UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

KURIN, INC., Plaintiff, v. MAGNOLIA MEDICAL TECHNOLOGIES, INC., Defendant.	Case No.: 3:18-cv-1060-L-LL **ORDER GRANTING IN PART AND DENYING IN PART KURIN'S MOTION FOR PARTIAL SUMMARY JUDGMENT, AND GRANTING MAGNOLIA'S MOTION FOR SUMMARY JUDGMENT**

Pending before the Court are Plaintiff Kurin Inc.'s ("Kurin") Motion for Partial Summary Judgment (doc. no. 50) and Defendant Magnolia Medical Technologies, Inc.'s ("Magnolia") Motion for Summary Judgment and to Exclude Kurin's Unreliable Expert Opinions (doc. no. 56). Both motions are fully briefed.[1] The Court determines these

[1] The parties filed more than 150 pages of briefs and more than 800 pages of exhibits. They did not follow the Court's Standing Order for Civil Cases in that they failed to coordinate and consolidate their briefing so as to avoid duplication. They also did not file affidavits explaining why they could not comply. Instead, the same issues were covered by the same party twice, once in connection with Kurin's motion and again in connection with Magnolia's cross-motion. Several exhibits were filed more than once,

motions without oral argument pursuant to Civil Local Rule 7.1.d.1. For the reasons that follow, Kurin's motion for partial summary judgment of its claims against Magnolia is granted only insofar as Kurin has established literal falsity of Magnolia's representation that the 93% average reduction in blood culture contamination is based on "multiple publications and peer-reviewed studies." Summary adjudication of Kurin's related request for permanent injunctive relief is denied. Kurin's motion for summary judgment on Magnolia's counterclaims is denied. Magnolia's motion for summary judgment on Kurin's claims is granted. Its related request to exclude the expert opinions of Jeffrey K. Shapiro and Patrick F. Kennedy is granted in part.

I. BACKGROUND

As part of normal testing procedures, medical professionals draw blood from patients to test for the presence of blood-borne infection such as sepsis. (Doc. no. 12 (Am. Answer and Countercl. ("Countercl.") at 9-10.)[2] If blood culture indicates a positive result, it influences clinical decision-making, including an antibiotic regimen and additional testing. (*Id.* at 10.) However, in many cases, a positive result is caused by a

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sometimes by the same party. (*Cf., e.g.*, doc. nos. 64-8 & 66-2, 56-17 & 64-3, and 65-14 & 64-10.) Many of the exhibits were filed under seal, yet the parties did not provide coherent courtesy copies, which necessitated searching through parallel sets of publicly-filed and sealed exhibits. *See* Electronic Case Filing Administrative Policies and Procedures Manual §2.e. (requiring courtesy copies). The relevant parts of many exhibits were barely legible. (*See, e.g.*, doc. nos. 56-17, 56-34, 64-6, 64-22.) Kurin's citations to Mr. Stuckert's deposition transcript were to non-existent page numbers. Several of the deposition excerpts and expert reports were not searchable. (*See, e.g.*, doc. nos. 65-5, 56-23, 65-6.) Some exhibits could not be opened on the docket. (*See, e.g.*, doc. no. 64-21.) Finally, all four sets of exhibits, one set each for the motion and cross-motion and one set each for the oppositions, all started with exhibit no. 1. None of the foregoing facilitated an efficient review of this matter. Any further failure to comply with this District's Civil Local Rules and this Court's Standing Order for Civil Cases may result in sanctions. *See* Civ. Loc. R. 83.1.

[2] Unless otherwise stated, all page citations are to page numbers generated by the CM/ECF System.

contaminant on the patient's skin rather than in the blood stream. (*Id.*) Preventing false positive results is important to reduce the expense and health risk from unnecessary antibiotic treatment and testing. (*Id.; see also* doc. no. 1 ("Compl.") at 2.)

Kurin and Magnolia are competing medical device companies marketing blood sample collection devices to health care providers. (Doc. no. 75 (Joint Statement of Undisputed Facts ("Joint Statement")) at 2.) Each markets its own device designed to minimize false positive results. (Countercl. at 11; Compl. at 2.)

Magnolia's Steripath device employs a proprietary specimen diversion mechanism which diverts the initial portion of blood draw into a separate chamber to sequester skin and other contaminants. (Countercl. at 10.) A new, second sterile blood flow path is then opened as the blood sample collected for testing. (*Id.*) Magnolia began distributing Steripath in June 2014 and started selling it commercially about a year later. Steripath is registered and listed with the United States Food and Drug Administration ("FDA"). (Doc. no. 75 (Joint Statement of Undisputed Facts ("Joint Statement")) at 2.)

