

NOT FOR PUBLICATION

FILED

UNITED STATES COURT OF APPEALS

OCT 7 2021

FOR THE NINTH CIRCUIT

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

QUIDEL CORPORATION,

No. 20-55933

Plaintiff - Appellant,

No. 3:16-cv-03059-BAS-AGS

v.

SIEMENS MEDICAL SOLUTIONS USA,
INC.,

MEMORANDUM*

SIEMENS HEALTHCARE
DIAGNOSTICS, INC.,

Defendants – Appellees.

LABORATORY CORPORATION OF
AMERICA HOLDINGS
Intervenor.

Appeal from the United States District Court
for the District of Southern California, San Diego
Cynthia A. Bashant, District Judge, Presiding

Argued and Submitted September 2, 2021
Pasadena, California

Before: NGUYEN, BENNETT, and R. NELSON, Circuit Judges.
Dissent by Judge BENNETT

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

In this false advertising case, Appellant Quidel Corporation (“Quidel”) challenges the district court’s grant of summary judgment for Appellees, Siemens Medical Solutions USA, Inc. and Siemens Healthcare Diagnostics Inc. (“Siemens”), on their Lanham Act false advertising claims (§ 43(a)), unfair competition claims (Cal. Bus. & Prof. Code § 17200), False Advertising Law claims (Cal. Bus. & Prof. Code § 17500), and intentional interference with prospective economic advantage claims.¹ We have jurisdiction under 28 U.S.C. § 1291 and we affirm.²

1. There is no triable issue on materiality as to the laboratories. Even if Siemens’ advertising of its assay, Immulite, was false, it was not material to the laboratories’—LabCorp and Sonic/CPL—decision to purchase Immulite and not Quidel’s assay, Thyretain. The laboratories “are the ones who pay Quidel and Siemens for the [assays]; once a physician orders a[n assay], the lab ships it and pays the manufacturer for that [assay].” *Quidel Corp. v. Siemens Med. Sols. USA, Inc.*, No. 16-CV-3059-BAS-AGS, 2020 WL 4747724, at *5 (S.D. Cal. Aug. 17, 2020). There is no direct evidence in the record for which a reasonable juror could

¹ The parties and the district court have treated the state law claims as rising and falling with the Lanham Act claim. We do the same. *See Cleary v. News Corp.*, 30 F.3d 1255, 1262-63 (9th Cir. 1994).

² None of Quidel’s claims were waived. We also agree with the district court that the false advertising and unfair competition claims were not precluded or preempted by the Federal Food, Drug, and Cosmetic Act (“FDCA”).

find that Siemens’ allegedly false statements were material to the decision-making processes of the two laboratory customers. The testimony of the lab representatives for LabCorp and Sonic/CPL establishes that the challenged statements in Siemens’ materials—scientific presentations, press releases, and other documents like the DocAlert and Instructions for Use (“IFU”) package insert³—are not likely to have “influence[d] purchasing decisions.”

TrafficSchool.com, Inc. v. eDriver Inc., 653 F.3d 820, 828 (9th Cir. 2011).

As to Sonic, its decision to switch from Thyretain to Immulite was clearly influenced by a comprehensive, internal validation process. Testimony from Dr. Mark Silberman establishes that its validation study was based on rigorous procedure and protocol independent of any marketing materials. For example, Dr. Silberman testified that he “does not believe that any of [Siemens’] press releases had any impact on the lab’s decision to assess and validate [Immulite]” and that “[p]rior to the adoption of [Immulite]” he “did not review statements on [Siemens’] website about the assay.” *Quidel Corp. v. Siemens Med. Sols. USA, Inc.*, No. 16-CV-3059-BAS-AGS, 2019 WL 5320390, at *7 (S.D. Cal. Oct. 21, 2019). Quidel’s cherry-picking of isolated and selective quotes from Dr.

Silberman’s testimony to argue that Sonic/CPL “relied on the package insert” and

³ Immulite’s IFU read in part: “TSHR autoantibody (TRAb) assays do not distinguish between TSI and TBI. The IMMULITE . . . TSI assay utilizes . . . receptors . . . for the specific detection of thyroid stimulating autoantibodies.”

