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### 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 GRANTING IN PART PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

[ECF No. 268]

Presently before the Court is Plaintiff Quidel Corporation's Motion for (1) Summary Judgment or, in the Alternative, Partial Summary Judgment as to All of Defendant Siemens Healthcare Diagnostics Inc.'s Claims; and (2) Partial Summary Judgment as to Defendants' Unclean Hands Affirmative Defense. ("Mot.," ECF No. 268.) Defendants Siemens Medical Solutions USA, Inc. and Siemens Healthcare Diagnostics, Inc. filed an opposition to the Motion, ("Opp'n," ECF No. 273), to which Quidel filed a reply, ("Reply," ECF No. 278). The Court finds this Motion

<sup>&</sup>lt;sup>1</sup> Pursuant to this Court's standing orders, the parties filed a joint statement of undisputed material facts along with the reply brief. (ECF No. 279.) The joint statement contains a total of three facts: (1) Quidel filed its complaint; (2) Siemens filed a motion for summary judgment; and (3) the Court granted in part and denied in part Siemens' motion. (*Id.*) The fact that the parties attest that they could agree on <u>no</u> substantive facts and merely presented the Court a timeline of with three filings

suitable for determination on the papers and without oral argument. Civ. L. R. 2 7.1(d)(1). For the reasons stated below, the Court **GRANTS IN PART** and **DENIES** 3 **IN PART** the Motion. 4

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#### 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.<sup>2</sup> 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

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that can be confirmed by the docket is offensive and unacceptable. The Court is disappointed that the parties' attorneys were unable to work together on such a simple task.

<sup>&</sup>lt;sup>2</sup> The Court refers to Defendants collectively as "Siemens."

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.) The Court specified that in amending the counterclaims, Siemens "may not add any new counterclaims or allegations, and the only change it may make is to excise the allegations of protected activity the Court discusses in this Order." Siemens filed an amended answer and counterclaims. ("Answer & CC," ECF No. 252.) Quidel then moved for sanctions against Siemens because Siemens had added new allegations to its counterclaims. (ECF No. 257.) The Court granted the motion, finding that Siemens had improperly added new material in an attempt to bolster its counterclaims. (ECF No. 276.) The Court "will not consider any material improperly added to Siemens' amended counterclaims." (*Id.* at 3.)

Finally, the Court has already analyzed two motions for summary judgment. The Court granted in part Siemens' motion, finding that even if Siemens' advertising of IMMULITE was false, any false advertising was not material to the laboratories' decision to purchase IMMULITE. 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 were deceived by the advertising of IMMULITE. The Court also denied Siemens' request for summary judgment as to its unclean hands defense. (*See* ECF No. 254.)

In the present Motion, Quidel seeks summary judgment as to Siemens' counterclaims of trade libel, abuse of process, and unfair competition, and as to the affirmative defense of unclean hands.

#### 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

#### A. Trade Libel Claim

California law defines trade libel as "an intentional disparagement of the quality of property [or a product], which results in pecuniary damage." *Erlich v. Etner*, 224 Cal. App. 2d 69, 73 (1964). The elements of trade libel are (1) a false publication, (2) which induces others not to deal with the party, and (3) special damages. *Aetna Cas. & Surety Co. v. Centennial Ins. Co.*, 838 F.2d 346, 351 (9th Cir. 1988).

In its trade label claim, Siemens alleges that Quidel published false statements that are disparaging to Siemens and the IMMULITE assay. (Answer & CC ¶ 63.) These false statements "induced Siemens' prospective and existing customers to not deal with it" which caused injury to Siemens. (*Id.* ¶¶ 65, 66.) Siemens further alleges that it suffered damages of legal fees, lost sales and customers, and loss of reputation and goodwill. (*Id.* at ¶¶ 10, 55, 61, 65–66.) Quidel moves for summary judgment because Siemens has not sufficiently alleged and cannot prove special damages. (Mot. at 6.)

