UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

CRITICAL CARE DIAGNOSTICS, INC., dba CRITICAL CARE DIAGNOSTICS, Plaintiff, v. AMERICAN ASSOCIATION FOR CLINICAL CHEMISTRY, INC., *et al.*, Defendants.	Civil No. 13cv1308 L (MDD) **ORDER GRANTING RAFAI'S MOTION TO STRIKE [doc. #30] and GRANTING AACC'S AMENDED MOTION TO STRIKE [doc. #37]**

Defendants Nader Rifai ("Rifai"), and American Association for Clinical Chemistry, Inc. ("AACC") each move to strike plaintiff's complaint under California Code of Civil Procedure § 425.16, known as the Anti-SLAPP[1] statute. The motions have been fully briefed and are considered without oral argument.

A. BACKGROUND

This action concerns a peer-reviewed scientific research article concerning heart disease entitled "Soluble ST2 Is Associated with All-Cause and Cardiovascular Mortality in a Population-Based Cohert: The Dallas Heart Study" ("the Article"). The Article was published by the American Association for Clinical Chemistry ("AACC") in its peer-reviewed scientific

[1] "SLAPP" stands for Strategic Lawsuit Against Public Participation.

journal, CLINICAL CHEMISTRY ("Journal"), which reported on the defendant authors' research regarding ST2 in asymptomatic patients. The article was published on AACC's website in December 2012, and in its March 2013 print edition. The AACC is an international scientific/medical society of clinical laboratory professionals, physicians, research scientists and other individuals involved with clinical chemistry and related disciplines. Defendant Nader Rifai, Ph.D., is the Editor-in-Chief of CLINICAL CHEMISTRY ("Journal"). As a peer-reviewed journal, independent professionals, namely scientists and scholars, review the journal's articles and research prior to publication. Comp., ¶ 16. Defendants Lu Q. Chen, James A. De Lemos, Sandeep R. Das, Colby R. Ayers and Anand Rohatgi ("Author Defendants")[2] are the credited authors of the Article. Comp., ¶¶ 4-8.

Plaintiff Critical Care Diagnostics, Inc. is a biomarker[3] company that focuses on cardiovascular diseases. It holds patent rights to an assay, Presage ® ST2 Assay, which the FDA approved for application to patients already diagnosed with and experiencing existing heart problems. ST2 can be a significant predictor of mortality due to cardiovascular disease in such a population. The Article at issue purports to describe one such test to measure ST2 – the Alere ST2 assay, and not the Presage ® ST2 Assay. However, the Article is not an evaluation of commercially available assays, approved FDA assays, or plaintiff or plaintiff's product. Instead, the Article focuses on ST2 research using an assay other than plaintiff's assay to be applied to the general asymptomatic population. The Alere ST2 assay is not FDA approved at this time.

The Journal has a regular policy and procedure for the review of articles it publishes. As Editor-in-Chief, defendant Rifai, reviews manuscripts for subject matter only. Then an associate editor reviews the manuscript and assigns it to two peer reviewers. After further review by the Deputy Editor, James C. Boyd, M.D., a manuscript is accepted for publication. Dr. Boyd's

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[2] The Author defendants have filed a motion to dismiss for lack of personal jurisdiction and for failure to state a claim. They have also filed a motion to strike under Texas Civil Practice & Remedies Code § 27.001. [doc. #38] These motions will be addressed in a subsequent Order.

[3] "Biomarker" refers to a biologic feature that can be used to measure the presence or progress of disease or the effects of treatment.

approval is the final approval required for publication.

Plaintiff contends that the Article contains false statements that were known to Rifai and the AACC publisher defendant because of prior studies and articles. Specifically, plaintiff points to what it alleges are three factually untrue statements:

– The Article states "to our knowledge, no prior study has evaluated sST2 as a cardiac biomarker in the general population." (Article at 537.) Plaintiff contend that a proper literature search would have revealed that two prior articles had performed such an evaluation.

