UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

QUIDEL CORPORATION,

Plaintiff,

v.

SIEMENS MEDICAL SOLUTIONS USA, INC., *et al.*,

Defendants.

Case No. 16-cv-3059-BAS-AGS

ORDER:
(1) DENYING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT
(2) GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

[ECF Nos. 301, 306]

Presently before the Court are the fourth and fifth summary judgment motions in this case. In May 2020, Defendants Siemens Healthcare Diagnostics, Inc. and Siemens Medical Solutions USA, Inc. (collectively "Siemens") moved to amend the scheduling order in this case so that they could file a successive motion for summary judgment. (ECF No. 288.) The Court held oral argument on Siemens' motion, and Plaintiff Quidel Corporation stated if the Court was inclined to grant the motion, it also would like to file a motion for summary judgment. The Court ordered any successive summary judgment motions to be filed by June 9, 2020. Both parties filed a motion. The Court held a telephonic oral argument on the Motions on August 13,

2020. For the foregoing reasons, the Court **DENIES** Quidel's Motion and **GRANTS** Siemens' Motion.

I. BACKGROUND

The Court detailed the factual background of this case in a prior order and does not repeat the full background here. (*See* ECF No. 254, at 2–4.) In short, Quidel and Siemens produce competing assays (blood tests) used for measuring thyroid stimulating immunoglobins, which can aid in the detection of Graves' disease. Generally, there are two types of assays available to aid in the diagnosis of Graves' disease: (1) TSH receptor antibody (TRAb) assays and (2) TSI only assays. TRAb assays detect both stimulating and blocking thyroid immunoglobins (also known as "TSI" and "TBI"), while TSI only assays detect only stimulating immunoglobins. Quidel's assay is called Thyretain and Siemens' assay is called Immulite. The crux of this matter lies in Siemens' advertising of Immulite. In Quidel's opinion, Immulite "measures the binding of antibodies to the TSH receptor without discrimination," meaning it does not distinguish between stimulating or blocking antibodies. However, Siemens advertised Immulite as a "TSI only" assay (i.e. one that does distinguish between stimulating and blocking antibodies).

Quidel filed its original complaint against Defendant Siemens Medical Solutions USA, Inc. Siemens Medical moved to dismiss the complaint, and Quidel filed a timely first amended complaint. The amended complaint added Siemens Healthcare as a defendant. Siemens moved to dismiss the amended complaint, and the Court denied the motion. Siemens answered the complaint and later requested leave to file an amended answer and counterclaims. The Court granted the motion. Siemens filed an amended answer, and within the answer, asserted counterclaims and affirmative defenses. (ECF No. 124.) Quidel moved to strike a portion of the counterclaims pursuant to California Code of Civil Procedure § 425.16, commonly known as the Anti-Strategic Lawsuits Against Public Participation ("Anti-SLAPP") law. (ECF No. 141.) The Court granted the motion to strike but granted Siemens

leave to file new counterclaims omitting the stricken material. (ECF No. 247.) Siemens did so.

There have been three motions for summary judgment in this case. First, Siemens moved for summary judgment on the issue of the falsity of its advertising and the materiality of it. The Court found a disputed material fact as to whether Siemens' advertisement of Immulite was false or misleading, but found even if it was false, any false advertising was not material to the laboratories' decision to switch from Thyretain to Immulite. (*See* ECF No. 254.) The Court also found that issues of material fact exist as to whether physicians are a part of the relevant market of purchasers of the assays and whether physicians are deceived by the advertising of Immulite. Second, Quidel moved for summary judgment on the issue of the falsity of Siemens' advertisements, which merited the same conclusion. (*See id.*) Third, Quidel moved for summary judgment on Siemens' affirmative defenses and unclean hands counterclaim, which the Court granted in part. (ECF No. 285.)

II. LEGAL STANDARD

Summary judgment is appropriate under Rule 56(c) where the moving party demonstrates the absence of a genuine issue of material fact and entitlement to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A fact is material when, under the governing substantive law, it could affect the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute about a material fact is genuine if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.*

A party seeking summary judgment always bears the initial burden of establishing the absence of a genuine issue of material fact. *Celotex*, 477 U.S. at 323. The moving party can satisfy this burden in two ways: (1) by presenting evidence that negates an essential element of the nonmoving party's case; or (2) by demonstrating that the nonmoving party failed to make a showing sufficient to establish an element essential to that party's case on which that party will bear the

burden of proof at trial. *Id.* at 322–23. "Disputes over irrelevant or unnecessary facts will not preclude a grant of summary judgment." *T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987).

If the moving party fails to discharge this initial burden, summary judgment must be denied, and the court need not consider the nonmoving party's evidence. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 159–60 (1970). If the moving party meets this initial burden, however, the nonmoving party cannot defeat summary judgment merely by demonstrating "that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986); *Triton Energy Corp. v. Square D Co.*, 68 F.3d 1216, 1221 (9th Cir. 1995) ("The mere existence of a scintilla of evidence in support of the non-moving party's position is not sufficient." (citing *Anderson*, 477 U.S. at 242, 252)). Rather, the nonmoving party must "go beyond the pleadings" and by "the depositions, answers to interrogatories, and admissions on file," designate "specific facts showing that there is a genuine issue for trial." *Celotex*, 477 U.S. at 324 (quoting Fed. R. Civ. P. 56(e)).

When making this determination, the court must view all inferences drawn from the underlying facts in the light most favorable to the nonmoving party. *See Matsushita*, 475 U.S. at 587. "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge, [when] he [or she] is ruling on a motion for summary judgment." *Anderson*, 477 U.S. at 255.