Rule 9(g) establishes that special damages must be specifically stated. Fed. R. Civ. P. 9(g). In its prior order, the Court noted that one court held that the defendant sufficiently alleged special damages when it alleged lost market share as a result of the plaintiff's false online reviews. (ECF No. 247, at 18 (citing *Swiss Am. Trading Corp. v. Regal Assets, LLC*, No. CV 14-4960 DDP (ASx), 2015 WL 631569, at \*3 (C.D. Cal. Feb. 13, 2015)).) "But the breadth of cases require much more." (*Id.*)

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In Homeland Housewares, LLC v. Euro-Pro Operating LLC, No. CV 14-3954 DDP (MANx), 2014 WL 6892141, at \*4 (C.D. Cal. Nov. 5, 2014), the plaintiffs alleged special damages by alleging they suffered "general statements of economic loss" and requested \$3 million total for all causes of action. The court held "to recover damages based on general business loss, Plaintiffs 'should have alleged facts showing an established business, the amount of sales for a substantial period preceding the publication, the amount of sales subsequent to the publication, [and] facts showing that such loss in sales were the natural and probable result of such publication[.]" Id. (quoting Isuzu Motors Ltd. v. Consumers Union of U.S., Inc., 12 F. Supp. 2d 1035, 1047 (C.D. Cal. 1998)). Because the plaintiffs had only generally alleged "lost sales, market share, and customer goodwill," they had not adequately alleged special damages for trade libel. *Id.*; see also Franklin Fueling Sys., Inc. v. Veeder-Root Co., No. S-09-580 FCD/JFM, 2009 WL 2462505, at \*5 (E.D. Cal. Aug. 11, 2009). Further, courts have held if a plaintiff alleges lost sales, it must "identify particular customers and transactions of which it was deprived as a result of the libel." Mann v. Quality Old Time Serv., Inc., 120 Cal. App. 4th 90, 109 (2004).

Siemens does not directly dispute the assertion that it has not presented sufficient evidence of special damages. However, Siemens argues that its trade libel claim does not require proof of special damages because the challenged statements are libel per se. (Opp'n at 12.)

A statement is libel for se when it "is defamatory without the need for explanatory matter such as an inducement, innuendo or other extrinsic fact." *Overstock.com, Inc. v. Gradient Analytics, Inc.*, 151 Cal. App. 4th 688, 700 (2007) (citing Cal. Civ. Code § 45a). If a plaintiff adequately alleges and proves a libel per se claim, it is unnecessary to prove special damages; rather, damage to reputation is presumed. *See Barnes-Hind, Inc. v. Superior Court*, 181 Cal. App. 3d 377, 381 (1986). The issue thus becomes whether the concept of libel per se may apply to trade libel claims. "Trade libel is generally distinguished from common-

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law defamation and is said to connote 'an intentional disparagement of the quality of property, which results in pecuniary damage to plaintiff.' Libel per se, on the other hand, is based in common law defamation, and thus relates to the standing and reputation of the businessman as distinct from the quality of his or her goods." *Id.* (citation omitted).

In Peak Health Center v. Dorfman, No. 19-cv-4145-VKD, 2019 WL 5893188 (N.D. Cal. Nov. 12, 2019), the defendant made a similar argument that Siemens makes here: that it need not allege special damages for its trade libel claim because "a claim for libel per se" does not require it. The court held, while it may be true that libel per se does not require an allegation of special damages, "Peak Health has chosen to pursue a claim for trade libel in its amended complaint, not libel per se—a distinction recognized in [various] cases." *Id.* at \*6. The court cited *Barnes-Hind* as well as *Erlich*, 224 Cal. App. 2d at 73, where the California Court of Appeal similarly held: "plaintiff elected to proceed against Etner solely on the theory of trade libel. . . . Trade libel is defined as an intentional disparagement of the quality of property, which results in pecuniary damage to plaintiff. While [] general damages are presumed in a libel of a businessman, this is not so in action for trade libel." Id. (citation omitted). Similarly, in *Universal Grading Service v. eBay, Inc.*, No. C-09-2755 RMW, 2011 WL 846060, at \*10 (N.D. Cal. Mar. 8, 2011), the court held, "plaintiffs cannot bypass the requirement to show special damages by now asserting trade libel per se because the [the complaint] clearly alleges 'common law trade libel."