– The Article states that plaintiff's Presage Assay was less sensitive at detecting ST2 than the Alere assay which was used in the study. (Article at 537.) Plaintiff asserts that the Presage Assay measures ST2 in 100% of the population and therefore, is more sensitive than the Alere assay.

– The Article states that "[t]he development of more sensitive assays is needed to fully explore the potential role of this biomarker for population screening." (Article at 544.) Plaintiff states that the "Presage Assay <u>was</u> a 'more sensitive assay' which had already been developed and utilized in exploring the potential role of the sST2 biomarker. (Opp. at 7-8. (emphasis in original.))

According to plaintiff, defendants "deliberately chose to make false statements which cast the Preage Assay in a negative light." *Id.* at 9. Also, plaintiff asserts that the publisher defendant allowed the author defendants to misstate their financial relationship with Alere.

Finally, plaintiff contends that after the print publication of the Article, it suffered at least one specific lost distribution deal with the SMS Gruppen Danmark company in Denmark, which was to be the Danish distributor of the Presage Assay. (Geliebter Decl. ¶8.)

B. LEGAL STANDARD

California Civil Procedure Code §425.16 was enacted "to provide for the early dismissal of unmeritorious claims filed to interfere with the valid exercise of the constitutional rights of freedom of speech and petition for the redress of grievances." *Club Members for an Honest Election v. Sierra Club*, 45 Cal.4th 309, 315 (2008). Section 425.16 thus allows a court to strike any cause of action that arises from the defendant's exercise of his or her constitutionally

protected free speech rights or petition for redress of grievances. §425.16 (b)(1); *see also Flatley v. Mauro*, 39 Cal.4th 299, 311–312 (2006). In ruling on a special motion to strike brought under § 425.16, the trial court must engage in a two-step process that involves shifting burdens. First, the court must determine whether defendant has made a threshold showing that the challenged cause of action "arises from" a protected activity. Second, if the defendant makes this showing, the trial court must determine whether the plaintiff has established a probability of prevailing on the claim. *Jarrow Formulas, Inc. v. LaMarche*, 31 Cal.4th 728, 733 (2003). "'Reasonable probability' in the anti-SLAPP statute has a specialized meaning" and "requires only a 'minimum level of legal sufficiency and triability.'" *Mindys Cosmetics, Inc. v. Dakar*, 611 F.3d 590, 598 (9th Cir. 2010) (quoting *Linder v. Thrifty Oil Co.*, 23 Cal.4th 429, 438 n. 5 (2000)). In order to satisfy this burden, the plaintiff "must demonstrate that the complaint is both legally sufficient and supported by a sufficient prima facie showing of facts to sustain a favorable judgment if the evidence submitted by the plaintiff is credited." *Wilson v. Parker, Covert & Chidester*, 28 Cal.4th 811, 821(2002); *see also Metabolife Int'l, Inc. v. Wornick*, 264 F.3d 832, 840 (9th Cir. 2001). "'The plaintiff's showing of facts must consist of evidence that would be admissible at trial.'" *Stewart v. Rolling Stone LLC,* 181 Cal. App.4th 664, 679 (2010). "[D]eclarations that lack foundation or personal knowledge, or that are argumentative, speculative, impermissible opinion, hearsay, or conclusory are to be disregarded." *Gilbert v. Sykes*,147 Cal. App.4th 13, 26 (2007).

Each challenged basis for liability must be examined individually to determine if the plaintiff has demonstrated a probability of prevailing, and if the plaintiff has failed to do so, then only that basis must be stricken from the plaintiff's pleading. *Navellier v. Sletten*, 29 Cal.4th 82, 89 (2002).

C. DISCUSSION

As noted above, both Dr. Rafai and the AACC move to strike plaintiff's entire complaint under the anti-SLAPP statute. Plaintiff has included causes of action for libel per se, libel per quod, trade libel, and violation of California Business & Professions Code §17200, *et seq*.