Siemens' communications that indicated Immulite is a TSI assay only and not a TRAb assay, does not establish a genuine issue of material fact on materiality. Rather, this evidence goes to whether Siemens' allegedly false statements "deceived or had the tendency to deceive a substantial segment of its audience." *Newcal Indus., Inc. v. Ikon Off. Sol.*, 513 F.3d 1038, 1052 (9th Cir. 2008). The dissent suggests that inferences can be made from these statements to establish deception. Diss. at 3–4. But such inferences would not be reasonable, as required to defeat summary judgment. And we must not elide otherwise distinct Lanham Act elements. *See also William H. Morris Co. v. Grp. W, Inc.*, 66 F.3d 255, 257 (9th Cir. 1995).

As to LabCorp, its decision to switch from Thyretain to Immulite was clearly influenced by an internal validation process. Dr. Andre Valcour explained how LabCorp's analytic evaluation involved "FDA submitted data," exhaustive literature review and its own procedures for independent verification of the assay's performance. At most, statements reflecting the lab representatives' reliance on information in the package insert and internal debate by the laboratories' decision-makers pertain to the required element of deception, not materiality. *See Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997). The extensive vetting completed by these sophisticated experts leading to their eventual purchase of Siemens' assay overcomes Quidel's position that the

challenged statements amount to conflicting evidence on materiality. In other words, the nature of the audience—highly-skilled and credentialed professionals—is such that representations about the type and quality of an assay are not reasonably likely to influence their purchasing decisions even if it attracted the labs’ primary interest.

2. There is no triable issue on actual injury based on allegedly false advertising to the physicians. *See Harper House, Inc. v. Thomas Nelson, Inc.*, 889 F.2d 197, 210 (9th Cir. 1989). The district court properly rejected both of Quidel’s damages theories as to the physicians. First, as the district court previously found, “Quidel cannot claim that its damages are caused by the lab carrying the product which in turn leads to the physicians ordering the product from the lab,” *Quidel Corp.*, 2020 WL 4747724, at *5, because it is “the labs [that] decided which product to carry on their own, not as a result of Siemens.” *Id.* Second, having determined that Quidel did not satisfy its obligations under Federal Rule of Civil Procedure 26, and that such error was not harmless, the district court did not abuse its discretion when it barred Quidel from presenting its alternative damages theory under Rule 37. *See Yeti by Molly, Ltd. v. Deckers Outdoor Corp.*, 259 F.3d 1101, 1106 (9th Cir. 2001).

An “award of profits with no proof of harm” is “appropriate in false *comparative* advertising cases, where it’s reasonable to presume that every

dollar defendant makes has come directly out of plaintiff's pocket.”

TrafficSchool.com, Inc., 653 F.3d at 831. The presumption is inapplicable when, as here, the “advertising does not directly compare defendant’s and plaintiff’s products.” *Id.*

The record shows that Siemens did not engage in false advertising to the physicians, comparative or otherwise. Siemens informed the physicians through its 2016 DocAlert message that its Immulite assay detects stimulating antibody “preferentially” —*i.e.*, with bias—in favor of stimulating over blocking antibodies. The record demonstrates that use of the term “preferentially” in this instance is accurate. Had Siemens informed the physicians that Immulite detects stimulating antibody “only,” as it represented elsewhere, then the statement would be false. *See also Southland Sod Farms*, 108 F.3d at 1139. While the 2016 DocAlert message specifically referenced Thyretain and informed physicians about Immulite—the information that identified “Thyretain” was not challenged as false.⁴ But even if Siemens’ representations were false, the advertisement is not a comparative one. The alleged false statements must be misleading in context—given comparative factors like pertinent market, graphics, and language. *Cf. U-*

⁴ Quidel’s opposition to the motion to dismiss stated: “The [Complaint] . . . does not allege that the name of the IMMULITE Assay nor its sensitivity and specificity data are false,” and Quidel acknowledges that it “is not challenging Immulite’s name and performance data.”

