider the literal falsity evidence as to the remaining claims. See CareDx, Inc. v. Natera, Inc., No. 23-2427, 2024 WL 4441418, at *2 (3d Cir. Oct. 8, 2024) ("CareDx II") (citing Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc., 546 U.S. 394, 401 (2006) ("[A] determination of whether a new trial should be granted or a judgment entered under Rule 50(b) calls for the judgment in the first instance of the judge who saw and heard the witnesses and has the feel of the case which no appellate printed transcript can impart." (internal quotation marks and citations omitted)). In its opinion on remand, the Court concluded that the remaining claims were literally false because they asserted that Prospera was superior to AlloSure based on comparisons between the results of the Sigdel and Bloom studies. CareDx III, 2024 WL 5201130, at *2. In doing so, the Court concluded that Natera's claims necessarily implied that the studies were comparable, but those studies did not establish this fact because the "data underlying the studies was not reliably comparable and lacked statistical significance." Id.

relationship, thereby precluding liability on CareDx's unfair competition claim; and (3) support a punitive damages award, id. at *5-6, *6 n.1. Consistent with the jury's liability verdict, the Court entered a stipulated injunction banning all nine advertisements but awarded no damages.[12] Id.

Both parties appeal.

II[13]

A[14]

Under the Lanham Act, "anyone who, in connection with goods or services in commerce uses . . . any false description or representation" may be liable for damages or subject to an injunction barring such activities. Parkway Baking Co. v. Freihofer Baking Co., 255 F.2d 641, 648 (3d Cir. 1958) (describing 15 U.S.C. § 1125(a)(1)). To prevail on a Lanham Act false advertising claim, a plaintiff must prove:

> 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

[12] Natera stipulated to the injunction without prejudice to its right to challenge the verdict.

[13] The District Court had jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1367(a). We have jurisdiction pursuant to 28 U.S.C. § 1291.

[14] We exercise plenary review of an order granting or denying a motion for judgment as a matter of law under Federal Rule of Civil Procedure 50(b). Curley v. Klem, 499 F.3d 199, 205 (3d Cir. 2007). Judgment as a matter of law should be granted "sparingly," and "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." Marra v. Phila. Hous. Auth., 497 F.3d 286, 300 (3d Cir. 2007) (internal quotation marks and citations omitted). "[W]e review the grant or denial of a motion for a new trial for abuse of discretion." Leonard v. Stemtech Int'l Inc., 834 F.3d 376, 386 (3d Cir. 2016) (citation omitted). A new trial should only be granted when "the great weight of the evidence cuts against the verdict and . . . a miscarriage of justice would result if the verdict were to stand." Id. (internal quotation marks and citations omitted).

> 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.

Groupe SEB USA, Inc. v. Euro-Pro Operating LLC, 774 F.3d 192, 198 (3d Cir. 2014) (citation omitted).[15] Only the first two elements, falsity and deception, are at issue here.

1

As to falsity, a plaintiff must prove "that the advertisement is either (1) literally false[,] or (2) literally true or ambiguous, but has the tendency to deceive consumers." Groupe SEB, 774 F.3d at 198 (internal quotation marks and citation omitted). At trial, CareDx proceeded under a literal falsity theory.

In analyzing whether an advertisement is literally false, "a court must decide first whether the claim conveys an unambiguous message and second whether that unambiguous message is false." Id. (citing Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co., 290 F.3d 578, 586 (3d Cir. 2002)). "A literally false message may be either explicit or conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated." Novartis, 290 F.3d at 586-87 (internal

[15] "[P]roof of a Lanham Act claim . . . necessarily meet[s] the requirements for a claim under the DTPA." Schering-Plough Healthcare Prods., Inc. v. Neutrogena Corp., 702 F. Supp. 2d 266, 272 (D. Del. 2010).

quotation marks and citation omitted).