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1. Arising from Protected Activity

Section 425.16(e) specifies the four categories of protected speech or petitioning activity. Relevant in this action are categories 3 and 4:

> (e) As used in this section, "act in furtherance of a person's right of petition or free speech under the United States or California Constitution in connection with a public issue" includes: . . .
>
> (3) any written or oral statement or writing made in a place open to the public or a public forum in connection with an issue of public interest, or (4) any other conduct in furtherance of the exercise of the constitutional right of petition or the constitutional right of free speech in connection with a public issue or an issue of public interest.

a. Public Forum

In order for defendants to fall within 425.16(e)(3), they must demonstrate that the written statements found in the Article were made in a "place open to the public or a public forum." California case law repeatedly notes that the "public forum" term in the statue is entitled to a broad reading. *See Nygard*, 159 Cal. App.4th at 1038, citing *Damon v. Ocean Hills Journalism Club*, 85 Cal. App. 4th 468, 476-77 (2000).

The Article was made available to the public on the AACC's website. Plaintiff's suggestion that interactivity is required for a public forum is not supported by case law. Instead, the California Supreme Court has held that "public access, not the right to public comment, is the hallmark of a public forum." *Nygard, Inc. v. Uusi-Kerttula*, 159 Cal. App.4th 1027, 1039 (2008) citing *Barrett v. Resenthal*, 40 Cal.4th 33, 41 fn.4 (2006). "The Internet is a classic public forum which permits an exchange of views in public about everything . . . ." *Chaker v. Mateo*, 209 Cal. App.4th 1138, 1146 (2012).

Because the Article is available on AACC's website, defendants have met their burden of showing that the publication of the Article was made in a public forum.

b. In Connection with an Issue of Public Interest

Like "public forum", the term "issue of public interest" is construed broadly in the anti-SLAPP context. *Hecimovich v. Encinal School Parent Teacher Organization,* 203 Cal. App.4th 450, 464 (2012). An issue of public interest is "any issue in which the public is interested." *Nygrd*, 159 Cal. App.4th at 1042. The issue does not need to be "significant" to be

covered by the anti-SLAPP statute. *Id.* Statements may be connected to an issue of public interest if they concern a person or entity in the public eye, a topic of widespread public interest, or conduct that could directly affect a large number of people beyond the direct participants. *Rivero v. American Federation of State, County and Municipal Employees, AFL–CIO105*, Cal. App.4th 913, 924 (2003).

Defendants argue that because the Article addresses research findings concerning ST2, which may be a predictor of mortality due to cardiovascular disease in asymptomatic patients, the public interest prong is met. As a result, because heart disease is the leading cause of death for both men and women, the Article is of public interest under either §425.16(e)(3) or (e)(4).

Plaintiff argues, however, that the alleged defamatory statements in the Article did not arise from constitutionally-protected activity. In so arguing, plaintiff contends that the issue must be of concern to a substantial number of people and not just to a relatively small, specific audience. *Weinberg*, 110 Cal. App. 4th at 1132, In other words, plaintiff contends that the Article does not concern a matter of widespread public interest, but instead is of interest to a narrow group of medical or laboratory professionals." (Opp. at 13.) According to plaintiff, because the Article was directed to a limited portion of the public and the Article was not published in the context of any ongoing medical controversy or debate, there can be no constitutionally protected activity. (Opp. at 14.) Plaintiff cites to *DuCharme v. International Broth. of Elec. Workers, Local 45*, 110 Cal. App.4th 107, 119 (2003).

In *DuCharme*, a union posted information on its website that plaintiff had been removed from office for financial mismanagement. The court found that the issue was of interest to only a limited but definable portion of the public:

> in order to satisfy the public issue/issue of public interest requirement of section 425.16, subdivision (e)(3) and (4) of the anti-SLAPP statute, in cases where the issue is not of interest to the public at large, but rather to a limited, but definable portion of the public (a private group, organization, or community), the constitutionally protected activity must, at a minimum, occur in the context of an ongoing controversy, dispute or discussion, such that it warrants protection by a statute that embodies the public policy of encouraging participation in matters of public significance.

Id.