Haul Int'l, Inc. v. Jartran, Inc., 681 F.2d 1159, 1159-60 (9th Cir. 1982) (holding false representation in a comparative advertising campaign for truck and trailer services where select advertisements featured pictures of the competitor's product and other advertising that did not mention the competitor or use pictures of its product but made "implicit[] compar[isons]"). And Quidel does not dispute the actual comparative statement here about the assays' performance data—on clinical sensitivity and specificity—which was FDA-approved.⁵ In fact, construing the DocAlert as a whole counsels against narrowing in on the one bullet-point phrase that references Thyretain's data in comparison to Immulite's (98.6 % as compared to 92%). The overall message conveyed by the DocAlert is the quality and characteristics of Immulite that improve management of Graves' disease. The document includes six bullet point phrases, aside from multiple headers and an introductory paragraph. Taken in context of all the DocAlert's features, the FDA-approved content that references Quidel cannot serve as the basis for a false comparative advertising claim.

⁵ The DocAlert, sent to physicians, contained the following allegedly false statements: "TRAb tests are not designed to discriminate stimulating, blocking, and neutral antibodies often present in [Graves' disease] patients. The IMMULITE . . . assay is specifically engineered to preferentially detect stimulating antibody." The DocAlert also specifically mentioned Thyretain: "Superior clinical sensitivity for diagnosis of Graves' disease (98.6%) vs. Thyretain bioassay (92%)." The FDA pre-approved the sensitivity and specificity data which Siemens was required to include in the IFU.

Because Quidel “failed to present sufficient evidence upon which a reasonable factfinder could conclude that [it] w[as] injured as a result of” Siemens allegedly false advertising to the physicians,” *Southland Sod Farms*, 108 F.3d at 1145, summary judgment was warranted.⁶

AFFIRMED.

⁶ To be sure, “a competitor need not prove injury when suing to enjoin conduct that violates section 43(a).” *Harper House, Inc.*, 889 F.2d at 210. But Quidel has not met the elements for a permanent injunction. *See eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

BENNETT, Circuit Judge, dissenting:

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I respectfully dissent because proper application of summary judgment standards compels the conclusion that summary judgment is inappropriate.

I.

Appellant Quidel Corporation (“Quidel”) sells Thyretain, an assay (blood test) that it claims detects only thyroid stimulating immunoglobulins (“TSI”). Appellees Siemens Medical Solutions USA, Inc. and Siemens Healthcare Diagnostics, Inc. (together, “Siemens”) sell Immulite, a competing assay. Two laboratories, Sonic Healthcare USA (“Sonic”) and Laboratory Corporation of America Holdings (“LabCorp”), switched from purchasing Thyretain to Immulite.

Quidel sued Siemens, alleging that Siemens engaged in false or misleading advertising by stating or implying that Immulite is a “TSI only” assay. According to Quidel, Immulite is not a “TSI only” assay; it is a “TRAb”¹ assay because it detects both TSI and thyroid blocking immunoglobulins (“TBI”). Quidel brought Lanham Act false advertising claims based on Siemens’s alleged false advertising directed at laboratories and physicians.² Although the district court found a triable

¹ TRAb stands for thyroid-stimulating hormone receptor antibody.

² The elements of a Lanham Act § 43(a) false advertising claim are:

(1) a false statement of fact by the defendant in a commercial advertisement about its own or another’s product; (2) the statement

issue on falsity, it granted summary judgment on the Lanham Act claim related to the laboratories because Quidel had failed to show a triable issue on the element of materiality.³ The district court also granted summary judgment on the Lanham Act claim related to the physicians because Quidel had failed to show a triable issue on the element of injury.

I would reverse and remand as to all claims because, construing the evidence in the light most favorable to Quidel, there are triable issues on materiality and injury.⁴ *See Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1138 (9th Cir. 1997).

II.

Materiality is a required element of a false advertising claim under the Lanham Act. *Id.* at 1139. A statement is material if “it is likely to influence the

actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the defendant caused its false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by a lessening of the goodwill associated with its products.

Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1139 (9th Cir. 1997) (footnote omitted).

³ I agree with the district court that there are triable issues of fact as to falsity.

⁴ Like the majority, I would treat the state law claims as rising and falling with the Lanham Act claims.

purchasing decision.” *Id.* This means that “plaintiffs are not required to present evidence that defendants’ misrepresentation actually influenced consumers’ purchasing decisions, but that it was *likely* to influence them.” *Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave.*, 284 F.3d 302, 313 (1st Cir. 2002).