A plaintiff's burden for proving literal falsity differs depending on the type of advertising claim at issue. See Castrol, Inc. v. Quaker State Corp., 977 F.2d 57, 63 (2d Cir. 1992); cf. Castrol Inc. v. Pennzoil Co., 987 F.2d 939, 952 (3d Cir. 1993) (Roth, J., dissenting) (highlighting the majority's implicit recognition that a plaintiff's burden is dependent upon the advertisement type). Some advertisements convey "establishment claims," while others convey "non-establishment claims." Pennzoil, 987 F.2d at 952 (Roth, J., dissenting). An establishment claim "explicitly or implicitly represents that tests or studies prove its product superior." Quaker State, 977 F.2d at 63. A non-establishment claim represents that a product is superior, without reference to or reliance on studies or data. See. Pennzoil, 987 F.2d at 952 (Roth, J., dissenting). A plaintiff challenging establishment claims, as here, "satisfies its burden by showing that the tests did not establish the proposition for which they were cited." Quaker State, 977 F.2d at 63.[16] This can be done by demonstrating (1) "that the tests were not sufficiently reliable to permit a conclusion that the product is superior," or (2) that "even if reliable, [the tests] do not establish the proposition asserted by the defendant." Id. (internal citations omitted).[17]

The District Court correctly concluded that there is sufficient evidence for a

[16] A plaintiff challenging a non-establishment claim "must affirmatively prove [the] defendant's product equal or inferior." Quaker State, 977 F.2d at 63.

[17] Cf. Pennzoil Co., 987 F.2d at 952 (Roth, J., dissenting) (describing this burden of proof as "quite logical because establishment claims state to the consumer that they are based upon tests, and therefore, provide the consumer with the expectation that tests actually support the claim at issue").

reasonable juror to find the challenged claims were literally false.

In Claim A, Natera represented that Prospera is "[m]ore sensitive and specific than current assessment tools across all types of rejection."[18] App. 668, 2156 (website), 2168 (physician's brochure). Based on evidence that "current assessment tool[s]" refer to AlloSure, App. 1253, a jury could reasonably find that Claim A was unambiguous[19] because it conveys one message, namely, that Prospera is more sensitive and more specific than AlloSure.[20] See Pennzoil, 987 F.2d at 947-48 (affirming findings that advertisement claiming motor oil brand protected against engine failure "better than its major competitors" was unambiguous and literally false). There is also sufficient evidence that Claim A is literally false because (1) both the Sigdel and Bloom studies demonstrated that Prospera's specificity rate was lower than AlloSure's, see App. 2118 (Sigdel study finding that Prospera has a specificity of 72.6%); 2137 (Bloom study

[18] Claim A is the only advertisement that uses the "more sensitive and specific" language, but other advertisements, including Claims C, D, H, and J, refer to Prospera's sensitivity.

[19] We address ambiguity only for advertisements Natera claimed were ambiguous. A claim is unambiguous when, read in the context of the entire claim, there is "one available conclusion and only one plausible meaning." Groupe SEB, 774 F.3d at 199-200.

[20] Accordingly, contrary to Natera's assertions that it was unreasonable for the jury to conclude "that transplant physicians could not reasonably read [this claim] to refer to AUC," Natera Br. at 42, there is sufficient evidence in the record to support the jury's finding that Claim A was unambiguous. Ambiguity is a question for the factfinder, and as noted above, the evidence was sufficient for the jury to find that the "more sensitive and specific" language was unambiguous and literally false. See Groupe SEB, 774 F.3d at 199 (reviewing the district court's findings that an advertising claim was unambiguous and literally false for clear error); Novartis, 290 F.3d at 589 (stating that an ambiguity finding is a question of fact reviewed for clear error).

finding that AlloSure has a specificity of 85%),[21] and (2) the record supports that the studies did not establish Prospera's superiority on these metrics given the evidence that the studies were not comparable, App. 830-31, 948, 955-56, 1085, 1364-65, 1612-13 (testimony acknowledging differences between the studies, discussed supra I & n.6), 2302 (email acknowledging that apples to apples comparisons in these studies are not possible, discussed supra I).[22] Thus, the jury could reasonably find that Claim A was literally false because the identified studies do not support Claim A's assertion of Prospera's superiority.