III. ANALYSIS

Quidel's Motion

In its counterclaim, Siemens alleges that Quidel has unclean hands by falsely advertising Thyretain as a TSI only assay, by promoting the wrong Current Procedural Terminology ("CPT") reimbursement code for its assay, and by advertising that Thyretain produced results in a shorter time than it actually does.

Quidel previously moved for summary judgment on this counterclaim. As to the first issue, the Court found a disputed material fact as to whether it is "literally false" for Quidel to call Thyretain a TSI only assay. (ECF No. 285, at 15.) As to the second issue, the Court found a disputed material fact as to whether Quidel misled physicians by advising them to use the incorrect CPT code when submitting claims to Medicare for the use of Thyretain. As to the third issue, the Court found there is a disputed material fact as to whether Quidel's advertising Thyretain with the claim: "Results in 3 to 4 hours assures a quick turnaround time in the lab" is misleading. (*Id.* at 17–18.) Thus, the Court denied the motion for summary judgment as to this counterclaim.

Quidel now again moves for summary judgment on the issue of its promotion of the reimbursement code 84445 for Thyretain and of its advertising of the turn-around time for Thyretain. ("Pl. MSJ," ECF No. 301.) Although the Court permitted any party to file a motion for summary judgment, there is a difference between a successive motion for summary judgment and a motion for summary judgment on the exact same issue the Court has already resolved. Really, Quidel's motion is a motion for reconsideration.

Where reconsideration of a non-final order is sought, the court has "inherent jurisdiction to modify, alter or revoke it." *United States v. Martin*, 226 F.3d 1042, 1048-49 (9th Cir. 2000). "The authority of district courts to reconsider their own orders before they become final, absent some applicable rule or statute to the contrary, allows them to correct not only simple mistakes, but also decisions based on shifting precedent, rather than waiting for the time-consuming, costly process of appeal." *Id.* at 1049. Thus, this district's Civil Local Rule 7.1(i) permits motions for reconsideration "[w]henever any motion or any application or petition for any order or other relief has been made to any judge . . . has been refused in whole or in part." S.D. Cal. Civ. LR 7.1(i). However, the party seeking reconsideration must show "what new or different facts and circumstances are claimed to exist which did not

exist, or were not shown, upon such prior application." *Id.* Reconsideration is an "extraordinary remedy, to be used sparingly in the interests of finality and conservation of judicial resources." *Kona Enters., Inc. v. Estate of Bishop*, 229 F.3d 877, 890 (9th Cir. 2000). "A motion to reconsider is not another opportunity for the losing party to make its strongest case, reassert arguments, or revamp previously unmeritorious arguments." *Reeder v. Knapik*, No. 07-cv-362-L(LSP), 2007 WL 2088402, at *2 (S.D. Cal. July 18, 2007); *see also Campion v. Old Republic Home Protection Co., Inc.*, No. 9-cv-748-JMA(NLS), 2011 WL 1935967, at *2 (S.D. Cal. May 20, 2011) ("[R]econsideration may not be used to get a second bite at the apple.").

Although Quidel is not directly seeking reconsideration of the Court's prior order, its MSJ re-hashing the same arguments that it made previously is a motion for reconsideration in disguise. Quidel cites no new evidence or a change in the law, and Quidel has not convinced the Court that it clearly erred in its evaluation of the issues. Quidel argues its prior challenges to the counterclaim "were made on purely legal grounds" but its current motion is made "on an evidentiary (or lack thereof) basis." ("Pl. Reply," ECF No. 315, at 1.) But there is no reason why Quidel could not have made these arguments earlier, as the alleged lack of evidence has been known to Quidel all along, and it does not now get a second bite at the apple. And, even if Quidel's MSJ is not deemed a motion for reconsideration, Quidel has not convinced the Court that it is now entitled to summary judgment on the issues, and the Court reaffirms its prior holding. Thus, the Court **DENIES** Quidel's Motion.

Siemens' Motion

Siemens' Motion focuses on physicians.[1] As noted, the Court previously found that there is disputed material fact as to whether Siemens' advertising of its assay is false. But even if it is false, any false advertising was not material to the

[1] Unlike Quidel's MSJ, Siemens' MSJ requests resolution of an issue that has not yet been briefed by the parties or decided by the Court.

labs' decisions to carry Siemens' assay instead of Quidel's. (ECF No. 254, at 16.) Without this deceit, Quidel cannot prove its claims as to the labs and the Court granted summary judgment as to the labs. However, the Court found there is a disputed material fact as to whether physicians are in the relevant purchasing market for the assays. (*Id.* at 16–17 (citing evidence on both sides of the issue).) And even if the Court were to assume the jury would find the physicians to be part of the market, the Court further found there is a disputed material fact as to whether the physicians were or are likely to be deceived by Siemens' advertising. (*Id.* at 17.) Plaintiff's expert conducted a survey and determined that a substantial portion of physicians were deceived by Siemens' statements, and this expert opinion created a disputed fact as to the issue of deceit.[2]

Now, Siemens argues that even if physicians are in the relevant market, and even if they were deceived, "the evidence is unequivocal that Quidel was not injured by, has not suffered damages, and will not face irreparable harm because of Siemens' advertising." ("Def. MSJ," ECF No. 306-1 at 1–2 (emphasis omitted).) Siemens contends the lack of injury is fatal to all of Quidel's claims—the Lanham Act claim, Unfair Competition Law claim, and claim of intentional interference with prospective economic advantage.