Indeed, there are courts that have found otherwise. The court in *Theme Productions, Inc. v. News Am. FSI, Inc.*, No. C-97-4617-VRW, 1998 U.S. Dist. LEXIS 23560, at \*20 (N.D. Cal. 1998) held, "[o]rdinarily, a cause of action for trade libel requires at a minimum: (1) a publication; (2) which induces others not to deal with plaintiff; and (3) special damages. A determination that a publication is libelous per se negates the necessity of pleading special damages." (citations omitted.) This

Court does not find such a holding to be supported and therefore disagrees. The Court finds *Peak Health*, *Erlich*, and *Universal Grading* to be well-reasoned and applicable. Like the defendant in *Universal Grading*, Siemens pled "trade libel under California common law." (*See* Answer & CC at 30.) If Siemens had intended to plead trade libel per se, it could have done so. Without this, special damages are required. Because Siemens has failed to sufficiently plead special damages, let alone provide evidence supporting such damages them, the Court **GRANTS** Quidel's Motion for Summary Judgment on the trade libel counterclaim.

#### B. Abuse of Process Claim

The California abuse of process tort has two elements: "(1) an ulterior motive; and (2) a willful act in the use of process not proper in the regular conduct of the proceedings." *Drum v. Bleau, Fox & Assocs.*, 107 Cal. App. 4th 1009, 132 (2003). Simply filing or maintaining a lawsuit—even with an improper motive—is not actionable. *Silver v. Gold*, 211 Cal. App. 3d 17 (Ct. App. 1989). The tort must involve a misuse of the power of the court, or "an act done under the authority of the court for the purpose of perpetrating an injustice." *Younger v. Solomon*, 38 Cal. App. 3d 289, 297 (1974). There must be "an improper act outside the scope of judicial proceedings[,]" *Carlock v. RMP Fin.*, No. 03-cv-688 W (AJB), 2003 WL 24207625, at \*2 (S.D. Cal. Aug. 5, 2003), because "maintenance of a lawsuit . . . is not a proper basis for an abuse of process action." *Oren Royal Oaks Venture v. Greenberg, Bernhard, Weiss & Karma, Inc.*, 42 Cal. 3d 1157, 1168 (1986).

Siemens alleges that Quidel abused the process through its action of sending its original complaint and amended complaint with letters to physicians and laboratories, who are the parties' customers. (Answer & CC  $\P$  68.) The first issue is whether these actions may form the basis of an abuse of process claim.

"[T]he essence of the [abuse of process] tort [is] . . . misuse of the power of the court; it is an act done in the name of the court and under its authority for the purpose of perpetrating an injustice." *Rusheen v. Cohen*, 37 Cal. 4th 1048, 1057

(2006) (quoting *Meadows v. Bakersfield S. & L. Assn.*, 250 Cal. App. 2d 749, 753 (1967).) The tort "requires misuse of a judicial process." *Stolz v. Wong Commc'ns Ltd. P'ship*, 25 Cal. App. 4th 1811, 1822 (1994). Quidel's action of sending its own complaints, with a letter detailing Quidel's opinions and research, to potential customers is not an act that uses "the power of the court[,]" nor was it done "in the name of the court" or "under its authority." Therefore, the abuse of process claim is not proper here. Further, even if the tort applied to Quidel's actions, the Court finds that Quidel is protected by the litigation privilege.

The purpose of California's litigation privilege "is to afford litigants . . . the utmost freedom of access to the courts without fear of being harassed subsequently by derivative tort actions." *Silberg v. Anderson*, 50 Cal.3d 205 (1990). The litigation privilege applies to any communication (1) made in a judicial proceeding; (2) by litigants or other participants authorized by law; (3) to achieve the objects of the litigation; and (4) that have some connection or logical relation to the action. *Id.* "[W]hether a given communication is within the privilege is an issue of law, and not fact." *Nguyen v. Proton Tech. Corp.*, 69 Cal. App. 4th 140, 147 (1999).

As to the first prong, the privilege pertains not only to statements made during a trial, but also to steps taken before trial and statements made "to achieve the objects of the litigation, even though the [statement] is made outside of the courtroom and no function of the court or its officers is invoked." *Albertson v. Raboff*, 46 Cal.2d 375, 381 (1956); *see also Castaline v. Aaron Mueller Arts*, No. C 09-2543 CRB, 2010 WL 583944, at \*4 (N.D. Cal. Feb. 15, 2010) (finding plaintiff's action of sending the complaint to distributors satisfies the first prong "because the Complaint relates to a judicial proceeding even though it was not made in the proceeding per se"). Quidel's acts of notifying potential customers that it believes IMMULITE is falsely advertised serves the "objects of the litigation" of preventing the sale of falsely advertised products. The first prong is met. Next, the second prong is satisfied because the action of sending the complaints and letters was performed by

Quidel, who is a party to the suit.