In Claim B, Natera represented that, "[w]hen comparing published clinical validation studies, Prospera demonstrated better performance in correctly classifying patients with active rejection," and then compared Prospera's sensitivity of 89%, with AlloSure's sensitivity of 59%. App. 669, 2169 (physician's brochure); see also App. 2118 (Sigdel study finding that Prospera has a sensitivity of 89%); 2137 (Bloom study finding that AlloSure has a sensitivity of 59%). The reference to Prospera's "better performance" in conjunction with the side-by-side studies necessarily implies that the studies are comparable and may be used to establish Prospera's superiority with respect

[21] See also App. 1222 (Ms. Shephalie Lahri, Natera's director of marketing for the organ transplant unit, testifying that it is false to say that Prospera is more specific than AlloSure), 2366 (Natera sales team preparation materials for potential consumer questions acknowledging that "Prospera had a specificity of 73%, which is slightly lower than AlloSure at 85%").

[22] Additionally, the fact that there was testimony that the different designs of the studies did not impact the results does not change the outcome of this appeal because the record need only contain evidence from which a jury could reasonably conclude that this claim is literally false. See Marra, 497 F.3d at 300.

to sensitivity. Cf. Groupe SEB, 774 F.3d at 202 (concluding, based on the placement of claims on the packaging, that "the proximity of the two claims necessarily and unavoidably conveys a message" of superiority of one product over the other).[23] The evidence, however, shows that the studies do not establish that Prospera performed better in sensitivity, e.g., App. 1219-20 (testimony from Natera's director of marketing that she "understood that [she] couldn't say Prospera is more sensitive than AlloSure" based on the studies),[24] given that the studies were not comparable. Accordingly, given the lack of comparability and hence the lack of a basis in the studies to judge whether one product is superior to the other, a jury could reasonably conclude that Claim B was literally false. Cf. Apotex Inc. v. Acorda Therapeutics, Inc., 823 F.3d 51, 67 (2d Cir. 2016) (concluding

[23] Natera argues that its claims are not literally false because they compare the accurate results of two studies. However, by placing the studies' results side-by-side, alongside claims that Prospera is superior to AlloSure, Natera necessarily implies that the results of the two studies are comparable and establish Prospera's superiority. A claim of superiority based on comparison of incomparable metrics can be literally false. Cf. Apotex Inc. v. Acorda Therapeutics, Inc., 823 F.3d 51, 67 (2d Cir. 2016).

The case Natera cites to support its argument that its cross-study comparison claims are not literally false, Pfizer, Inc. v. Miles, Inc., 868 F. Supp. 437 (D. Conn. 1994), is distinguishable. In Miles, the district court concluded that the studies in the cross-study comparison were reliable, id. at 455, but here, the evidence shows that (1) the Sigdel test was not a reliable basis on which to assert Prospera's superiority over AlloSure because the studies were not comparable, discussed supra I & n.6, and (2) the cited studies did not show Prospera's superiority to AlloSure, e.g., App. 1219-20 (testimony that Natera could not assert, based on the studies, Prospera's superiority in sensitivity).

[24] See also App. 1114 (Dr. Billings's testimony that Prospera's higher sensitivity was due to patient variables impacting the data), 2540 (internal emails at Natera stating the same), 1371 (Dr. Weisbord testifying that Prospera was not more sensitive than AlloSure because the studies did not conduct "statistical testing" and thus, one could not conclude that the "sensitivity of one assay is superior based on the data that were presented without doing that [statistical] testing").

that a brochure that placed text on top of a figure to convey its drug's impact on consumers presented a literally false message because the text and figure were based on different data metrics and thus were not comparable).

