UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

QUIDEL CORPORATION, a Delaware corporation, Plaintiff, v. SIEMENS MEDICAL SOLUTIONS USA, INC., a Delaware corporation, SIEMENS HEALTHCARE DIAGNOSTICS, INC. a California corporation, and DOES 1-50 INCLUSIVE, Defendants.	Case No.: 16-cv-3059-BTM-AGS **ORDER DENYING DEFENDANTS' MOTION TO DISMISS** **[ECF No. 14]**

Defendants Siemens Medical Solutions USA, Inc. and Siemens Healthcare Diagnostics Inc. ("Defendants") have filed a motion to dismiss Plaintiff Quidel Corporation's First Amended Complaint. For the reasons discussed below, the Court denies Defendants' motion.

I. BACKGROUND

Plaintiff is a Delaware Corporation with its principal place of business in San Diego, California. (ECF No. 12 ("FAC") ¶ 2). Plaintiff is a "diagnostic healthcare manufacturer" that "developed, promotes and sells the Thyretain TSI Reporter

BioAssay ("Thyretain")," which is "intended for the qualitative detection in serum of thyroid-stimulating immunoglobins ("TSI")." *Id.* ¶¶ 12, 13. The detection of TSI may be "useful as an aid in the differential diagnosis of patients with Graves' disease." *Id.* ¶ 13. According to Plaintiff, Thyretain "is the only commercially available assay that detects TSI only, as opposed to those that fail to differentiate between thyroid-stimulating and thyroid-blocking immunoglobins [("TBI")]," commonly known as "TRAb" assays. *Id.*

Defendant Siemens Medical Solutions USA, Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. *Id.* ¶ 3. Defendant Siemens Healthcare Diagnostics, Inc. is a California corporation with its principal place of business in Tarrytown, New York. *Id*. ¶ 4. Plaintiff alleges that each defendant, including unknown defendants DOES 1 through 50, was "responsible in some manner" for the below events and acted as the "agents, servants, and/or employees" of the Defendants. *Id*. ¶¶ 6,7.

Defendants "developed, promote[ ], and sell[ ]" the IMMULITE 2000/2000 XPi TSI assay ("IMMULITE"), which is intended to compete with Thyretain. *Id*. ¶ 14. On March 3, 2016, Defendants obtained clearance from the Federal Drug Administration ("FDA") to market IMMULITE, with the device receiving a "substantial equivalence" finding through the Section 510(k) premarket notification process. *Id.*

Pointing to the results of seven scientific studies, Plaintiff alleges that IMMULITE detects both TSI and TBI, and therefore "compares similarly to other TRAb assays, detecting but not differentiating between stimulating and blocking antibodies." *Id.* ¶ 16. According to Plaintiff, one study concluded that its testing of IMMULITE "[did] not provide full evidence that this assay [was] specific for S-TRAb only, and future studies . . . [were] required." *Id.* Another study found that while IMMULITE was "about as sensitive and consistent as the Thyretain bioassay," it did not "consistently distinguish[ ] between stimulating and blocking activities in 20

selected cases of hypothyroid Hashimoto's thyroiditis." *Id.*

Plaintiff therefore alleges that the following statements from Defendants' IMMULITE marketing materials are false or misleading because they explicitly state or imply that IMMULITE detects TSI only:

A. From Defendants' October 8, 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." *Id.* ¶ 15.

B. From Defendants' website in May 2016: "The IMMULITE 2000/2000 XPi TSI assay detects only thyroid stimulating antibodies." *Id.*

C. From Defendants' April 8, 2016 press release: "Unlike other currently available diagnostic tests, the IMMULITE 2000/2000 XPi TSI assay detects the presence of thyroid stimulating antibodies only, making the differential diagnosis of GD faster and more accurate." *Id.*

D. From Defendants' product label on August 17, 2015: "TSHR autoantibody (TRAb) assays do not distinguish between TSI and TBI. The IMMULITE 2000 TSI assay utilizes recombinant human TSH receptors (hTSHR) for the specific detection of thyroid stimulating autoantibodies." *Id.*

E. From IMMULITE's current product description on Defendants' website: "The IMMULITE® 2000/2000 XPi TSI assay is the first automated and semiquantitative TSI assay available today. TSH receptor antibody (TRAb) assays detect both thyroid-blocking and -stimulating antibodies. However, blocking antibodies inhibit TSH stimulation of thyroid cells and lead to hypothyroidism. The IMMULITE 2000/2000 XPi TSI assay detects thyroid stimulating antibodies, the specific cause of GD pathology, with 98.5% specificity." *Id.* ¶ 20.