The California Supreme Court has characterized the third prong of the test as being "simply part of" the fourth. Silberg, 50 Cal. 3d at 219–20. Under the fourth prong, "other participants authorized by law" include non-parties who have a "substantial interest in the outcome of the pending litigation." Castaline, 2010 WL 583944, at \*4. In Youngevity International Corp. v. Smith, Youngevity issued a press release to a trade publication announcing the initiation of the litigation. No. 16-cv-704-BTM-JLB, 2017 WL 6389776, at \*3 (S.D. Cal. Dec. 13, 2017), aff'd in part, rev'd in part, dismissed in part sub nom. Youngevity Int'l Corp. v. Andreoli, 749 F. App'x 634 (9th Cir. 2019). Judge Moskowitz found that the litigation privilege did not apply to the republication of the complaint to non-participating third parties. He reasoned, "[t]hough out-of-court statements may fall within the protections of the litigation privilege, here, there is no indication that the republication to a nonparticipating party functioned as a necessary step in the litigation process." *Id.* at \*7. The Ninth Circuit disagreed, finding that Youngevity's press release which summarized the complaint is protected speech. Youngevity Int'l Corp. v. Andreoli, 749 F. App'x 634 (9th Cir. 2019). The panel reasoned that the litigation privilege "applies to communications made in judicial proceedings and extends to communications regarding such judicial proceedings made to people with 'a substantial interest in the outcome of the pending litigation." Id. at 635 (citations omitted).<sup>3</sup>

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<sup>&</sup>lt;sup>3</sup> In arguing the privilege does not apply, Siemens points to *Rothman v. Jackson*, 49 Cal. App. 4th 1134 (1996). There, the court concluded that, to be sufficiently in furtherance of the litigation, the communication must "function intrinsically, and apart from any consideration of the speaker's intent, to *advance a litigant's case*." *Id.* at 1143. "Statements to persons with no connection to a case are not covered by the litigation privilege." A communication must have a "functional connection" to the litigation, meaning that the communicative act "must function as a necessary or useful step in the litigation process and must serve its purposes." *Id.* While the district court in *Youngevity* analyzed whether the communication served as a "necessary step" in the litigation pursuant to *Rothman*, the Ninth Circuit did not. Siemens appears to argue that the

preventing continued infringement of" the patent. *Id.* (citation omitted). The recipients had a substantial outcome in the pending litigation because they could be exposed to potential liability for the patent depending on the outcome of the litigation. *Id.* at \*8. The act was a necessary and useful step in the litigation process because it pertained directly to the subject matter of the lawsuit and served to deter the continued infringement of the patent. *Id.*Similarly, in *Epistar Corp. v. Philips Lumileds Lighting Co.*, No. C 07-5194 CW, 2008 WL 3930030 (N.D. Cal. Aug. 26, 2008), the plaintiff alleged that the defendant sent false and misleading letters that misled plaintiff's customers into believing that plaintiff's products infringe patents. Defendant claimed its conduct was protected by the litigation privilege. *Id.* at \*6. The court found that the customers have a substantial interest in the proceeding, as they "purchased [plaintiff's] products, incorporated them into their own and intended to import those products." *Id.* at \*7. The letters are protected by the litigation privilege. *Id.*; *see also Weiland Sliding Doors & Windows, Inc. v. Panda Windows & Doors, Inc.*, 814

The case Tri-Star Electronics International, Inc. v. Preci-Dip Durtal SA, No.

CV 08-4226 GAF (AJWx) 2011 WL 13176071 (C.D. Cal. May 27, 2100) is also

instructive. There, the plaintiff sued for patent infringement. Plaintiff then sent

letters to defendant's customers and distributors informing them of the complaint and

the alleged infringement. The court found the litigation privilege applies to the

communications. Id. at \*7. The letter served "the objects of the litigation,' i.e.

These cases are applicable here. The customers who received the complaint

F. Supp. 2d 1033, 1041 (S.D. Cal. 2011) (holding the recipients of plaintiff's press

release which detailed the lawsuit and the alleged infringement have a substantial

interest in the outcome of the pending litigation because those considering buying

the products would want to know whether the products are effective).