A. Actual Injury

The first issue is whether Quidel has suffered any damages as a result of the allegedly false advertising to the physicians. The interplay between the manufacturers, the laboratories, and the physicians as it relates to the purchase of the assays is not entirely clear. Physicians order tests from labs for their patients. (*See* "Bitcoin Depo.," Exhibit E, ECF No. 310-1, at 314:6–8 ("The clinicians have to order an assay in order for the laboratory run [sic] to run it."); ("Dauscher Depo.,"

[2] Thus, Siemens' assertion that the Court relied only on "Quidel's representations in its opposition motion" to determine that there was a question of fact as to whether physicians were deceived, (Def. MSJ at 1) is incorrect.

Exhibit G, ECF No. 310-1, at 106:23–25 (testifying if physicians do not order the test, there is no point in having it at the lab).

Labs carry one "TSI only" test at a time; indeed, one of the main allegations in this case is that the two labs "switched" from Thyretain to Immulite. Labs decide which assays to carry after much analysis and independent evaluation. (*See* ECF No. 254, at 15–16 (the Court finding "the evidence shows that the laboratories come to the conclusion to use IMMULITE after their own sophisticated processes").

Exactly how much physicians defer to the lab in determining which test to use, or whether they do their own research and pick a lab that carries a specific test, appears to vary. Quidel's senior medical director testified that physicians "very much rely on what the manufacturer and the laboratories that run the test tell them about the assay." ("Olivo Depo.," Exhibit Y, ECF No. 310-1, at 65:8–10.) In ordering tests, physicians may or may not specify which product they want; they could simply request a Graves' disease test or they could specifically request Thyretain or Immulite. When asked who decides what type of assay to run, Mark Silberman, a representative for Sonic/CPL testified, "[i]t's substantially the responsibility of the clinicians. The clinicians in consultation with the laboratory. We – the laboratory directors, the pathologists [–] engage with the medical community for the appropriate assay to offer for a particular diagnostic need. The . . . more sophisticated [clinicians] do have the capability of and ask for it by name, like level of specificity, and in some circumstances they will specify." ("Silberman Depo.," ECF No. 310-1, at 117:12–22.) Silberman also testified that when Sonic switched from Thyretain to Immulite, the lab sent an announcement to physicians regarding the switch, and no physician sent an objection. (*Id.* at 169:15–19.)

A LabCorp representative similarly testified that when LabCorp switched assays, he does not believe any physician contacted LabCorp and expressed concerns about it running the Immulite assay. ("Valcour Depo.," Exhibit 28, ECF No. 319-2, at 195:21–196:1.) Expert witness Dr. Sipos confirmed that, "as a general rule, most

physicians are looking at the particular test that they are asking for and are not thinking about things in terms of brand name or . . . who creates that particular test." ("Sipos Depo.," Exhibit 23, ECF No. 306-25, at 138: 10–15. Physicians also reach out to the labs and the lab tells them "what [they] offer and what the methodology of the offering is." (Silberman Depo. at 117: 23–25; *see also* "Larriva Depo.," Exhibit V, ECF No. 310-1 at 175:6–10 (testifying it is important to educate physicians about the product because the physicians are the ones requesting the test for their patients)). There is no testimony from any physicians on the subject, thus, Quidel has not produced any direct evidence that physicians researched the assays and chose to use one lab over the other due to which assay that lab carries.

Labs are the ones who pay Quidel and Siemens for the tests; once a physician orders a test, the lab ships it and pays the manufacturer for that test. (*See* "Wunderlich Report," Exhibit BBB, ECF No. 322-1 ("The direct customers for Thyretain and the IMMULITE TSI Assay are laboratories and hospitals that perform the assays, not the clinicians who rely on the results of the laboratory tests to treat patients.").

A physician's use of the assays could play out in a number of ways. In one scenario, the physician has a patient with a thyroid problem and therefore requests a Graves' disease test from a lab. The physician does not specify, but instead has trusted the lab to do its own research to carry an effective test. The lab carries Immulite and runs that test, then pays Siemens. In this scenario, the Court has already determined that Quidel is not damaged because the lab did not rely on any allegedly false advertising to cause it to carry Immulite, and the physician relied on the lab in determining what test to use. In another scenario, the physician requests a lab use Thyretain for his or her patient's test. The lab does not carry Thyretain but instead carries Immulite. If the physician defers to the lab, and Immulite is used, then again Quidel is not damaged by Siemens, due to the lab's decision to carry Immulite not being caused by any false advertising. If the physician will only use

Thyretain, then he or she could call another lab that carries Thyretain, and request that lab run the test. (*See* "Houtz Depo.," Exhibit XX, ECF No 322-1 at 205:18–24 (testifying that some physicians reached out to Quidel saying they would switch labs.) In that scenario, Quidel is again not harmed because it still received the sale from another lab.

In a third scenario, the physician wants to use Immulite on the patient because the physician has seen Siemens' allegedly false advertising. That physician would use LabCorp or Sonic, who carry Immulite. This is what Quidel now claims to be its damages— those resulting from Siemens "misleading clinicians into ordering Immulite from LabCorp and Sonic/CPL." ("Pl. Opp'n," ECF No. 310, at 14; *see id.* at 18 ("If LabCorp and Sonic/CPL offered Immulite for what it truly is (a TRAb assay), the hundreds of thousands of orders clinicians have placed for Immulite under the assumption that it is a TSI-only test would be actually be placed with other laboratories that offer Thyretain. Instead, Siemens' false advertising has successfully usurped Quidel's ability to fulfill those TSI orders at LabCorp and Sonic/CPL.").