When Plaintiff raised its concerns about Defendants' marketing of IMMULITE

as a TSI only assay, Defendants agreed to remove the term "only" from its marketing statements. *Id.* ¶ 20. However Plaintiff alleges that these "prior marketing statements and press releases are still readily available on the internet and that [Defendants have] done nothing proactive to correct the prior false and misleading statements that the IMMULITE Assay detects TSI only." *Id.* In addition, Plaintiff alleges that Defendants' current product description of IMMULITE still implies that it is TSI only and misleadingly omits that IMMULITE "is substantially similar to TRAb assays that fail to differentiate between stimulating and blocking antibodies." *Id.* ¶¶ 20, 24.

Plaintiff further alleges that IMMULITE costs less and works faster than Thyretain. *Id.* ¶ 21. Therefore, according to Plaintiff, Defendants' false and misleading statements about IMMULITE are causing confusion in the marketplace and creating an incentive for customers to choose IMMULITE over Thyretain. *Id.* Plaintiff alleges that at least one reference laboratory in Texas has switched from Thyretain to IMMULITE, damaging Plaintiff in the amount of $250,000 a year. *Id.* ¶ 22. Finally, according to Plaintiff, as a response to Defendants' marketing, it has "spent significant resources sending individuals to laboratories and other customers in an effort to educate them on the significant differences between Thyretain and the IMMULITE Assay." *Id.*

Plaintiff brings the following causes of action against Defendants: (1) false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a); (2) unfair competition and false advertising in violation of Cal. Bus. & Prof. Code §§ 17200 and 17500; and (3) intentional interference with prospective economic advantage. *Id.* ¶¶ 27, 34, 37.

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II. STANDARD

A. Rule 12(b)(6)

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) should be granted only where a plaintiff's complaint lacks a "cognizable legal theory" or sufficient facts to support a legal claim. *Balistreri v. Pacifica Police Dept.*, 901 F.2d 696, 699 (9th Cir. 1988). When reviewing a motion to dismiss, the allegations of material fact in plaintiff's complaint are taken as true and construed in the light most favorable to the plaintiff. *Parks Sch. of Bus., Inc. v. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995). Although detailed factual allegations are not required, factual allegations "must be enough to raise a right to relief above the speculative level." *Bell Atlantic v. Twombly*, 550 U.S. 544, 555 (2007). "A plaintiff's obligation to prove the 'grounds' of his 'entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not show[n] that the pleader is entitled to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009) (internal quotation marks omitted). Only a complaint that states a plausible claim for relief will survive a motion to dismiss. *Id.*

B. Rule 9(b)

Under Federal Rule of Civil Procedure 9(b), a plaintiff "must state with particularity the circumstances constituting fraud or mistake." A plaintiff alleging fraud "must state the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations." *Alan Neuman Prods., Inc. v. Albright*, 862 F.2d 1388, 1392–93 (9th Cir. 1988) (quoting *Schreiber Distrib. Co. v. Serv-Well Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986)).

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III. DISCUSSION

A. Sufficiency of the Pleadings[1]

1. Lanham Act Claim

Plaintiff alleges that Defendants have violated Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1). Section 43(a) of the Lanham Act "allows one competitor to sue another if it alleges unfair competition arising from false or misleading product descriptions." *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2233 (2014). To establish a false advertising claim under the Lanham Act, a plaintiff must allege: "(1) a false statement of fact by the defendant in a commercial advertisement about its own or another's product; (2) the statement 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).

Defendants argue that Plaintiff has failed to adequately allege the elements of falsity and materiality and therefore its First Amended Complaint should be dismissed under Fed. R. Civ. P. 12(b)(6) for failure to state a claim. [2]

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[1] The parties dispute whether all or part of the Declaration of Erik Haas in Support of Defendants' Motion to Dismiss Plaintiff's First Amended Complaint should be judicially noticed. (ECF No. 14-2). The Court does not rely on the Declaration and therefore makes no decision on this issue.