In Claims C and D, Natera announces that its study demonstrated "[s]uperior [d]ata" and "[s]uperior precision," respectively, in detecting rejection. Claim C reported "higher sensitivity and nearly 18% higher [AUC]." App. 670, 2200 (press release). Claim D reported "higher sensitivity (89% vs. 59%) and higher [AUC] (0.87 vs. 0.74)" than CareDx's test. App. 671, 2209-10 (press release), 2220-23 (press release), 2225 (press release). See also App. 2118, 2124 (Sigdel study finding that Prospera has a sensitivity of 89% and AUC of 0.87); 2137 (Bloom study finding that AlloSure has a sensitivity of 59% and AUC of 0.74). The direct comparison between the Bloom and Sigdel studies' results necessarily implies that these results are comparable and may be used to establish Prospera's superiority with respect to sensitivity and AUC. See Groupe SEB, 774 F.3d at 202.[25] Evidence adduced at trial, however, established that the studies were not comparable because they had different designs, methods, and patient populations, and were thus not "head-to-head" comparisons, as asserted in these claims, discussed supra I & n.6. See, e.g., App. 955-58, 1612-13, 1085, 2302. As described with respect to Claim B, the record contains evidence that the studies do not establish Prospera's superiority with respect to sensitivity, given that the studies were not

[25] Natera's argument that these claims cannot be literally false because they report the accurate results of two studies fails for the same reasons discussed in the foregoing analysis of Claim B. See supra note 23.

comparable. The record also supports that the studies do not establish Prospera's superiority with respect to AUC. Specifically, the evidence shows that: (1) the statement "[h]igher [AUC] driven by superior clinical data" is not accurate because one cannot "compare AUC from one study to another" unless one accounts for "a statistically significant difference," App. 1375-76 (Dr. Weisbord), (2) Prospera's AUC could not be described as "superior" or "higher" than that of AlloSure because there was not a statistically significant difference between the tests' AUCs, App. 1022-23 (Dr. Felipe Acosta, Natera's senior data scientist), and (3) "there is with the current data NO EVIDENCE of a difference between our two assays. The AUCs overlap and therefore could very well be the same," App. 2286 (Dr. Billings's email). Accordingly, given the lack of comparability, a jury could reasonably conclude that Claims C and D were literally false because the studies were not sufficiently reliable to support this assertion of superiority. Cf. Apotex Inc., 823 F.3d at 67.

Claims E and F compare the NPVs for Prospera and AlloSure. Claim E compares results from Bloom and Sigdel studies in two bar graphs, demonstrating that AlloSure had an NPV of 84% (16% missed rejections) and Prospera had an NPV of 95% (5% missed rejections), and stating that Prospera had "3x fewer rejections missed." App. 672, 2163 (website); see also App. 2131 (Sigdel study finding an NPV of 95% for Prospera); 2137 (Bloom study finding that AlloSure has an estimated NPV of 84%). Claim F also graphically depicts NPV data and states that "Prospera misses nearly three times fewer rejections" than treatments like AlloSure. App. 673, 2169 (physician's brochure). The side-by-side comparison of the data from the Bloom and Sigdel studies necessarily

implies that the studies are comparable and that their comparison demonstrates Prospera's superiority with respect to NPV. Cf. Groupe SEB, 774 F.3d at 202.[26] However, the evidence shows that the studies were not "a true head to head" when comparing NPVs and thus, they do not establish this claim. See, e.g., App. 2430 (Ms. Shephalie Lahri, Natera's director of marketing for the organ transplant unit.[27] Accordingly, a reasonable juror could conclude that these claims communicate a literally false message because the studies are not sufficiently reliable to support their assertion of

[26] Natera's argument that these claims cannot be literally false because they report the accurate results of two studies fails for the same reasons stated with respect to Claims B, C, and D. See supra note 23.

[27] Further, there were differences in how the Bloom and Sigdel studies reached their NPV values. For example, the Sigdel study measures NPV at a "25% prevalence," App. 2131, while the Bloom study measures NPV "with the 1.0% dd-cfDNA cutoff," App. 2137. According to the record, for purposes of its marketing campaign, Natera recalculated the products' NPVs so the studies' results would be comparable. See, e.g., App. 2369-70 (email thread, where Ms. Lahri stated, "I kept our calculated NPV for 10% prevalence based on Sigdel numbers," and another Natera employee asked whether they "ha[d] a calculation . . . for Allosure's NPV at 10%"), 2403 (email and attachment from Ms. Lahri containing talking points for physicians, with slide noting that, because the Bloom study "provides NPV . . . at a 10% prevalence using a 1% dd-cfDNA cutoff," the Prospera NPVs "ha[d] been re-calculated at a 10% prevalence for active rejection"). Despite these efforts to recalculate, the record also contains evidence that "different cohorts/incidences" means that there is not a "direct comparison," further supporting the jury's finding that Claims E and F are literally false because the NPVs were not comparable. App. 2431 (email from Trudy McKanna, director of medical education at Natera, stating, "[h]as anyone pushed back yet about the limitations of comparing NPV . . . from different cohorts? . . . Since it's different cohorts/incidences, it isn't a direct comparison."), 1317 (video deposition of Adam Prewett, product manager for Prospera**,** stating, "it would be not an apples-to-apples comparison to look at an NPV calculated with a 10 percent prevalence versus one with a 25 percent prevalence").