Ninth Circuit holding is incorrect and incomplete, (see Opp'n at 16 n.9) but this Court is bound by and follows the Ninth Circuit precedent.

and letters from Quidel have a substantial interest in the litigation. Quidel is alleging that Siemens' assay is falsely advertised, and the purchasers of that assay are interested in the efficacy of it. As a final note, "[a]ny doubt about whether the privilege applies is resolved in favor of applying it." *Kashian v. Harriman*, 98 Cal. App. 4th 892, 913 (2002). Therefore, because all of the *Silberg* prongs are met, the litigation privilege applies to Quidel's acts of sending the complaint and letter to the customers. The Court **GRANTS** Quidel's Motion for Summary Judgment as to the abuse of process counterclaim.

#### C. Unfair Competition Claims

Siemens claims Quidel violated California's Unfair Competition Law ("UCL") through its unlawful and unfair practices. Siemens alleges Quidel engaged in unlawful practices by violating (1) the False Claims Act (31 U.S.C. § 3729); (2) California common law prohibition against trade libel; and (3) California's False Claims Act (Cal. Gov't Code § 12651). Siemens also alleges Quidel engaged in unfair practices through its misrepresentations regarding Thyretain. (Answer & CC ¶¶ 59–60.) Quidel moves for summary judgment on a number of grounds, the first being standing.

To establish standing under the UCL, a party must demonstrate that it "suffered injury in fact and [] lost money or property as a result of the unfair competition." Cal. Bus. & Prof. Code § 17204. Quidel moves for summary judgment on this claim because Siemens has no "evidence that it lost any money or property as a result of Quidel's alleged unfair competition." (Mot. at 15.) Siemens disagrees, noting it has alleged that it "suffered economic injury in the form of 'harmed business reputation, lost goodwill, and lost sales." (Opp'n at 17 (quoting Answer & CC ¶ 61).)

A party's burden, in any standing inquiry, must be supported "with the manner and degree of evidence required at the successive stages of litigation." *Lujan v. Defs.* of Wildlife, 504 U.S. 555, 561 (1992). "To survive a motion for summary judgement,

a [party] need not definitively establish standing. Rather, [it is] only required to set forth sufficient evidence to create a genuine issue of material fact concerning such requirements." *Murphy v. Best Buy Stores, L.P.*, 690 F. App'x 553, 554–55 (9th Cir. 2017).

Here, while Siemens has certainly <u>alleged</u> that it has been injured by Quidel's actions, it has not pointed to one piece of evidence showing said harm. Instead, it contends it "has alleged and will prove at trial" economic injury, and cites four cases in support of its assertion that this is sufficient. (Opp'n at 17.) But in those four cases, the courts were addressing motions to dismiss, and found that the defendants there had sufficiently alleged injury at that stage. This authority does not support Siemens in its attempt here to survive summary judgment. *See In re Actimmune Mktg. Litig.*, No. C 08-2376 MHP, 2010 WL 3563491, at \*11 (N.D. Cal. Sept. 1, 2010) (granting defendant's motion to dismiss a UCL claim predicated on a violation of the False Claims Act because plaintiff had not alleged how it was injured "as a result of" the conduct). Because Siemens has not pointed to any evidence that would create an issue of fact as to whether it has suffered an injury (and thus has standing), the Court **GRANTS** Quidel's Motion for Summary Judgment on the unfair competition counterclaim.<sup>4</sup>

#### D. <u>Unclean Hands Defense</u>

Siemens claims Quidel's conduct is barred by its unclean hands. Specifically, Siemens argues Quidel engages in false and misleading advertising in a variety of ways: first, because it advertises Thyretain as "TSI-only" when the assay detects both TSI and TBI and "may lead to misdiagnosis." (Answer & CC at 8–9.) Second, Siemens claims that Quidel tells the parties' customers to use the incorrect reimbursement code when using Thyretain so that Quidel may gain more profit. (*Id.* at 9.) Third, Siemens claims Quidel advertises Thyretain as an assay that provides

<sup>&</sup>lt;sup>4</sup> Because the Court grants the Motion for Summary Judgment as to the three counterclaims, it does not address Quidel's argument that the claims are partially barred by statutes of limitations.