The Kurin Lock device operates on a similar principle. (*See* Comp. at 2.) Kurin received its FDA 510(k) clearance to market the Kurin Lock on December 23, 2016 and launched its product around January 2017.

On May 29, 2018, Kurin filed a complaint claiming Magnolia makes false and misleading representations in its marketing of Steripath. It alleged claims for false advertising in violation of the Lanham Act, 15 U.S.C. § 1125(a) ("Lanham Act"), and California Business and Professions Code § 17500 et seq. ("FAL"), as well as unfair competition under California Business and Professions Code § 17200 et seq. ("UCL"). Kurin seeks injunctive relief and damages. Magnolia filed counterclaims alleging Lanham Act and FAL violations, seeking the same relief against Kurin based on Kurin's marketing of Kurin Lock.

In its pending motion, Kurin requests summary adjudication of some of its claims for injunctive relief, and summary judgment on Magnolia's counterclaims. In its cross-

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motion, Magnolia seeks summary judgment on each of Kurin's claims and exclusion of expert opinions offered by Jeffrey K. Shapiro and Patrick F. Kennedy.

II. DISCUSSION

Federal Rule of Civil Procedure 56 empowers the Court to enter summary judgment on factually unsupported claims or defenses. Summary judgment or adjudication of issues is appropriate if depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a), (c)(1).

The burden on the party moving for summary judgment depends on whether it bears the burden of proof at trial.

> When the party moving for summary judgment would bear the burden of proof at trial, it must come forward with evidence which would entitle it to a directed verdict if the evidence went uncontroverted at trial. In such a case, the moving party has the initial burden of establishing the absence of a genuine issue of fact on each issue material to its case.

See C.A.R. Transp. Brokerage Co., Inc. v. Darden Restaurants, Inc., 213 F.3d 474, 480 (9th Cir. 2000).[3]

On the other hand, if the moving party would not bear the burden at trial, it can meet its burden on summary judgment by "either of two methods." *Nissan Fire & Marine Ins. Co., Ltd. v. Fritz Companies, Inc.*, 210 F.3d 1099, 1106 (9th Cir. 2000). It may

> produce affirmative evidence . . . negating an essential element of the nonmoving party's case, or, after suitable discovery, the moving party may . . . meet its initial burden of production "by 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party's case."

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[3] Unless otherwise noted, internal quotation marks, ellipses, brackets, citations, and footnotes are omitted from all quotations.

Id. at 1105-06 (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986)).[4] "A moving party may not require the nonmoving party to produce evidence supporting its claim or defense simply by saying that the nonmoving party has no such evidence." *Nissan Fire & Marine Ins.*, 210 F.3d at 1105.

> If a moving party fails to carry its initial burden of production, the nonmoving party has no obligation to produce anything, even if the nonmoving party would have the ultimate burden of persuasion at trial. In such a case, the nonmoving party may defeat the motion for summary judgment without producing anything.

Id. at 1102-03; *see also Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 160 (1970).

"If, however, a moving party carries its burden of production, the nonmoving party must produce evidence to support its claim or defense." *Nissan Fire & Marine Ins.*, 210 F.3d at 1103. In this regard, the nonmoving party must "go beyond the pleadings and by [its] own affidavits, or 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. The nonmoving party

> must do more than simply show that there is some metaphysical doubt as to the material facts[, but] must come forward with specific facts showing that there is a genuine dispute for trial. Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial.

Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986).

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[4] As an example of the latter method, in *Celotex* it was sufficient

> for Celotex to direct the district court's attention to Catrett's answer to interrogatories admitting that she had no witnesses who could testify that her husband had been exposed during the statutory period to asbestos manufactured by Celotex, and to the absence of any other evidence of exposure in the materials compiled during discovery.

Nissan Fire & Marine Ins. Co., 210 F.3d at 1105.

> Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge . . .. The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor.

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986).

"[I]f the nonmoving party produces enough evidence to create a genuine issue of material fact, the nonmoving party defeats the motion." *Nissan Fire & Marine Ins.*, 210 F.3d at 1103. If it does not produce enough evidence, then the moving party wins the motion for summary judgment. *Id.*

"The district court may limit its review to the documents submitted for the purpose of summary judgment and those parts of the record specifically referenced therein." *Carmen v. San Francisco Unified Sch. Dist.*, 237 F.3d 1026, 1030 (9th Cir. 2001). The Court is not obligated "to scour the record in search of a genuine issue of triable fact." *Keenan v. Allen*, 91 F.3d 1275, 1279 (9th Cir. 1996).