superiority. Cf. Apotex Inc., 823 F.3d at 67.[28]

Claim G contains a heading stating, "[s]tronger test performance demonstrated with unique clinical capabilities," then asserts that Prospera has "[h]igher [AUC]; driven by superior clinical data," and represents that Prospera has an AUC of 0.87 and AlloSure has an AUC of 0.74. App. 674, 2252 (presentation at organ transplant summit). Like Claims C and D, Claim G conveys that Prospera is superior with respect to AUC. The evidence discussed regarding Claims C and D similarly shows that there is sufficient evidence that the studies do not show that Prospera's AUC is superior to AlloSure's, so the jury could reasonably conclude that Claim G is literally false.[29]

Claim H is a circle in the middle of a slide that says: "Unparalleled Precision. Optimized by Prospera" with four quadrants surrounding it. App. 675, 2169 (physician's brochure). The two quadrants on the right of the circle are Claims B and F, which convey that Prospera has superior sensitivity and NPV. App. 675, 2169 (physician's brochure). Because Natera argues that Claim H is ambiguous, we first assess its ambiguity. The term "[u]nparalleled [p]recision," clearly refers to Prospera's superiority with respect to NPV and sensitivity based on its incorporation of Claims B and F and is thus unambiguous. Cf. Groupe SEB, 774 F.3d at 199-200 (concluding that packaging stating its product had "more powerful steam" than a competing product was

[28] To the extent NPV reflects sensitivity, as described above, there is ample record evidence to support the conclusion that Natera's claims of superiority with respect to sensitivity are literally false.

[29] Natera's argument that these claims cannot be literally false because they report the accurate results of two studies fails for the same reasons as stated with respect to Claims B, C, D, E, and F. See supra note 23.

unambiguous where elsewhere on the packaging defined how steam power is measured).[30] Given the evidence that the studies do not establish Prospera's superiority on sensitivity or NPV, see supra, a jury could reasonably conclude that Claim H communicates a literally false message.[31]

Claim J is a slide with a heading that says, "[h]ighly sensitive across a range of rejection types and patients," and a subheading that says, "[v]ariety of ethnic and racial demographics," as well as "[a]ges," including "[b]elow 18 years of age (n=49)."[32] App. 677, 2249 (presentation at organ transplant summit), 2269 (Dr. Billings's presentation). Contrary to Natera's assertion, this claim is unambiguous. The statement that Prospera is "highly sensitive across a range of . . . patients" above a subheading for various

[30] The fact that Claim H incorporates other advertisements does not render ambiguous the message that Prospera is superior regarding NPV and sensitivity. Although the "greater the degree to which a message relies upon the viewer or consumer to integrate its components and draw the apparent conclusion, . . . the less likely it is that a finding of literal falsity will be supported," Novartis, 290 F.3d at 587 (quoting United Indus. Corp. v. Clorox Co., 140 F.3d 1175, 1181 (8th Cir. 1998)), a court must still view the claim in the context of the entire advertisement and thus must incorporate all aspects of the claim in determining its falsity, cf. Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1144 (9th Cir. 1997) (concluding that, even where an advertisement contained information of the true timeframe of tests in which data was collected, reading the advertisement "as a whole," a reasonable jury could conclude that the tests were conducted in a different, false timeframe and so supported a finding of literal falsity); Groupe SEB, 774 F.3d at 200 (in determining literal falsity, reviewing the claim as a whole, including a symbol that "expressly links" the definition of a term used in the claim because ignoring that symbol would "not only . . . read the claim out of context, but also . . . ignore part of the claim itself denoted by the symbol").