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results within three to four hours but the true time for results is eighteen to twenty-one hours. (*Id.*)

There is no dispute that "[u]nclean hands is a defense to a Lanham Act infringement suit." *Fuddruckers, Inc. v. Doc's B.R. Others, Inc.*, 826 F.2d 837, 847 (9th Cir. 1987) (citations omitted). To prevail, "the defendant must demonstrate that the plaintiff's conduct is inequitable and that the conduct relates to the subject matter of its claims." *Id.* (citation omitted).

#### 1. Siemens' Harm

First, Quidel argues it is entitled to summary judgment on this affirmative defense because Siemens has no evidence that it was harmed as a result of Quidel's conduct. (Mot. at 20.) Siemens disagrees that such evidence is necessary for an unclean hands defense. Both parties cite cases in their favor. See Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd., 518 F. Supp. 2d 1197, 1222–23 (C.D. Cal. 2007) ("To establish unclean hands, a defendant must demonstrate (1) inequitable conduct by the plaintiff; (2) that the plaintiff's conduct directly relates to the claim which it has asserted against the defendant; and (3) plaintiff's conduct injured the defendant."); contra Intamin, Ltd. v. Magnetar Techs. Corp., 623 F. Supp. 2d 1055, 1075 (C.D. Cal. 2009) (holding it is inconsistent with controlling Supreme Court, Federal Circuit and Ninth Circuit authority to require the defendant to "additionally demonstrate that it was injured or prejudice by [plaintiff's] conduct" to establish unclean hands"). The Court agrees with *Intamin* that there is a clear two-part test for unclean hands, and a third requirement of harm has not been definitively established. See TrafficSchool.com v. Edriver Inc., 653 F.3d 820, 833 (9th Cir. 2011) (applying two-part test); Fuddruckers, 826 F.2d at 847 (same). Therefore, the Court declines to issue summary judgment on this ground. The Court now turns to the specific allegations behind the unclean hand defense.

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### 2. Quidel's Allegedly False Advertising of Thyretain as TSI Only

In its prior summary judgment motion, Siemens argued that the Court should grant summary judgement in its favor due to Quidel's unclean hands, specifically with respect to its allegedly false advertising of Thyretain as a TSI only assay. The Court found there to be "evidence on both sides of the argument" as to whether it is "literally false" for Quidel to call Thyretain a TSI only assay. (ECF No. 254, at 19.) "Given this dispute of material fact, the Court cannot determine at this stage whether Plaintiff's advertising is false; therefore, the Court cannot determine whether Plaintiff has unclean hands due to its advertising of Thyretain as a 'TSI only assay." (*Id.*) The same holding applies here, and the Court **DENIES** summary judgment for this specific unclean hands allegation.

### 3. Quidel's Allegedly False Advertising of Thyretain's Reimbursement Code

Siemens alleges that Quidel advises customers that they may submit claims to Medicare for the use of Thyretain under the Current Procedural Terminology ("CPT") code 84445. Siemens alleges that because Thyretain is a "qualitative" assay, it is not entitled to the higher reimbursement under code 84445, which is available for only "quantitative" assays. (Answer & CC at 8–9.) The Court also previously analyzed this claim. It recognized that the unclean hands defense is not designed so a party may bring up "misconduct in the abstract, unrelated to the claim to which it is asserted as a defense." *Republic Molding Corp. v. B.W. Photo Utils.*, 319 F.2d 347, 349 (9th Cir. 1963). "Because the Court grants judgment as to Plaintiff's claims regarding the laboratories in this Order, Defendants' unclean hands claim no longer is related to the claims at issue. Defendants claim Plaintiff told laboratories to use the wrong billing code, and thus profited more than it should have. This defense is not sufficiently related to what is left of Plaintiff's case after this Order." (ECF No. 254, at 20.) As noted above, whether physicians were deceived

by Siemens' advertising is still an issue in this case. Siemens now argues that Quidel also misled physicians because it "blanketed laboratories and physician offices with letters claiming that the 'Thyretain test is available from most national reference labs by ordering CPT code 84445." (Opp'n at 7.) Siemens points to many documents, one being a pamphlet answering frequently asked questions about Thyretain. (Exhibit 30 to Haas Decl., ECF No. 273-3, at 93.) The pamphlet notes that the CPT code for Thyretain is 84445. (*Id.*) Another document, entitled "Important Graves' Disease Facts" also provides information about Thyretain, and similarly states that one may order Thyretain from a lab by using CPT code 84445. (Exhibit 27 to Haas Decl., ECF No. 273-3, at 2.) Quidel does not directly respond to the allegation regarding the CPT code or explain why 84445 is the correct code for Thyretain.