The court highlighted that the posting on the union website merely reported on the fact of DeCharme's termination. As a result, members of the local union "were not being urged to take any position on the matter. . . . To grant protection to mere informational statement, in this context, would in no way further the statute's purpose of encouraging participation in matters of public significance." *Id.* at 118. Thus, because the notification of plaintiff's termination was a "fait accompli", there could be no furthering of participation. *Id.*

The AACC is an "international scientific/medical society of clinical laboratory professionals, physicians, research scientists and other individuals involved with clinical chemistry and related disciplines," with over 8,000 members. (AACC Mtn to Strike, Exh.1.) Although the various published CLINICAL CHEMISTRY articles are available to the general public by way of the AACC website, they are not directed to the general public but to a small, definable portion of the population. The Court finds that § 425.16(e)(4) more readily fits the current situation described in *DuCharme*. Therefore, even if the Article was not of interest to the public at large, it occurred in the context of an ongoing controversy, dispute or discussion that encouraged participation in an issue of public significance, *i.e.*, the use of an ST2 biomarker for screening cardiovascular disease in asymptomatic people.

Plaintiff points to some articles that have discussed its ST2 Assay, but there has been no ST2 assay approved by FDA for use with the nonsymptomatic patient and there is no uniformity in the literature about ST2 as a biomarker for population screening, which demonstrates that the issue requires further research and development. The Article was not providing mere undisputed, fixed information about ST2 assays in general, but reported scientific conclusions based on a particular study, and invited additional research and study of a public issue or a matter of public significance.

Accordingly, defendants have met their burden of showing that the allegedly defamatory statements in the Article were "in furtherance of the exercise of the constitutional right of petition or the constitutional right of free speech in connection with a public issue or an issue of public interest" and were published in the context of any ongoing controversy or debate.

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2. Reasonable Probability of Prevailing on the Merits

Because defendants have made the threshold showing that the challenged causes of action, libel per se, libel per quod and trade libel, arise from a protected activity, plaintiff must establish a probability of prevailing on the claims alleged. Defamation requires that the allegedly false statements be unprivileged. CAL. CIV. CODE § 45 ("Libel is a false and ***unprivileged*** publication . . . which has a tendency to injure him in his occupation."). Section 47 "extends a conditional privilege against defamation to statements made without malice on subjects of mutual interests." *Hui v. Sturbaum*, 166 Cal. Rptr.3d 569, 577 (Cal. App. 2014). The existence of the conditional privilege against defamation is ordinarily a question of law for the court. CAL. CIV. CODE § 47. Defendants contend that the common interest privilege applies in this situation.

The conditional privilege against defamation to statements made without malice on subjects of mutual interests is "recognized where the communicator and the recipient have a common interest and the communication is of a kind reasonably calculated to protect or further that interest." *Hawran v. Hixson*, 209 Cal. App.4th 256, 287 (2012). The "interest" is restricted to "proprietary or narrow private interests." *Id*.

Defendants correctly note that scholarly activity generally fits within the common interest privilege. *See Harkonen v Fleming*, 880 F. Supp.2d 1071, 1079 (N.D. Cal. 2012), citing *Taus v. Loftus*, 40 Cal. 4th 683, 721 (2007). In both *Harkonen* and *Taus*, the courts found the common interest privilege applicable and accordingly did not delve into "whether the statements were capable of defamatory meaning or if they were constitutionally protected opinion instead of fact." Ameet Kaur Nagra, Note, *A Higher Protection for Scholars Faced with Defamation Suits,* 41 HASTINGS CONST. L.Q., 175, 200 (2013). "In deciding whether the privilege applied – instead of attempting to discern defamatory meaning – the court in both cases considered the context in which the statements were made and the purpose and identity of the individuals that produced them." *Id.* at 201.

In the present case, it is beyond dispute that the author defendants conducted serious and rigorous research that was peer-reviewed prior to publication in a well-respected scientific journal. As noted above and conceded by plaintiff, the Article was directed to an interested

audience and not to the general population. The author defendants, through the publisher of the scholarly journal and the editor of the journal, presented their findings to an audience that shared their scholarly interests and activities. Accordingly, defendants have established that the statements at issue are privileged.