This is a problematic argument no matter which way Quidel argues it. 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. As the Court previously found, the labs decided which product to carry on their own, not as a result of Siemens; Siemens' advertising to the labs has essentially been removed from the equation. Quidel's argument that it no longer has the ability to fulfill orders at the labs is a result of the labs themselves, not a result of Siemens. (*See* Pl. Opp'n at 10 ("Sonic/CPL started offering Immulite instead of Thyretain, causing Quidel $300,000 per year in lost sales."). Quidel cannot blame the labs (*see id.* at 11 (claiming damages "as a result of clinicians no longer being able to order Thyretain from LabCorp and Sonic/CPL") and this cannot form its basis for damages.

And if Quidel is arguing that Siemens' advertising caused the physicians to order Immulite over Thyretain, this theory of damages has never before been disclosed. Rule 26(a)(1)(A)(iii) requires the disclosure of "a computation of each category of damages claimed by the disclosing party."[3] The level of detail required in this "computation" is not specified in the rules. But one court held in a well-reasoned and logical opinion:

> The plaintiff's computation of damages should provide sufficient detail to enable the defendants to understand the contours of their potential exposure and make informed decisions regarding settlement and discovery. The word "computation" contemplates some analysis beyond merely setting forth a lump sum amount for a claimed element of damages. The party seeking damages must also timely disclose its theory of damages as well as the computation of those damages. A plaintiff should disclose the basic method or formula by which it contends its damages should or will be calculated even if it cannot identify the specific dollar amount of damages pending further discovery.

Allstate Ins. Co. v. Nassiri, No. 2:08-CV-00369-JCM, 2011 WL 2977127, at *4 (D. Nev. July 21, 2011) (citations omitted). "Rule 37(c)(1) gives teeth to these requirements by forbidding the use at trial of any information required to be disclosed by Rule 26(a) that is not properly disclosed." *Yeti by Molly, Ltd. v. Deckers Outdoor Corp.*, 259 F.3d 1101, 1106 (9th Cir. 2001).

In Quidel's initial disclosures pursuant to Rule 26(a)(1), it contended as to damages:

> [A]t a minimum to date, Defendants' wrongful conduct has resulted in Quidel losing contracts for Thyretain in the neighborhood of $300,000 in revenues on an annual basis, as a direct result of Sonic Healthcare USA, a reference laboratory in Texas, switching from Thyretain to the IMMULITE Assay. In addition, Defendants' conduct may directly result in the loss of an additional $3 million in annual revenue from the cancellation of other Quidel contracts with third parties, including

[3] Rule 26(e)(1)(A) requires disclosing parties to supplement their prior disclosures "in a timely manner" when the prior response is "incomplete or incorrect."

> LabCorp. These contracts would have continued into the foreseeable future and losses from this business alone will cost Quidel in excess of $10 million in damages. Additional damages may include consequential losses from lost business relating to reputational harm to Quidel's overall Thyroid portfolio. These damages will likely increase significantly as the effects of Defendants' false and misleading advertising and unfair competition continue to come to light.

(Exhibit 4, ECF No. 306-6, at 9.) When asked to identify every customer it lost a result of Siemens' false advertising, Quidel identified Sonic and LabCorp. (Exhibit 5, ECF No. 306-7, at 8–9.) Although Quidel reserved the right to update this information as it learned more, it did not change its answers. (Exhibit 6, ECF No. 306-8, at 4–7, Exhibit 13, ECF No. 306-15, at 5 (answering the same as in Exhibits 4 and 5).) Quidel's Vice President of Finance testified that she is not aware of any other customers that switched from Thyretain to Immulite other than LabCorp and Sonic. ("Caltrider Depo.," ECF No. 322-1, at 138:2–6.)

This contention was reiterated by Quidel's damages expert Robert Wunderlich. Wunderlich evaluated Quidel's economic damages in terms of its lost income from lost sales of Thyretain to two of its former customers: LabCorp and Sonic/CPL. (Wunderlich Report at 160; "Wunderlich Depo.," Exhibit 27, ECF No. 322-1, at 77:21–24 ("I quantified damages in terms of the lost sales to the two customers that in total stopped buying from Quidel."). He testified "the ones who purchase the products" are labs and hospitals. The clinicians "may be involved in the purchase decision, but the ones who literally purchase it are the labs and hospitals." (Wunderlich Depo. at 69:6–9). He did not consider the actions of individual physicians in his damages evaluation. (*Id.* at 76:14–17.) He does not "offer an opinion on whether any physicians were misled by Siemens' advertising" nor does he "offer an opinion on whether physicians drive purchasing decisions for reference laboratories." ("Wunderlich Depo.," Exhibit 20, ECF No. 322-1 at 33:7–18.) He "think[s] [physicians are] in the background of what's happening in the marketplace" and he has "the general understanding that some of the potential

influences of what's happening in the marketplace would be how doctors feel about the assays." (*Id.* at 75:15–18; 76:4–8.) But he admitted he has not done "any analysis to determine whether the laboratories decision-making was influenced by sentiment among doctors." ("Wunderlich Depo.," Exhibit 27, ECF No. 322-1, at 77:7–12.) He testified that any lost profits "from a physician that used to order Thyretain . . . but now orders IMMULITE . . . could be embedded in the numbers" but he "didn't consider individual physicians." (*Id.* at 73:22–74:2.) And his report clearly states: "The direct customers for Thyretain and the IMMULITE TSI Assay are laboratories and hospitals that perform the assays, not the clinicians who rely on the results of the laboratory tests to treat patients." (Wunderlich Report at 6.)