“[M]ateriality focuses on whether the false or misleading statement is likely to make a difference to purchasers.” *Id.* at 312 n.10. Thus, statements that concern “important factors in consumer purchasing decisions” can be material, *ThermoLife Int’l, LLC v. Gaspari Nutrition Inc.*, 648 F. App’x 609, 615 (9th Cir. 2016), and a statement “need not be the only basis for the consumer’s decision” to be material, *Oil Heat Inst. of Or. v. Nw. Nat. Gas*, 708 F. Supp. 1118, 1123 (D. Or. 1988).

Drawing all reasonable inferences in Quidel’s favor, Siemens’s statements that expressly or impliedly communicated that Immulite is a TSI assay and not a TRAb assay were material to the laboratories’ decision to switch from Thyretain to Immulite. Dr. Silberman, a Sonic representative, testified that whether Immulite was a TSI assay was an important factor to Sonic and that Sonic wanted to replace Thyretain with another TSI assay, not with a TRAb assay. Similarly, Dr. Valcour, a LabCorp representative, testified that LabCorp wanted a TSI assay and would not have been interested in Immulite if it were a TRAb assay. Quidel also submitted evidence that scientists within LabCorp did not want to switch to Immulite because

it appeared to be a TRAb assay. And in advertising Immulite, Siemens repeatedly highlighted the distinction between TSI and TRAb.

A rational juror could easily infer from this evidence that whether Immulite was a TSI assay was an important factor to the laboratories—one *likely to influence* their decisions—and that Siemens made the representations it did because it knew the distinction between TSI and TRAb was important *to the purchasers*. Indeed, that the laboratories were only interested in a TSI assay to replace Thyretain supports that the laboratories would not have even considered Immulite had Siemens advertised it as a TRAb assay. Put another way, a juror could easily find that Siemens's statements were likely to influence the laboratories' purchasing decision because its statements attracted the laboratories and prompted them to conduct their own tests before ultimately purchasing Immulite.⁵ Siemens's alleged false statements were the catalyst that led to the purchasing decision and therefore likely influenced the purchasing decision. Thus, I would find a triable issue on materiality.

The majority reaches a contrary conclusion by fully crediting Dr. Silberman's and Dr. Valcour's testimonies that the laboratories' decision to switch

⁵ I note that even if the laboratories' purchasing decision may have been partly influenced by their own testing, that fact would not preclude a juror from concluding that Siemens's statements were likely to (and did, at least in part) influence their purchasing decision. *See Oil Heat Inst. of Or.*, 708 F. Supp. at 1123.

to Immulite resulted from the laboratories' internal validation processes, not Siemens's alleged false statements. Maj. at 2–5. But a reasonable juror could reject this testimony given that the laboratories' witnesses had strong incentives to give testimony validating their prior decisions. The laboratories' sophisticated experts would be reluctant to admit that they had been deceived and had incorrectly recommended switching to Immulite. More importantly, the majority ignores the evidence discussed above, which supports the inference that Siemens's alleged false statements were material to the laboratories. But even if the majority were correct in fully crediting the testimonies on summary judgment, thereby rejecting the inferences that favor the *non-moving* party, summary judgment for Siemens would still be improper. Even fully crediting the testimonies, a rational juror could surely find that these crucial representations were *likely to influence* the purchasing decisions.⁶

III.

The parties agree that a presumption of injury could apply to the Lanham Act false advertising claim related to the physicians if: (1) Quidel and Siemens

⁶ Even if a jury were to determine (were the question relevant) that the laboratories ultimately purchased based on their own tests, that doesn't matter to whether the representations were *likely to influence* the purchasing decisions. Indeed, even in the light most favorable to the *moving* party, it would be difficult for anyone to seriously claim that the purchasing decisions would have been the same had Siemens represented what Quidel claims is the truth (even with puffery): "Immulite—An exceptional TRAb assay!"

operate in a two-player market, *or* (2) Siemens engaged in false comparative advertising. *See TrafficSchool.com, Inc. v. Edriver Inc.*, 653 F.3d 820, 831 (9th Cir. 2011); *see also ThermoLife Int'l*, 648 F. App'x at 616; *Munchkin, Inc. v. Playtex Prods., LLC*, 600 F. App'x 537, 537–38 (9th Cir. 2015).