[31] Natera's argument that these claims cannot be literally false because they report the accurate results of two studies fails for the same reasons as stated with respect to Claims B, C, D, E, F, and G. See supra note 23.

[32] The number "49" refers to the number of patients in the Sigdel study that were under 18 years old, none of whom showed rejection.

demographic groups, including an age group of under 18-year-olds, unambiguously conveys that it is highly sensitive for patients in that age group. See Groupe SEB, 774 F.3d at 202 (where a statement appeared "directly above" another statement, "the proximity of the two claims" construed together conveyed an unambiguous message).[33]

The record also shows that this claim is literally false. The Sigdel study did not establish Prospera's sensitivity in any capacity with respect to patients under 18. See, e.g., App. 1129-30, 2292 (Dr. Billings's email stating that Natera could "make NO CLAIM about [its] assay in pediatric age groups and there is NO INDICATION that it works in them. Period."), 1047-48 (Dr. Solomon Moshkevich, who managed Natera's organ transplant group, testifying that they "did not investigate sufficiently to make specific claims about - - about test performance in the pediatric population because there were no cases of rejection in [their] study from the pediatric population"), 1381-82 (Dr. Weisbord's testimony that "it's not accurate to say that it's highly sensitive across a range of populations and include specifically the children there. The children did not have any rejections," so it was not possible to calculate sensitivity). Accordingly, there is sufficient evidence supporting the jury's finding that Claim J's assertion that Prospera is "highly sensitive" when used by this age demographic is literally false.

Because the evidence supports the jury's findings that Claims A, B, C, D, E, F, G,

[33] Further, this reading of Claim J is consistent with Natera's characterization of the information on this slide when presenting it. E.g., App. 1318-19 (Prewett agreeing that the slide says that "the Prospera test is highly sensitive across a range of different types of patients," including the "different age groups," and testifying that, when presenting this slide, he did not clarify otherwise).

H, and J were literally false, the District Court did not err in denying Natera's motion for judgment as a matter of law on CareDx's Lanham Act and DTPA false advertising claims, and so we will affirm this ruling.[34]

2

As to actual deception, a plaintiff's burden varies depending on the relief sought.[35] To obtain damages, a plaintiff must prove both that the advertisement was false and that the falsehood "actually deceive[d] a portion of the buying public." Parkway Baking, 255 F.2d at 648 (citations omitted). A plaintiff may demonstrate deception through evidence that the consumer either (1) purchased the competing product because of the false claim,

[34] Contrary to Natera's argument that CareDx failed to present evidence to demonstrate how the audience of nephrologists read and understood these comparisons, **,** the determination that a claim is unambiguous or false by necessary implication does not require a showing of the audience's perception of that claim. See, e.g., Pennzoil, 987 F.2d at 947 & n.9 (concluding that advertisements "had an unambiguous meaning by necessary implication" of a product's superiority over another product without reference to consumer perception of the claim and rejecting that literal falsity requires a showing of consumer perception); Am. Home Prods. Corp. v. Johnson & Johnson, 577 F.2d 160, 165 (2d Cir. 1978) (noting that in literal falsity claims, "relief can be granted . . . without reference to the reaction of the buyer or consumer of the product").

Additionally, Natera's argument that the District Court's remand opinion was inconsistent with the jury's finding that Claim I was not literally false also fails. Claim I asserted that Prospera detected t-cell mediated rejection ("TCMR") better than AlloSure. The jury's finding that the studies were reliable with respect to claims about TCMR detection is not inconsistent with its finding that the studies did not establish Prospera's superiority with respect to sensitivity, AUC, or NPV, which are distinct from TCMR and are at issue in Claims A, B, C, D, E, F, G, H, and J.