In short, Quidel has not put Siemens on notice of a claim that physicians have caused the lost sales by relying on the advertising and then ordering the assays from LabCorp and Sonic. Quidel broadly alleged its lost sales were from LabCorp and Sonic, and even though Quidel now contends that those lost sales resulted from physicians not ordering from the labs, Quidel has never before asserted this and has not included this in its damages calculation. If any of Quidel's damages were attributable to lost sales through physicians, rather than due to the labs (as disclosed), this should have been provided to Siemens in Quidel's "computation." *See* Fed. Rule Civ. P. 26(a)(1)(A)(iii). Quidel's failure to do so was not harmless. Had Quidel provided Siemens with its full damages theory, Siemens likely would have followed up, asking which physicians were misled and who stopped ordering Thyretain. Instead, Siemens focused on the labs. Quidel's failure to make this damages contention made it impossible for Siemens to defend against this theory. *See Song v. Drenberg*, No. 18-CV-06283-LHK-VKD, 2019 WL 1949785, at *2 (N.D. Cal. May 2, 2019) (holding Fed. R. Civ. P. 26(a)(1)(A)(iii) requires a party claiming damages from lost business opportunities to "disclose the value of that loss sufficiently" including "how such damages may be calculated"); *Use Techno Corp. v. Kenko USA, Inc.*, No. 06-cv-2754, 2007 WL 4169487, at *3 (N.D. Cal. Nov. 20,

2007) (holding "because the failure to disclose any damages calculation was not harmless, Plaintiffs are barred from presenting evidence of damages" and dismissing false advertising claim).

And even if Quidel had adequately disclosed this damages theory, it has produced no evidence of lost profits that resulted from false advertising towards physicians. As the Ninth Circuit recently reiterated,

> When a party seeks damages for an allegedly false advertisement under the Lanham Act, "actual evidence of some injury resulting from the deception is an essential element of the plaintiff's case." Summary judgment is thus proper when the plaintiff "fail[s] to present any evidence of injury resulting from defendants' deception." Later decisions have not altered this requirement. Most recently, in *TrafficSchool.com, Inc. v. Edriver Inc.*, 653 F.3d 820 (9th Cir. 2011), we held that the plaintiffs could not prevail under the Lanham Act because they "didn't produce any proof of past injury or causation."

VBS Distribution, Inc. v. Nutrivita Labs., Inc., 811 F. App'x 1005, 1007 (9th Cir. 2020) (citations omitted). Quidel argues it has evidence of damages for four reasons.

First, Quidel states: "In the year before LabCorp stopped offering Thyretain, clinicians ordered approximately 143,000 TSI assays. Within just the first seven months of LabCorp offering Immulite, it had purchased 104,000 kits, annualizing at almost 180,000 tests per year. This increase in Siemens' revenue at a time when Quidel's revenue was decreasing by millions of dollars is sufficient to find that Quidel has suffered damages." (Pl. Opp'n at 15 (citations omitted).) But, as the Court previously held, the labs came to the decision to sell Immulite without relying on any false advertising, thus, evidence of changed sale patterns by the labs does not show Quidel's damages due to false advertising. Second, Quidel points to the testimony of Robert Wunderlich, arguing he "testified consistently that clinicians influence the purchasing decisions of laboratories." (*Id.*) This bare testimony is unsupported, and the issue of physician influence is not addressed in parties' prior briefing on the actions a lab takes before deciding which product to run. In the

Court's prior order, it detailed the testimony of the labs' representatives, who testified regarding the labs' evaluation of new products. The testimony did not include any evidence of physician influence. (*See* ECF No. 254, at 11–13.) And Quidel presents no evidence from the laboratories that they consider physician preference in determining which test to carry.

Third, Quidel points out that it has evidence that individual clinicians were misled, noting that Siemens and Sonic/CPL received inquiries from clinicians regarding whether Immulite could differentiate between TSI and TBI, and Siemens and Sonic/CPL did not disclose the truth. (*Id.* at 16.) Importantly, Quidel cannot claim it is entitled to damages due to anything the labs did or did not tell the physicians. And further, Siemens allegedly not informing clinicians regarding Immulite's ability to detect TSI is not proof that those physicians switched to using Immulite (as a result of Siemens) and therefore caused Quidel damages. Quidel continues to confuse the assertion that physicians received false or misleading advertising with the assertion that those physicians then took action (i.e. stopped purchasing Thyretain) and this caused damage. (*See id.* at 16–17.) There is no evidence of this.

Fourth, as Quidel noted in its interrogatory responses, it also argues it incurred damages because it spent "hundreds of thousands of dollars trying to remedy the damage caused by Siemens' false statements." (*Id.* at 11.) It sent letters to endocrinologists "in an attempt to educate them about LabCorp's switch to Immulite and to let them know that if they still wanted to order Thyretain, it was available from other reference laboratories" and Quidel representatives also attended endocrinology conferences to present data. (*Id.*) Quidel also "lowered its price for Thyretain in an attempt to maintain its competitive position." (*Id.*)[4]

[4] Although Quidel's expert specifically testified that he does not offer any opinion regarding these mitigation damages, "[s]ection 1117 demands neither empirical quantification nor expert testimony to support a monetary award of actual damages; many sources can provide the requisite information upon which a reasonable jury may calculate damages." *Skydive Arizona, Inc. v. Quattrocchi*, 673