The filing of cross-motions for summary judgment "does not necessarily mean there are no disputed issues of material fact and does not necessarily permit the judge to render judgment in favor of one side or the other." *Starsky v. Williams*, 512 F.2d 109, 112 (9th Cir. 1975). Furthermore, "each motion must be considered on its own merits," and the court must consider evidence submitted in support of and in opposition to both motions before ruling on each one. *Fair Hous. Council of Riverside County, Inc. v. Riverside Two*, 249 F.3d 1132, 1136 (9th Cir. 2001).

Issues in both summary judgment motions involve false advertising under the Lanham Act. To prevail, a party must prove the following elements:

> (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). State law UCL and FAL claims are substantially congruent to claims made under the Lanham Act. *Cleary v. News Corp.*, 30 F.3d 1255, 1262-63 (9th Cir. 1994); *see also Appliance Recycling Ctrs. of Am. v. JACO Environmental, Inc.*, 378 Fed. Appx. 652, 656 (9th Cir. 2010).

A. Kurin's Motion for Summary Adjudication of Its Own Claims

Kurin moves for summary adjudication of its injunctive relief claims against Magnolia based on statements regarding Steripath's efficacy and representations that Steripath eliminates or virtually eliminates false positive results. For the reasons stated below, the motion is granted only insofar as Magnolia represented that the 93% average reduction in culture contamination is based on "multiple publications and peer-reviewed published studies." The related request for summary adjudication of injunctive relief is denied.

1. Steripath Efficacy Claims

Kurin argues that a number of advertising claims relating to Steripath's efficacy are literally false. It attacks statements that Steripath reduced blood culture contamination and false positive results by an average of 92 or 93% across, variously, 30,000 or 100,000 blood cultures. Kurin claims the statements are literally false in three respects: (1) the percentage of reduction; (2) that the percentage is an average; and (3) that the average is based on 30,000 or 100,000 cultures. Magnolia counters that the statements are true because they are based on customer data and controlled clinical studies.

Magnolia sponsored two Steripath efficacy studies. The first was a peer-reviewed study conducted at the University of Nebraska Medical Center ("UNMC") by Rupp et al., titled Reduction in Blood Culture Contamination Through Use of Initial Specimen Diversion Device ("Rupp Study"). It was published in the journal *Clinical Infectious*

Diseases in May 2017. (Magnolia Ex. 11 (Expert Report of Mark Roberts ("Roberts Rept.")) App'x C; Magnolia Ex. 12 ("Rupp Article").)[5] The second sponsored peer-reviewed study was conducted at the Hebrew University-Hadassag Medical School, Shaare Zedek Medical Center by Zimmerman et al., titled Reducing Blood Culture Contamination Using an Initial Specimen Diversion Device. It was published in the *American Journal of Infection Control* in July 2019. (Roberts Rept. App'x C.)

Another peer-reviewed efficacy study, not sponsored by Magnolia, was jointly conducted at four hospitals in Florida by Bell et al., titled Effectiveness of a Novel Specimen Collection System on Reducing Blood Culture Contamination Rates. It was published in April 2018 in the *Journal of Emergency Nursing*. (Roberts Rept. App'x C.) Two additional peer-reviewed studies of the clinical and economic effect of Steripath use were published in the *Journal of Clinical Microbiology* and *Journal of Hospital Infection* in January and March 2019, respectively. (*Id.*)

In addition to peer-reviewed medical journal articles, Steripath efficacy was the subject of at least seven clinical studies between the summer of 2016 and June 2018, conducted at the San Antonio Military Medical Center, VA North Texas Health Care System, Rush University Medical Center, and others. Their results were included in poster presentations at meetings such as American Society of Microbiology, and Emergency Nurses Association.[6] (Roberts Rept. App'x C.)

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[5] Magnolia's exhibits are found in doc. nos. 56-4, 56-13 through 15, 56-17, 56-19, 56-23, 56-34, 56-38, 56-39, 65-1 through 29, and 67-1 through 67-3.