[35] For injunctive relief, actual deception is presumed and need not be proven once a plaintiff "proves that an advertisement is unambiguous and literally false." Pernod Ricard USA, LLC v. Bacardi U.S.A., Inc., 653 F.3d 241, 248 (3d Cir. 2011). Accordingly, Natera's assertion that CareDx failed to show how the relevant consumers were deceived is not relevant to the propriety of an injunction based on literally false claims. See Groupe SEB, 774 F.3d at 201 (noting that claims of literal falsity do not require evidence of actual consumer deception).

or (2) would not have purchased the competing product had they known that the claim was false. Id. Although a plaintiff need not "prov[e] detailed individualization of loss of sales" because such proof goes to the damages amount, not the right to recover, "there must be a showing of some customer reliance" on the false claim. Id.

CareDx directs us to three categories of evidence it argues were sufficient to prove actual deception and reliance: (1) the existence of consumer confusion; (2) the success of Natera's advertising campaign; and (3) Natera's willfulness. None of this evidence, however, shows reliance and actual deception.

The first category of evidence that purports to prove consumer confusion appears in the testimony of two CareDx employees, but that testimony (1) contained only vague and conclusory statements about consumer confusion, and (2) failed to link the advertisements to any consumer purchasing decisions. Specifically, Dr. Maag testified that Natera's superiority claims "caused a lot of confusion . . . with our customers," and that although there was not "significant patient impact initially," later "there was more and more confusion, and then . . . [more] usage of Prospera." App. 830, 838. He did not, however, explain how these customers were confused. Likewise, Ms. King, who oversaw CareDx's marketing, testified that CareDx formed a team to respond to Natera's messaging and "the confusion" the company was "hearing" without describing the nature of customers' confusion. App. 985. These generalities do not satisfy CareDx's burden of introducing evidence sufficient for a rational jury to find that consumers actually relied

on or were deceived by Natera's false claims in deciding to purchase Prospera instead of AlloSure.[36] Parkway Baking, 653 F.3d at 648.

The second category of evidence relates to Natera's advertising campaign, but it too fails to show an impact on actual consumer behavior. There is evidence that (1) the comparative claims were a focus of Natera's advertising campaign; (2) a "small factor" in Natera's increase of sales was that the claims "pique[d] doctors' interest[s]" in looking to the literature, App. 1247-48; and (3) Natera's sales team was successful in converting "at least one AlloSure user[]" to Prospera, App. 1200. Such evidence, however, does not establish that any consumers decided to use Prospera over AlloSure based on Natera's false claims.

The third category of evidence demonstrates Natera's willful conduct,[37] but it does not show any consumers were deceived by it. See Parkway Baking, 653 F.3d at 648

[36] Although CareDx asserts that there is evidence that consumer confusion led to lost sales, the testimony on which it relies neither establishes a loss of sales nor ties any purported loss of sales to Natera's false claims. See App. 837-38 (Dr. Maag acknowledging that certain transplant centers used Prospera and that to counter Natera's false claims, CareDx engaged in corrective advertising); App. 981, 988-89 (Ms. King testifying that, based on Natera's false claims, CareDx expanded its sales team and focused on purported corrective advertising among its existing consumer base, rather than targeting new consumers); App. 1647-48 (James Malackowski, CareDx's expert in economic and calculations of damages, speculating that "in the but-for-world, without the alleged false advertising, the demand for [the product] would have stayed with CareDx").

[37] See, e.g., App. 1219, 1222 (Ms. Lahri testifying that she "knew that [she] could not say Prospera is better than AlloSure" and that it would be false to say that Prospera is more specific than AlloSure); App. 2284-85 (internal Natera emails stating that it would be "misleading" to compare Natera's data against CareDx's because of the differences in their studies), 2366 (internal Natera document acknowledging that Prospera's specificity is lower than AlloSure's), 2539 (internal Natera email stating that it would be misleading to claim better sensitivity "without also stating that it came at the price of lower

(requiring "a showing of some customer reliance on the false advertisement" to recover damages).[38]

In sum, even viewing the evidence in CareDx's favor, there was insufficient evidence for a reasonable juror to find actual deception. Thus, the District Court properly granted Natera judgment as a matter of law on CareDx's claim for false advertising damages and vacated the jury's damages award.