[2] Defendants also contend that Defendant Siemens Medical Solutions USA, Inc ("SMS") did not develop, market, or sell IMMULITE in this forum and therefore should be dismissed from this action. Plaintiff alleges Defendant SMS was "responsible in some manner" for the alleged events and at all times acted as the "agent[ ], servant[ ], and/or employee[ ]" of the Defendants. FAC ¶¶ 6, 7. "In ruling on a 12(b)(6) motion, a court may generally consider only allegations contained in the pleadings, exhibits attached to the complaint, and matters properly subject to judicial notice." *Swartz v. KPMG LLP*, 476 F.3d 756, 763 (9th Cir. 2007). The Court therefore declines, at the pleading stage, to dismiss Defendant SMS.

a. Falsity

"To demonstrate falsity within the meaning of the Lanham Act, a plaintiff may show that the statement was literally false, either on its face or by necessary implication, or that the statement was literally true but likely to mislead or confuse consumers." *Id.* at 1139. Plaintiff alleges that "Defendants' conduct was undertaken willfully and with the intention of causing confusion, mistake, or deception." FAC ¶ 31. Accordingly, Defendants argue that Plaintiff's complaint must meet the heightened pleading standards of Fed. R. Civ. P. 9(b).[3] It does. Plaintiff identifies at least five statements in Defendants' marketing materials that it alleges to be either false or misleading. FAC ¶¶ 15, 20. Plaintiff attributes all the statements to Defendants and provides the date, location, and specific content of each statement. *Id.* Plaintiff explains that each statement is false or misleading because it either explicitly states or implies that IMMULITE is a TSI only assay and omits that IMMULITE "is substantially similar to TRAb assays that fail to differentiate between stimulating and blocking antibodies." *Id.* ¶¶ 15, 24. These allegations satisfy Rule 9(b)'s requirement that a plaintiff alleging fraud "must state the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations." *See Alan Neuman Prods., Inc. v. Albright*, 862 F.2d 1388, 1392–93 (9th Cir. 1988). [4]

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[3] Lower federal courts have applied this heightened pleading standard to claims under the Lanham Act that are grounded in fraud. *See Seoul Laser Dieboard Sys. Co. v. Serviform, S.R.L.*, 957 F. Supp. 2d 1189, 1200 (S.D. Cal. 2013); *see also EcoDisc Tech. AG v. DVD Format/Logo Licensing Corp.*, 711 F. Supp. 2d 1074, 1085 (C.D. Cal. 2010).

[4] Defendants also argue that Plaintiff cannot demonstrate falsity because the name of Defendants' assay as well as the sensitivity and specificity numbers are unambiguously true. However the product name and performance numbers are not themselves disputed in Plaintiff's complaint. Rather, Plaintiff contends that a number of statements made in Defendants' marketing materials, which may include that information, are false or misleading. *See* FAC ¶ 15.

b. Materiality

Under the Lanham Act, a false advertisement's deception is "material" if "it is likely to influence the purchasing decision" of the advertisement's audience. *Southland*, 108 F.3d at 1139. According to Plaintiff, Defendants' advertising deception involves explicitly stating or implying that IMMULITE is a TSI only assay and omitting that IMMULITE "is substantially similar to TRAb assays that fail to differentiate between stimulating and blocking antibodies." FAC ¶ 24. Plaintiff contends this deception "concerns the inherent quality, characteristics and efficacy of [IMMULITE] and is likely to influence the purchasing decisions of Defendants' customers." *Id.* ¶ 25. According to Plaintiff, IMMULITE is less expensive and faster than Thyretain. *Id.* ¶ 21. If Defendants advertise that IMMULITE operates in the same manner as Thyretain (by only detecting TSI), but works faster and is less expensive, it is reasonable to infer that this would influence customers' purchasing decisions.[5] Plaintiff has adequately alleged materiality and has stated a plausible claim for relief under the Lanham Act.

2. State Law False Advertising and Unfair Competition Claims

Plaintiff's claims under Cal. Bus. & Prof. Code §§ 17200 and 17500 are based on the same allegations set forth in its Lanham Act claim. FAC ¶ 32. The Court finds these claims to be sufficiently pled for the same reasons above. *See Cleary v. News Corp.*, 30 F.3d 1255, 1262–63 (9th Cir. 1994) (the Court of Appeal "has consistently held that state common law claims of unfair competition and actions pursuant to California Business and Professions Code § 17200 are 'substantially congruent' to claims made under the Lanham Act"); *Kasky v. Nike,*

[5] Defendants also contend that Plaintiff has inadequately pled materiality because the laboratories that purchase assays are sophisticated parties and are required to independently verify an assay's performance data, citing *Cty. of Santa Clara v. GSK (In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.)*, 2011 U.S. Dist. LEXIS 124458, at *14 (E.D. Pa. Oct. 26, 2011). However that case's reference to sophisticated parties was with regard to reliance, which is not a necessary component of Lanham Act materiality. *See Southland*, 108 F.3d at 1139 (under the Lanham Act, a false advertisement's deception is "material" if "it is likely to influence the purchasing decision" of the advertisement's audience).