[6] "Poster presentations" are "a common format for the communication of early research results in the academic and public health fields." (Roberts Rept. at 11.) Compared to publication in a peer-reviewed medical journal, the peer-review process for poster presentations "is very simplified and abbreviated." (*Id.* at 11.) "The peer-review of poster presentations is dependent on the forum where the poster topic is presented, such as an internal employer poster session or a poster session at a large annual meeting of a professional society." (*Id.*) Once accepted for presentation, posters are usually presented by the author, who explains the study to the attendees at the conference or

The results of Steripath's clinical studies are incorporated into Magnolia's advertising. (*See* Gerberich Dep. at 36-37; *see also id.* at 33-35.)[7] Magnolia's marketing emphasizes the Rupp Study, a "prospective, controlled trial" at the UNMC Emergency Department. (Rupp Article at 2.) The study tested Steripath's efficacy "against standard phlebotomy procedures in patients requiring blood cultures due to clinical suspicion of serious infection." (*Id*.) One aspect of the standard practice to avoid false positive results is to draw two blood samples from the same patient, one from each arm. (*See id.* at 6.) During the study one of those samples was drawn using Steripath and the other without it. (*Id.* at 3.) The study was conducted over a 12-month period on 904 nonduplicative patients, yielding 1,808 blood cultures for comparison. (*Id.* at 2.) The cultures drawn without Steripath showed a 1.78% contamination rate, while those drawn using Steripath showed a 0.22% rate. (*Id.* at 3.) The difference is an 87.6% reduction in contamination rate using Steripath (*id.* at 7 (graphic, rounding to 88%)), thus increasing the probability that a positive result was a true positive, *i.e.*, reducing the likelihood of a false positive (*id.* at 3 (97% probability of true positive with Steripath vs. 81% without it)).

A post hoc analysis of blood cultures obtained in the same emergency department was performed after the conclusion of the controlled study comparing the 0.2% contamination rate achieved with Steripath during the study with the contamination rates during the six-month periods before and after the study, when Steripath was not used. (Rupp Article at 3.) The contamination rates for the six-month periods before and after the study were 2.6 % and 2.8%, respectively. (*Id.* at 5 & Table 2.) When these rates are compared to the contamination rate of 0.2% for blood cultures obtained using Steripath,

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meeting. This provides an opportunity to "review the data and challenge the content of the poster." (*Id.* at 12.)

[7] Excerpts are found in docs. no. 65-9 and 66-10. Page references to all deposition transcripts are to the page numbers in the transcript.

the results show that Steripath reduced the contamination rate by 92% when compared to the six-month period before the study and by 93% when compared to the six-month period after the study. (*Id.* at 7 (graphic); *see also* Roberts Rept. at 19-20.) In addition to the Rupp Study, Magnolia's advertising references other studies published in peer-reviewed medical journals, presented as posters at medical conferences, and unpublished clinical data collected by customers using Steripath.

Kurin argues that Magnolia's marketing claims regarding Steripath's efficacy are literally false.

> To prove that an advertisement claim based on product testing is literally false, a plaintiff must do more than show that the tests supporting the challenged claim are unpersuasive. Rather, the plaintiff must demonstrate that such tests are not sufficiently reliable to permit one to conclude with reasonable certainty that they established the claim made. A plaintiff may meet this burden either by attacking the validity of the defendant's tests directly or by showing that the defendant's tests are contradicted or unsupported by other scientific tests. Moreover, if the plaintiff can show that the tests, even if reliable, do not establish the proposition asserted by the defendant, the plaintiff has obviously met its burden of demonstrating literal falsity.

Southland Sod, 108 F.3d at 1139. Kurin attacks reliability of the controlled clinical studies cited in Magnolia's advertising and contends they do not establish Magnolia's efficacy claims.

"When evaluating whether an advertising claim is literally false, the claim must always be analyzed in its full context." *Southland Sod*, 108 F.3d at 1139. This includes reviewing "the face of the statement in its entirety," *id.*, and in light of its intended audience, *Core-Vent Corp. v. Nobel Indus. Sweden A.B.*, 163 F.3d 605 (9th Cir. 1998) (considering that the statement was made to a professional conference or a scientific journal).