"Corrective advertising may be appropriate to remedy consumer confusion caused by false advertising messages." *Healthport Corp. v. Tanita Corp. of Am.*, 563 F. Supp. 2d 1169, 1182 (D. Or. 2008), *aff'd*, 324 F. App'x 921 (Fed. Cir. 2009). However, there must be some evidence that the allegedly false advertising "likely caused an injury making this [corrective] advertising necessary." *In re Century 21-RE/MAX Real Estate Advert. Claims Litig.*, 882 F. Supp. 915, 925 (C.D. Cal. 1994). Quidel claims the corrective advertising was necessary to inform clinicians "about LabCorp's switch to Immulite." (Pl. Opp'n at 18 n.4.) But LabCorp's switch to Immulite was not due to Siemens' advertising. And Quidel has no evidence that it was damaged by Siemens' advertising as it relates to physicians, so it cannot now recover for amounts spent correcting that advertising. "If the false statements have no material impact, there is nothing to correct." *Nichia Am. Corp. v. Seoul Semiconductor Co.*, No. CV 07-8354 PA (CWX), 2008 WL 11342571, at *10 (C.D. Cal. Oct. 7, 2008); *Healthport Corp.*, 563 F. Supp. 2d at 1182 (finding corrective advertising not necessary when there was "no evidence that a large audience actually viewed the [allegedly false] site or that consumers were and continue to be actually deceived about the nature of" the products).

Quidel is unable to show any evidence of damages as a result of the allegedly false advertising to physicians.

B. Presumption of Injury

Quidel next argues that the Court should presume injury because Siemens and Quidel are direct competitors and Siemens' advertising mislead their customers. (Pl. Opp'n at 19.)

"We have generally presumed commercial injury when defendant and plaintiff are direct competitors and defendant's misrepresentation has a tendency to mislead consumers." *TrafficSchool.com, Inc. v. Edriver Inc.*, 653 F.3d 820, 826 (9th Cir. 2011). "[W]hen plaintiff competes directly with defendant, a misrepresentation will

F.3d 1105, 1113 (9th Cir. 2012).

give rise to a presumed commercial injury that is sufficient to establish standing." *Id.*; *U–Haul Int'l, Inc. v. Jartran, Inc.*, 793 F.2d 1034, 1040–41 (9th Cir. 1986) ("Publication of deliberately false comparative claims gives rise to a presumption of actual deception and reliance." (citation omitted)).

Siemens argues that the presumption only affords a plaintiff standing, not injury, ("Def. Reply," ECF No. 319, at 7), but the Ninth Circuit has rejected this argument. The defendant in *ThermoLife International, LLC v. Gaspari Nutrition Inc.* argued the same, and the court held:

> but the two standards—which are derived from the same statutory language—are one and the same. *See id.* ("The Lanham Act permits 'any person' to sue if he 'believes that he . . . is *likely* to be damaged.'" (alterations in original) (quoting 15 U.S.C. § 1125(a))); *Southland Sod Farms*, 108 F.3d at 1139 ("The elements of a Lanham Act § 43(a) false advertising claim are: . . . the plaintiff has been or is likely to be injured as a result of the false statement . . . ." (footnote omitted)).

648 F. App'x 609, 615–16 (9th Cir. 2016). The court found that plaintiff ThermoLife had established a presumption of commercial injury. *Id.* at 616.

Siemens also argues that the presumption of injury is inconsistent with the Ninth Circuit holding that "actual evidence of some injury *resulting from the deception* is an essential element of the plaintiff's case." *See Harper House, Inc. v. Thomas Nelson, Inc.*, 889 F.2d 197, 210 (9th Cir.1989). The *ThermoLife* court addressed this too:

> But *Harper House* held only that a court cannot assume injury without any evidence of causality and consumer deception. *See id.* at 209–10. Consistent with that observation, *TrafficSchool.com* permits a jury to infer injury based on evidence of direct competition (which provides a causal link) and a likelihood of consumer deception. *See* 653 F.3d at 826.

Id.; *see also Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1146 (9th Cir. 1997) ("Because a reasonable jury could conclude, based on the evidence submitted by Plaintiffs, that Defendants comparative advertisement claims were deliberately

false within the meaning of § 43(a), Plaintiffs may be entitled to a presumption of actual consumer deception and reliance, and would therefore be entitled to appropriate monetary relief unless Defendants could rebut the presumption.").

Thus, the Court must determine if there is evidence of direct competition and a likelihood of consumer deception.

1. Direct Competition

Quidel contends that it and Siemens are direct competitors because Thyretain was the only TSI assay on the market until Siemens sought to develop and sell one. (Pl. Opp'n at 22.) Quidel agrees that there were TRAb assays available, but it contends that the manufacturers of TRAbs are not competitors to the parties. (*Id.*) Thus, Quidel contends that anytime Siemens advertised that Immulite was a TSI only assay, this "constituted quintessential 'comparative advertising.'" (*Id.* at 23.)

The presumption does not apply "when advertising does not directly compare defendant's and plaintiff's products." *TrafficSchool.com, Inc.*, 653 F.3d at 831. Comparative advertising has been recognized where the defendant distributes ads specifically comparing its product with the plaintiff's, for example, in *Southland Sod Farms*, the defendant distributed ads claiming that its product grows much slower "than other dwarf tall fescues, including those produced by Plaintiffs." 108 F.3d at 1137, 1146. This comparative statement was the allegedly false advertisement.