Inc., 27 Cal. 4th 939, 951 (2002) ("to state a claim under [§ 17500], based on false advertising or promotional practices, it is necessary only to show that members of the public are likely to be deceived").

3. Intentional Interference With Prospective Economic Advantage Claim

Plaintiff's intentional interference with prospective economic advantage claim is also based on the same allegations set forth in its Lanham Act claim. FAC ¶ 36. Defendants contend that this claim fails because Plaintiff cannot allege that Defendants engaged in any independent wrongful conduct. *See Della Penna v. Toyota Motor Sales, U.S.A., Inc.*, 11 Cal. 4th 376, 393 (1995) (defendant's conduct must be "wrongful by some legal measure other than the fact of interference itself"). Defendants premise this argument on the assumption that Plaintiff's Lanham Act and state law false advertising and unfair competition claims are deficient. Because these claims remain, Plaintiff has alleged independent "wrongful" conduct for the basis of its intentional interference with prospective economic advantage claim.

B. Preclusion of Lanham Act Claim

Defendants next argue that Plaintiff's Lanham Act claim is precluded because the FDA pre-approved Defendants' product name and performance data and, under 21 C.F.R. § 809.10(a), required Defendants to include that information on the IMMULITE label and packaging insert. Defendants further contend that, in accordance with 21 C.F.R. § 807.81(a)(3), they cannot change IMMULITE's name or alter its specificity and sensitivity data without prior FDA approval.

IMMULITE is a Class II device under the Food, Drug, and Cosmetic Act ("FDCA"). A "manufacturer of a Class II device need only submit a premarket notification to the FDA, in accordance with the . . . 510(k) process. Under the 510(k) process, if the Class II device is deemed substantially equivalent to a pre-existing device with prior clearance, it can be marketed without further regulatory analysis.

FDA regulations provide that a manufacturer who has successfully navigated the 510(k) process for a device must make a new 510(k) submission [in according with 21 C.F.R. § 807.81(a)(3)] whenever the device is about to be significantly changed or modified in design, components, method of manufacture, or intended use." *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 925 (9th Cir. 2010) (internal citations omitted).

"[N]either the Lanham Act nor the FDCA, in express terms, forbids or limits Lanham Act claims challenging labels that are regulated by the FDCA." *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2237 (2014). "The Lanham Act and the FDCA complement each other in major respects, for each has its own scope and purpose . . . the Lanham Act protects commercial interests against unfair competition, while the FDCA protects public health and safety." *Id.* at 2238. However, in *Photomedex*, the Court of Appeals explained that in some circumstances, "a private action brought under the Lanham Act may not be pursued when . . . the claim would require litigation of [an] alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was a violation." *Id.* at 924. In those circumstances, proceeding "would intrude on the exclusive government enforcement authority established under the FDCA." *Id.* at 925.

In *Photomedex*, the defendants marketed a device as "FDA Approved" that did not go through its own separate 510(k) clearance process but rather was derived from a predecessor device that was granted 510(k) clearance. *Id.* at 922-23. At issue was whether the subsequent device was significantly different enough from its predecessor to trigger 21 C.F.R. § 807.81(a)(3) such that the defendants should have submitted a separate 510(k) premarket notification before advertising the device as "FDA Approved." *Id.* at 926. The plaintiff contended the devices were significantly different and complained to the FDA that the defendants were marketing the device without clearance, in violation of the FDCA. *Id.* at 930.

However the FDA never took any action and ultimately approved the defendants' device when the defendants later filed a separate 510(k) premarket notification. *Id.* at 927.

The plaintiff alleged in its Lanham Act claim that for the period before the defendants submitted a separate 510(k) premarket notification for the subsequent device, their advertisement of the device as "FDA Approved" was false and misleading. *Id.* at 927-28. Determining whether this statement was false or misleading would have required the court to resolve whether the defendants had violated the FDCA for not initially submitting a 510(k) notification for the subsequent device. *See id.* at 930. The Court of Appeals explained that preclusion of the plaintiff's Lanham Act claim was warranted in that particular circumstance because the plaintiff was "not permitted to circumvent the FDA's exclusive enforcement authority by seeking to prove that [d]efendants violated the FDCA, when the FDA did not reach that conclusion." *Id.* at 928.