The Court first finds that Siemens' claim that Quidel is using an incorrect reimbursement code is related to claims that Quidel asserts. *Fuddruckers, Inc.*, 826 F.2d at 847 (holding for the unclean hands affirmative defense, "the defendant must demonstrate that the plaintiff's conduct is inequitable and that the conduct relates to the subject matter of its claims"). Quidel asserts that Siemens' marketing of IMMULITE "as detecting TSI only may lead to reimbursement that should be reserved for TSI only assays because true TSI only assays are reimbursed at higher rates than assays that cannot differentiate between" TSI and TBI. (First Amended Complaint, "FAC," ECF No. 12 ¶ 18.) And the Court has already determined that there is an issue of material fact as to whether physicians are in the relevant market. (ECF No. 254, at 16.) Therefore, whether Quidel misled physicians by advertising that CPT code 8445 is appropriate for Thyretain is a question of fact. Whether Quidel has unclean hands due to its advertising of this code is also a question of fact, and the Court **DENIES** the Motion for Summary Judgment as to this unclean hands allegation.

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#### 4. Quidel's Allegedly False Advertising of Thyretain As Producing Results in Three to Four Hours

Siemens alleges Quidel incorrectly advertises Thyretain as producing results in three to four hours. (Answer & CC at 10.) Quidel argues this claim is now irrelevant because it only relates to the claims regarding the laboratories (which have been dismissed). (Mot. at 21 ("It is the laboratories that run the test and would be concerned about run time.").) Siemens responds that this claim remains viable because Quidel "advanced the same wrongful reimbursement statements to physicians that it made to laboratories." (Opp'n at 24.) Siemens produced a screenshot from Quidel's website that provides information about Thyretain. (Exhibit 43 to Haas Decl., ECF No. 273-3, at 266.) The website states, "Thyretain specifically detects TSI in a user-friendly format. . . . Results in 3 to 4 hours assures a quick turnaround time in the lab." (*Id.*) The Court agrees that because this statement was on Quidel's website and widely available, it is possible that physicians were exposed to the information and Siemens' claim is thus relevant.

Dr. Lollar testified that to get the results for Thyretain, first the cells grow for fifteen to eighteen hours, then one "add[s] the serum and controls, and allow[s] it to react" for three hours. (Exhibit 5 to Haas Decl., ECF No. 273-2, at 128:16–24.) He clarifies that "after you add the specimen[,]" results are available in three hours, but the full, overall time is eighteen to twenty-one hours. (*Id.* at 121:1–19; 178:23–179:25.) Dr. Maio testified to the same. (Exhibit 17 to Haas Decl., ECF No. 273-2, at 108:11–109:10 (testifying that the assay takes about twenty-one hours "if you count the cell seeding" overnight).

And indeed, Quidel does not disagree that the cells must be cultured overnight. The Court finds that given this evidence, there is a question of 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. Doctors and laboratories who will be recommending or using the assay would want the full picture and know

the amount of work that must take place before Thyretain produces results. The Court **DENIES** Quidel's Motion for Summary Judgment as it relates to this assertion of unclean hands by Siemens.

#### IV. **CONCLUSION**

For the foregoing reasons, the Court GRANTS IN PART and DENIES IN PART Quidel's Motion for Summary Judgment. Specifically, the Court grants the Motion for Summary Judgment as to the three affirmative defenses. The Court grants in part the Motion for Summary Judgment as to the unclean hands counterclaim, as detailed above.

Subject to the Order of the Chief Judge No. 18, *In re Suspension of Jury Trials* and Other Proceedings During the Covid-19 Public Emergency (S.D. Cal. Mar. 17, 2020), the Court orders the parties to contact the Magistrate Judge's chambers to reset their mandatory settlement conference. Upon conclusion of this conference, the parties shall coordinate with the Magistrate Judge to set new dates for a pretrial conference and trial.

IT IS SO ORDERED.

DATED: April 9, 2020

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