The only comparative advertising the parties point to in this case is a 2016 message sent by Siemens. (*See* Pl. Opp'n at 23.) In 2016, Siemens prepared a "DocAlert"—a message sent to doctors informing them about Immulite. (Exhibit CC, ECF No. 310-1.) The alert informed the doctors that Immulite is "specifically engineered to preferentially detect stimulating antibody" and that "TSI testing" is different than TRAb testing. (*Id.* at 1.) The Alert informed doctors that Immulite has "superior clinical sensitivity for diagnosis of Graves' disease (98.6%) vs Thyretain bioassay (92%)." (*Id.*) But Quidel is not alleging that Immulite's sensitivity and specificity data are false. (ECF No. 18, at 12 (Quidel arguing its

complaint does not allege that Immulite's sensitivity and specificity data are false but instead "attacks Defendants' false and misleading message that the assay . . . detect[s] TSI only and differentiate[s] between stimulating and blocking antibodies").) Thus, this DocAlert comparison is inapplicable to the current suit.

It is clearer that Siemens' advertising continually contrasted Immulite and TRAb assays. As one example, Siemens advertised in an October 2015 press release: "Unlike TRAb (TSH receptor antibody) assays which detect both stimulating and blocking antibodies, the Siemens TSI assay specifically detects only thyroid stimulating antibodies, which are the hallmark of Graves' disease." (Wunderlich Report at 4.) There is no evidence that a similar comparative advertising was made regarding Thyretain. Accordingly, Quidel has not established that Siemens engaged in any advertising comparing Thyretain and Siemens as it relates to the allegedly falsely advertised claim—the TSI only claim. *See Pom Wonderful LLC v. Ocean Spray Cranberries, Inc.*, No. CV 09-00565, 2011 WL 4852472 at *3 (C.D. Cal. Oct. 12, 2011) (finding a presumption of injury did not apply because Pom's alleged false advertising only referred to a generic product or class of products and did not name Ocean Spray's juice).

Siemens certainly advertised Immulite and touted its ability to detect TSI, but it did not tie this representation to Thyretain. "[W]here a defendant is guilty of misrepresenting its own product without targeting any other specific product, it is erroneous to apply a rebuttable presumption of harm in favor of a competitor. Otherwise, a plaintiff might enjoy a windfall from a speculative award of damages by simply being a competitor in the same market." *Porous Media Corp. v. Pall Corp.*, 110 F.3d 1329, 1334 (8th Cir. 1997) (citing *Harper House, Inc.*, 889 F.2d at 209). Thus, the Court cannot presume injury and damages based on any direct comparison. *See Nat'l Prod., Inc. v. Gamber-Johnson LLC*, 699 F. Supp. 2d 1232, 1241 (W.D. Wash. 2010) ("[D]eliberate falsity yields a presumption of consumer

deception in cases of non-comparative advertising and a presumption of consumer deception and injury in cases of direct comparative advertising.").

Quidel next argues that even if Siemens did not issue any directly comparative ads, any ads by Siemens would be implicitly comparative because the two parties are in a two-player market. But Quidel's expert testified, "the overall marketplace is not a two-player market. There are people who sell TRAb products." ("Wunderlich Depo.," Exhibit 20, ECF No. 322-1, at 141:2–4; *see also* Exhibit I, ECF No. 324-6 (Siemens' presentation regarding the "Current TRab/TSI Market" notes there are "[m]ultiple players in the TRab market"). Quidel's senior medical director testified that one of the issues Quidel had with Immulite is that it "has results that are at least comparable as [sic] Thyretain . . . [a]nd many other TRAb tests." (Olivo Depo. at 219:5–9.) And Quidel's sales representative for Thyretain testified that Quidel has "other competitors that have TRAb assays" and that Quidel considers "TRAb assays to be competitors of its Thyretain TSI assay . . . [because they] can be used in thyroid testing." ("Brooks Depo.," Exhibit 1, ECF No. 322-1, at 236:12–21; 238:5–6.)

The parties have compared their assays to each other's, as well as to TRAb assays, in briefings throughout this case. Indeed, the main contention in this case is that a TSI only assay is better than a TRAb assay, so it is undeniable that the TRAb assays are also in the market, and the manufacturers of TRAb assays are competing for purchase. And it is also undeniable that both parties strive to prove that their products are better than TRAb products. The presumption of injury may apply in "false *comparative* advertising cases, where it is reasonable to presume that every dollar defendant makes has come directly out of plaintiff's pocket." *TrafficSchool, Inc.*, 653 F.3d at 831. When a defendant's advertising does not directly compare its products with the plaintiff's products or when numerous competitors participate in the market, "injury to a particular competitor may be a small fraction of the defendant's sales, profits, or advertising expenses." *Harper House, Inc.*, 889 F.2d at 209 n.8. Because injury under these circumstances is likely to be slight, "actual

evidence of some injury *resulting from the deception* is an essential element of the plaintiff's case." *Id*. at 210. Otherwise, "a plaintiff might enjoy a windfall from a speculative award of damages by simply being a competitor in the same market." *Porous Media Corp*., 110 F.3d at 1334 (citing *Harper House*, 889 F.2d at 209); *see also CKE Rest. v. Jack in the Box, Inc*., 494 F. Supp. 2d 1139, 1146 (C.D. Cal. 2007) ("The injury in cases involving non-comparative statements 'accrue[] equally to all competitors. . . . Thus [courts] require[ ] some indication of actual injury and causation to satisfy Lanham Act standing requirements and to ensure a plaintiff's injury was not speculative.'" (quoting *McNeilab, Inc. v. Am. Home Products Corp*., 848 F.2d 34, 38 (2d Cir. 1988) (alterations in original))); *see also Campagnolo S.R.L. v. Full Speed Ahead, Inc*., No. C08-1372 RSM, 2010 WL 455195, at *2 (W.D. Wash. Feb. 1, 2010) ("*Harper House* makes clear that a showing of consumer deception does not necessarily entitle a plaintiff to damages if the plaintiff cannot show injury.").