B

To prevail on an unfair competition claim, a plaintiff must prove (1) a reasonable expectancy of entering a valid business relationship, (2) wrongful interference with that expectancy, (3) causation, and (4) harm. See Total Care Physicians, P.A. v. O'Hara, 798 A.2d 1043, 1057 (Del. Super. Ct. 2001).

---

specificity"), 2540 (internal Natera email noting that members of Natera's statisticians team believe that its "better sensitivity was driven [] by patient selection variables").

[38] CareDx argues that a jury could reasonably infer actual deception from Natera's false advertising campaign because Natera would not have knowingly and intentionally engaged in such a campaign if consumers were not actually deceived by the superiority claims. In support, CareDx points to out-of-circuit case law stating that "where a plaintiff adequately demonstrates that a defendant has intentionally set out to deceive the public," and the defendant's deliberate conduct is of an egregious nature, a "presumption [arises] that consumers are, in fact, being deceived." Res. Devs., Inc. v. Statue of Liberty-Ellis Island Found., 926 F.2d 134, 140 (2d Cir. 1991) (internal quotation marks and citation omitted). CareDx concedes that our Court has not adopted this presumption. Moreover, the District Court instructed the jury, without objection, that (1) there was "no presumption here for the [false advertising] damages question," and (2) that the plaintiff was required to prove by a preponderance of the evidence that "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," and as a result, "the plaintiff sustained injury." App. 2087-88; Parkway Baking Co., 653 F.3d at 648. Although CareDx does not challenge the instruction, it asserts that other courts of appeals' adoption of a presumption suggests that the jury's inference was reasonable. This might be so, but it ignores the absence of evidence in the record to prove actual deception.

CareDx failed to prove this claim at trial. For the same reasons why there was no evidentiary basis for a reasonable juror to find that consumers relied on or were actually deceived by Natera's false claims in deciding to use Prospera over AlloSure, there was insufficient evidence from which the jury could find that Natera interfered with a legitimate CareDx business expectancy. See Agilent Techs., Inc. v. Kirkland, No. 3512, 2009 WL 119865, at *9 (Del. Ch. Jan. 20, 2009) (unpublished) (holding that harm is compensable "when the derailment [of an expectancy] is caused by the wrongful acts of others"). Although CareDx points to evidence that Natera's false advertising cost CareDx sales—including testimony that certain transplant centers began using Prospera, and that without the false advertisements, the demand for AlloSure would have been higher—this evidence fails to link any purported lost sales to Natera's false claims.[39] As a result, the District Court properly granted Natera's motion for judgment as a matter of law on CareDx's unfair competition claim and correctly vacated the associated punitive damages award.[40]

III

For the foregoing reasons, we will affirm.

[39] CareDx adds that its harm consisted not only of lost sales, but also corrective advertising costs. Although this view is understandable, as one who seeks to correct a misimpression in the marketplace about its product might spend money to do so, here, the record does not show that consumers were confused and made purchasing decisions based on the false statements. See Agilent Techs., 2009 WL 119865, at *5 (explaining that the harm contemplated is that flowing from the "defeat[ed] . . . legitimate [business] expectancy").

[40] Punitive damages were only sought and awarded on CareDx's unfair competition claim.

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 23-2427, 23-2428

CAREDX, INC.,
Appellant

v.

NATERA, INC.

CAREDX, INC.,

v.

NATERA, INC.,
Appellant

(D.C. Civ./Crim. No. 1-19-cv-00662)

SUR PETITION FOR REHEARING

Present: CHAGARES, Chief Judge, SHWARTZ, KRAUSE, RESTREPO, BIBAS, PORTER, MATEY, PHIPPS, FREEMAN, CHUNG, BOVE, and *FISHER, Circuit Judges

The petition for rehearing filed by Appellant in the above-entitled case having

---

*Hon. Michael D. Fisher vote is limited to panel rehearing only.

been submitted to the judges who participated in the decision of this Court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the judges of the circuit in regular service not having voted for rehearing, the petition for rehearing by the panel and the Court en banc, is denied.

BY THE COURT,

s/Patty Shwartz
Circuit Judge

Dated: October 10, 2025
JK/cc: All Counsel of Record