Even though the parties agree that a presumption of injury could apply if Quidel and Siemens operate in a two-player market and the district court ruled on the issue, the majority fails to address it. The evidence supports that the parties operate in a two-player market. As discussed above, Sonic and LabCorp wanted to replace Thyretain with Immulite. The laboratories did not want to replace Thyretain with a TRAb assay. Because the laboratories considered *only* Immulite and *not* TRAb assays, a factfinder could reasonably infer that Quidel and Siemens operate in a two-player market—the TSI player market. Quidel's survey evidence, which shows that a majority of the physicians surveyed are likely to order both a TSI assay and a TRAb assay for a patient, also supports the inference that TSI and TRAb assays are complements, not competitors, and therefore Thyretain and Immulite do *not* compete with TRAb assays. Based on this evidence, I would find that there is a triable issue on whether Quidel and Siemens operate in a two-player market.

There is also a triable issue on whether the 2016 DocAlert message was a false comparative advertisement. The DocAlert message contained the allegedly

false statements, which communicated that Immulite was a TSI assay and not a TRAb assay: “TRAb tests are not designed to discriminate stimulating, blocking, and neutral antibodies often present in [Graves’ disease] patients. The Immulite . . . assay is specifically engineered to preferentially detect stimulating antibody.”⁷ Appellant’s Excerpts of Record at 398. The DocAlert message also expressly mentioned Thyretain and compared Immulite to Thyretain: “[Immulite’s] [s]uperior clinical sensitivity for diagnosis of Graves’ disease (98.6%) vs. *Thyretain* bioassay (92%).” Appellant’s Excerpts of Record at 398 (emphasis added). Viewing the DocAlert as a whole and in Quidel’s favor, a factfinder could conclude that it was a false comparative advertisement because it falsely communicated that Immulite, like Thyretain, is a TSI assay (not a TRAb assay), and Immulite is better than Thyretain. The majority errs by failing to construe the DocAlert as a whole and in favor of Quidel. Maj. at 7–8. *Cf. Southland Sod*, 108 F.3d at 1139 (“When evaluating whether an advertising claim is literally false, the claim must always be analyzed in its full context.”).

Because there are triable issues on whether the parties operate in a two-player market and whether Siemens engaged in false comparative advertising,

⁷ As the district court found, there is a triable issue on whether these statements were false given Quidel’s evidence: “Plaintiff’s expert Dr. Gupta opine[d] that Immulite is unable to distinguish between TSI . . . and TBI [S]he believes Immulite ‘is not specific for TSI as claimed.’” Thus, viewing this evidence in Quidel’s favor, the statements in the DocAlert were false.

there is also a genuine dispute about whether a presumption of injury applies. The district court therefore erred in granting summary judgment on the Lanham Act claim related to the physicians.⁸

In sum, the majority's decision rests on the improper application of summary judgment standards. The majority ignores evidence favorable to Quidel and fails to draw all reasonable inferences in Quidel's favor. I therefore respectfully dissent.⁹

⁸ Because a presumption of injury could apply to the Lanham Act claim, I would reverse the district court's holding that Quidel cannot establish the harm necessary to support a permanent injunction. I note that under the newly amended version of 15 U.S.C. § 1116(a), it appears that Quidel, if successful on its Lanham Act claims, might obtain permanent injunctive relief without affirmative proof that it suffered irreparable harm. *See* 15 U.S.C. § 1116(a) ("A plaintiff seeking any such injunction shall be entitled to a rebuttable presumption of irreparable harm upon a finding of a violation identified in this subsection in the case of a motion for a permanent injunction"); *see* Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, § 226(a), 134 Stat. 1182, 2208 (2020).

⁹ I agree with the majority that none of Quidel's claims were waived and that its false advertising and unfair competition claims were not precluded or preempted by the Federal Food, Drug, and Cosmetic Act. Maj. at 2 n.2.