Here, the money Siemens makes from the sale of Immulite does not necessarily flow exactly from Quidel's prior sales of Thyretain. If TSI only assays are substantially better than TRAb assays, as both parties claim, then Siemens could be making sales to those who used to use TRAb assays but switched over to using Immulite. There is more to the equation than simply: those who use Thyretain now use Immulite. A Siemens advertisement lists Immulite's competitors as Roche anti-TSHR, Thyretain, microplate methods, and RRA methods. (*See* Exhibit B, ECF No. 310-1.) Accordingly, it would be unfair to assume that all of Immulite's profits are equal to what Thyretain's profits would have been. Thus, Quidel has not established that the two companies are in direct competition in a two-player market. *See Falcon Stainless, Inc. v. Rino Cos., Inc*., No. SACV0800926AHSMLGX, 2011 WL 13130703, at *15 (C.D. Cal. Oct. 21, 2011), *aff'd*, 572 F. App'x 483 (9th Cir. 2014) (finding a presumption of damages would be erroneous because the defendant's ad

"made comparisons to five other products" and did not "involve[] a direct comparison between two competitors' products").

Because Quidel cannot point to any comparative ads and the parties are not in a two-player market when it comes to the sale of their products, Quidel is not entitled to a presumption of injury. And Quidel is also unable to show injury, as noted above. "The trial court must dismiss a non-comparative false advertising claim where the plaintiff fails to produce proof of past injury or causation because it has 'no way to determine with any degree of certainty what award would be compensatory.'" *Cascade Yarns, Inc. v. Knitting Fever, Inc.*, No. C10-861 RSM, 2015 WL 1735517, at *5 (W.D. Wash. Apr. 15, 2015) (quoting *TrafficSchool.com, Inc.*, 653 F.3d at 831).

2. Likelihood of Consumer Deception

Given that the Court has already determined that there is a question of material fact as to whether the advertising is false and/or misleading, there is also a question of material fact as to whether consumers would be deceived by the advertising.

Quidel is not entitled to a presumption of injury.

C. <u>Injunctive Relief</u>

Quidel's final argument is that it need not prove injury because it is suing to enjoin Siemens' conduct. (Pl. Opp'n at 24.) "[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 as this Court previously recognized, "[t]hough [defendant] does not need to prove injury when requesting injunctive relief for the elements of a Lanham Act claim, [it] still must meet all the prongs for [a] permanent injunction." *Obesity Research Inst., LLC v. Fiber Research Int'l, LLC*, 310 F. Supp. 3d 1089, 1128 (S.D. Cal. 2018). A plaintiff seeking a permanent injunction must establish:

> (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff

> and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006). "Though [defendant] does not need to prove injury to satisfy the 'likelihood of injury' element for its Lanham Act claim, this showing does not equate to satisfying the irreparable harm prong for a permanent injunction." *Obesity Research*, 310 F. Supp. 3d at 1128. When a plaintiff moves for injunctive relief on a defendant's false statements, "[a] showing of literal falsity alone is insufficient to warrant permanent injunctive relief" as "the Lanham Act requires proof of likelihood of future injury" and "a plaintiff seeking a permanent injunction must satisfy [the *eBay, Inc.*] four-factor test." *Kurin, Inc. v. Magnolia Med. Techs., Inc.*, No. 3:18-CV-1060-L-LL, 2020 WL 4049977, at *9 (S.D. Cal. July 20, 2020).

Quidel cites to the *Obesity Research* holding but also argues there is a difference between the issuance of a preliminary injunction and "whether a plaintiff could continue with a claim for injunctive relief under the Lanham Act." (Pl. Opp'n at 24 & 24 n.8.) It claims it is harmed because "Siemens has refused to admit to the public, the FDA, the laboratories, and clinicians that Immulite cannot distinguish between TSI and TBI, actually detects TBI, and cannot, by its very design, detect TSI only." (*Id.* at 25.) It argues due to this, clinicians "have continued to order TSI tests from LabCorp and Sonic/CPL instead of selecting a laboratory that offers Thyretain" and if Siemens admits that Immulite is a TRAb assay, this will "inform clinicians as to Immulite's significant limitations" and will allow Quidel to share with those reference laboratories that did not switch from Thyretain to Immulite that they made the correct decision." (*Id.* at 25.) Unpacking this, the Court first notes that Quidel getting the ability to remind labs that still carry Thyretain that they should continue to do so is not evidence of irreparable harm, so this argument is incorrect. The Court focuses on the claim that clinicians continue to order from LabCorp and Sonic (that carry Immulite) rather than from a lab that offers Thyretain, and this

harms Quidel. But loss of sales is monetary loss, and Quidel has not argued that there is any loss beyond this. Without any evidence "that remedies available at law, such as monetary damages, are inadequate to compensate for [an irreparable] injury" *eBay Inc*., 547 U.S. at 391, Quidel cannot establish that an injunction is warranted. And therefore, it cannot use this as a reason of why it is not required to prove damages.

IV. CONCLUSION

First, Quidel's Motion for Summary Judgment is **DENIED**. (ECF No. 301.) Second, Quidel has not produced any evidence that is has suffered damages due to physicians as a result of Siemens' allegedly false advertising. Quidel is not entitled to a presumption of injury and Quidel has not met elements for a permanent injunction. Accordingly, Siemens' Motion for Summary Judgment is **GRANTED**. (ECF No. 306.) Because injury is required for all of Quidel's claims, this concludes the case and the Clerk is instructed to close the file.

IT IS SO ORDERED.

DATED: August 17, 2020

Hon. Cynthia Bashant
United States District Judge