Because the statements fall within the common interest privilege, plaintiff now bears the burden of showing the statements were made with malice. The malice necessary to defeat the qualified common interest privilege is actual malice. *Hui*, 166 Cal. Rptr.3d at 579. In *Agarwal*, the California Supreme Court stated that "[t]he malice referred to by the statute is actual malice or malice in fact, that is, a state of mind arising from hatred or ill will, evidencing a willingness to vex, annoy or injure another person." *Agarwal v. Johnson*, 25 Cal.3d 932, 944 (1979). There is, however, an alternative method of showing malice: defendant lacked reasonable grounds for belief in the truth of the publication and therefore acted in reckless disregard of the plaintiff's rights. *Sanborn v. Chronicle Pub. Co.*, 18 Cal.3d 406, 413 (1976); *see also Noel v. River Hills Wilsons, Inc*., 113 Cal. App.4th 1363, 1370 (2003). "In demonstrating reckless disregard, it is not sufficient that the statements are shown to be inaccurate, or even unreasonable." *Glenn K. Jackson, Inc. v. Rose* 273 F.3d 1192, 1202 (9th Cir. 2011). Instead, "[o]nly willful falsity or recklessness will suffice." *Id*., quoting *Cabanas v. Gloodt Assocs.*, 942 F.Supp. 1295, 1301 n. 7 (E.D. Cal.1996); *see also Rogers v. Home Shopping Network, Inc.*,73 F. Supp.2d 1140 (C.D.Cal. 1999)(a libel plaintiff must establish that the defendant realized that his statement was false or that he subjectively entertained serious doubt as to the truth of his statement). Mere negligence does not provide a showing of lack of reasonable grounds. Malice is shown only when the negligence amounts to a reckless or wanton disregard for the truth, so as to imply a willful disregard for, or avoidance of, accuracy. *Noel v. River Hills Wilsons, Inc.*, 113 Cal. App.4th 1363, 1370-71 (2003).

Plaintiff has failed to provide any evidence establishing that any defendant possessed a state of mind arising from hatred or ill will toward plaintiff or plaintiff's Presage ST2 Assay. Nor has plaintiff presented evidence that defendants knew the statements plaintiff refers to as defamatory were false or that even if negligently made, defendants acted with reckless or wanton

disregard for the truth. As a result, plaintiff's defamation claims must be stricken under California Code of Civil Procedure § 425.16

c. Trade Libel

Although the common interest privilege appears to be applicable to a cause of action for trade libel much like libel per se and libel per quod, there is an additional factor that prevents this cause of action from going forward in this action under the anti-SLAPP statute.

"'Trade libel is defined as an intentional disparagement of the quality of property, which results in pecuniary damage to plaintiff.... "Injurious falsehood, or disparagement, then, may consist of the publication of matter derogatory to the plaintiff's title to his property, or its quality, or to his business in general, ... [T]he plaintiff must prove in all cases that the publication has played a material and substantial part inducing others not to deal with him, and that as a result he has suffered special damages.... Usually, ... the damages claimed have consisted of loss of prospective contracts with the plaintiff's customers." *Nichols v. Great American Ins. Companies,* 169 Cal. App.3d 766, 773 (1985); *see also Leonardini v. Shell Oil Co.,* 216 Cal. App.3d 547, 572 (1989). To constitute trade libel, a statement must be false. *Id.*; *see also Polygram Records, Inc. v. Superior Court,* 170 Cal. App.3d 543, 548 (1985).

Further, a claim based on trade libel "must specifically refer to, or be 'of and concerning,' the plaintiff in some way." *Blatty v. New York Times Co.* 42 Cal.3d 1033, 1042 (1986), cert. den. 485 U.S. 934 (1988).

> The "of and concerning" or specific reference requirement limits the right of action for injurious falsehood, granting it to those who are the direct object of criticism and denying it to those who merely complain of nonspecific statements that they believe cause them some hurt. To allow a plaintiff who is not identified, either expressly or by clear implication, to institute such an action poses an unjustifiable threat to society.