No such circumvention is at issue here. Relying on *Photomedex*, Defendants contend that they cannot the change the name of IMMULITE or alter its specificity and sensitivity data without prior FDA approval. However the product name and performance data are not disputed, rather Plaintiff contends that Defendants' marketing statements are false or misleading. FAC ¶ 15. Therefore, the Court need not inquire into whether the FDA properly approved the product name and performance data during the 510(k) process for IMMULITE. The Court simply needs to conduct a limited inquiry into whether Defendants' marketing statements that describe IMMULITE as a TSI only assay and omit that IMMULITE "is substantially similar to TRAb assays that fail to differentiate between stimulating and blocking antibodies" are literally false or likely to mislead and confuse customers. Accordingly this inquiry does not intrude upon the "FDA's exclusive enforcement authority." *See PhotoMedex*, 601 F.3d at 928; *Church & Dwight Co. Inc. v. SPD Swiss Precision Diagnostics, GmbH*, 104

F. Supp. 3d 348, 361-62 (S.D.N.Y. 2015) ("[a] mere finding that a medical device is falsely advertised does not necessarily proscribe use of a device that the FDA has pre-approved or labeling that the FDA has required. . . . [T]here may be any number of ways to advertise the product that do not mislead consumers and comply with FDA requirements"). Preclusion of Plaintiff's Lanham Act claim is not warranted.

C. Preemption of State Law Claims

Defendants also contend that Plaintiff's claims under Cal. Bus. & Prof. Code §§ 17200 and 17500 are preempted. Relying on *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), Defendants argue that the state law claims, if successful, would force Defendants to change the name of their assay and alter its performance data, which they cannot do without prior FDA approval.

At issue in *PLIVA* were state tort law claims against generic drug manufacturers for failing to provide adequate warning labels. *Id*. at 610. The state tort laws required "a drug manufacturer that is or should be aware of its product's danger to label that product in a way that renders it reasonably safe." *Id.* at 611. This placed a duty on drug manufacturers of a generic drug "to use a different, stronger label" than they actually used and were required to use under federal law. *Id.* at 617. "Federal drug regulations, as interpreted by the FDA, prevented [manufacturers] from independently changing their generic drugs' safety labels" because labels of generic drugs need to match the labels of their corresponding brand-name drugs. *Id.* at 13,17. Therefore, in order for the defendants to change the label of their generic drug, "federal law . . . required [them] to ask for FDA assistance in convincing the brand-name manufacturer to adopt a stronger label, so that all corresponding generic drug manufacturers could do so as well." *Id.* at 17. In holding that the state tort laws were preempted, the Court found "impossibility," explaining that "[i]t was not lawful under federal law for the [m]anufacturers to do what state law required of them. And even if they had fulfilled

their federal duty to ask for FDA assistance, they would not have satisfied the requirements of state law." *Id.* at 618. The key inquiry for "impossibility" was "whether the private party could independently do under federal law what state law require[d] of it" and "finding no pre-emption where the defendant could 'unilaterally' do what state law required." *Id.* at 620.

Impossibility is not the case here. Contrary to Defendants' characterization of Plaintiff's complaint, Plaintiff is not disputing IMMULITE's name or performance data. Rather Plaintiff is asserting that Defendants marketing materials are false or misleading because they explicitly state that IMMULITE is a TSI only assay or imply so by omitting that IMMULITE "is substantially similar to TRAb assays that fail to differentiate between stimulating and blocking antibodies." FAC ¶¶ 15, 24. If Defendants' marketing statements are found to be false or misleading under state law, Defendants could "unilaterally" correct those statements without violating FDA mandates. *See PLIVA*, 564 U.S. at 620. Removing the phrase "TSI only" from Defendants' marketing materials or adding a disclaimer that IMMULITE does not differentiate between stimulating and blocking antibodies does not reasonably lead to Defendants being forced to change their assay's name or performance data such that Defendants would first need FDA approval. Plaintiff's state law claims for false advertising and unfair competition are not preempted.

IV. CONCLUSION AND ORDER

For the foregoing reasons, the Court DENIES Defendants' motion to dismiss Plaintiff's First Amended Complaint.

IT IS SO ORDERED.

Dated: October 16, 2017

Barry Ted Moskowitz, Chief Judge
United States District Court