Id. at 1044.

Plaintiff contends that the statements it identified from the Article are disparaging or would persuade a consumer to avoid its product. But the study at the center of the Article did not involve research of an assay or assays in assessing the prognosis of patients already diagnosed with chronic heart failure – the precise clinical use of plaintiff's FDA approved Presage ST2 assay. Any use of plaintiff's ST2 assay would have been an off-label use. Accordingly, the

statements in the Article do not and could not discourage the purchase of plaintiff's product for its FDA-approved use. In other words, the statements do not specifically refer to or concern the plaintiff or plaintiff's product in some way.

Plaintiff's claim for trade libel is neither legally sufficient nor supported by a sufficient prima facie showing of facts to sustain a favorable judgment if the evidence submitted by the plaintiff is credited. Because plaintiff has not established a probability of prevailing on the trade libel claim, it will be stricken under § 425.16.

d. California Business and Professions Code §17200, et seq

Plaintiff alleges in its unfair competition law ("UCL") cause of action that defendants' actions in publishing false statements about the Presage ST2 assay constitutes an unlawful, unfair, or fraudulent business practice and amounts to unfair competition. However, "California's consumer protection laws, like the unfair competition law, govern only commercial speech . . . noncommercial speech is beyond their reach." *Rezec v. Sony Pictures Entertainment, Inc*., 116 Cal. App.4th 135, 140 (2004). "Commercial speech" is usually defined as speech that does no more than propose a commercial transaction. *Bernando v. Planned Parenthood Federaltion of America*, 115 Cal. App.4th 322, 343 (2004).

"In typical commercial speech cases, the speaker is likely to be someone engaged in commerce—that is, generally, the production, distribution, or sale of goods or services—or someone acting on behalf of a person so engaged, and the intended audience is likely to be actual or potential buyers or customers of the speakers goods or services, or persons acting for actual or potential buyers or customers, or persons (such as reporters or reviewers) likely to repeat the message to or otherwise influence actual or potential buyers or customers...." *Rezec*, 116 Cal. App.4th at 140-41. "In short, commercial speech is speech that does 'no more than propose a commercial transaction'" *Id.* at 141 [citations omitted].

Here, the Article at issue does not in any manner propose a commercial transaction in its content. Instead, it is provides a scholarly report of the results of a specific scientific study. For plaintiff to suggest otherwise is disingenuous. Accordingly, plaintiff has failed to show a reasonable probability of prevailing on its UCL claim because the Article is not commercial in

nature or that the intended audience of the Article was likely to be actual or potential customers of plaintiff or the Alere assay used in the study. As a result, dismissal of plaintiff's UCL claim under the anti-SLAPP statute is required.

D. CONCLUSION

The Court has determine that defendants AACC and Dr. Rafai have made a threshold showing that all of plaintiff's causes of action "arise from" a protected activity. Further, the Court finds and concludes that plaintiff has not established a probability of prevailing on the libel claims because of the applicability of the common interest privilege and plaintiff's failure to show malice, and on the UCL claim because the Article at issue it is not commercial speech.

Section 425.16(c) provides: "In any action subject to subdivision (b), a prevailing defendant on a special motion to strike shall be entitled to recover his or her attorney's fees and costs."

Based on the foregoing, **IT IS ORDERED:**

1. Defendant Rafai's motion to strike the complaint in its entirety is **GRANTED**;

2. Defendant AACC'S amended motion to strike the complaint in its entirety is **GRANTED**;

3. Defendants Rafai and AACC, as the prevailing defendant, are entitled to attorney's fees and costs. Defendants shall file their motions for attorney's fees and costs within 20 days of the filing of this Order. Counsel is advised to contact the chambers of the undersigned within three days of the filing of this Order so as to obtain a hearing date in conformity with the Civil Local Rules.

IT IS SO ORDERED.

DATED: February 18, 2014

M. James Lorenz
United States District Court Judge

COPY TO:

HON. MITCHELL D. DEMBIN
UNITED STATES MAGISTRATE JUDGE
ALL PARTIES/COUNSEL