Magnolia's advertising was directed at a sophisticated audience. "Magnolia and Kurin market their devices to healthcare providers seeking to reduce the number of false-positive blood cultures." (Joint Statement at 2.) Kurin concedes that Magnolia's

statements were made in the course of marketing Steripath directly to hospitals, medical distribution channels and medical professionals such as purchasing managers for hospitals. (Doc. no. 64 ("Kurin Mot.") at 14 n.3 (citing Countercl. ¶90).) Kurin also adopts Magnolia's expert's conclusion that published clinical data is an important resource in hospitals' consideration whether to purchase a medical device such as Steripath. (Kurin Mot. at 14 n.3 (citing Roberts Rept.).) Health care professionals involved in the purchasing decision often ask for peer-reviewed studies to review before meeting with a sales representative. (*See* Roberts Rept. at 16.) Accordingly, purchasing decisions are not based solely on advertising.

a. Reliability of Controlled Clinical Studies

Kurin argues that Magnolia's use of controlled clinical study results, including the Rupp Study results, in its advertising is literally false because they do not reflect "real world" results. Such studies "are only for those patients on which SteriPath was used," while in real life the medical personnel might not use Steripath 100% of the time. (Kurin Mot. at 13 n.2; doc. no. 66 ("Kurin Opp'n") at 16-17.) This argument confuses the difference between controlled clinical research and day-to-day medical practice. (*See* Roberts Dep. at 57-59.)[8]

The Rupp Study, a controlled clinical research study, tested Steripath's efficacy by comparing results when Steripath was used and when it was not used. (Rupp Article at 3.) This is how a controlled clinical study measures performance of a particular device. (Roberts Rept.at 7-8; *see also* Heindel Dep. at 119-20.)[9] The contamination rate achieved when only the relevant device is used establishes its efficacy. (Heindel Dep. at 123.) Kurin's Vice President of Business Development agrees that the Rupp study is "good

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[8] Excerpts are found in doc. no. 67-1.

[9] Excerpts are found in doc. no. 65-20.

data in verifying the efficacy of the device." (*Id.* at 121; *see also id.* at 119 ("I compliment Steripath on their data," referencing the Rupp Study).)

Kurin takes the view that it is more important for customers to know if the device will work in "the real world," when, realistically, a 100% compliance cannot be achieved.[10] (Heindel Dep. at 67, 121-22, 296.) It advocates for the use of a "blended rate," which "blends together all results experienced at a facility for a given time period" regardless of the blood sample collection device used. (Kurin Opp'n at 17 n.6; *see also* Heindel Dep. at 120-21.) In essence, the blended rate results are the opposite of controlled study results, because the study does not control for the use of the relevant device.

The fact that a non-controlled study will result in a different contamination rate than a controlled study does not render controlled study results unreliable. Controlled clinical studies such as the Rupp Study follow "recognized scientific methods and customary study designs" which are familiar to medical professionals. (Roberts Rept. at 18.) Kurin has provided no evidence to show that Magnolia's citation to controlled clinical study results renders its advertising literally false.

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[10] In addition, Kurin criticizes the Rupp Study results as flawed based on "selection bias" because they do not reflect all emergency department blood cultures drawn during the 12-month period, but only a subset of those cultures. (*See* Heindel Dep. at 296.) The results reported for the 12-month period of the study are based on the blood cultures drawn from 904 patients. (Rupp Article at 2.) The number of participating patients was a function of the UNMC Institutional Review Board's requirement of informed consent before participating. (*Id.* at 6; *see also* Roberts Rept. at 19.) The limitations of the study, including the selection of participating patients, are disclosed and evaluated in the study. (Rupp Article at 6.) The requirement of informed consent "exclud[ed] incompetent patients and those requiring immediate attention." (*Id.*) In addition, the phlebotomists avoided using Steripath on "uncooperative patients or those with poor vascular access." (*Id.*)

b. Claims of 92% and 93% Reduction

Alternatively, Kurin contends it was literally false to state that any study reported a 93% reduction in contamination rates or false positives,[11] and that only one study reported a 92% reduction. (Kurin Mot. at 12-13.)[12] However, both rates are supported by clinical studies.

Kurin argues that the Rupp Study does not support Magnolia's claims because it reported only an 87.6% reduction in the contamination rate, rather than the 92% or 93% reduction as claimed by Magnolia. (Doc. no. 82 ("Kurin Reply") at 6 n.3.) This contention is negated by the study itself.

The 87.6% reduction was reported for the 12-month controlled study period which compared contamination rates of samples drawn from the same patient with Steripath and without it. (Rupp Article at 7.) When the rate achieved with Steripath is compared to the contamination rates during the six-month periods before and after the study, when Steripath was not used, the difference was 92% and 93%, respectively. (*Id.*) This analysis is explained in the Rupp Article. It was not literally false for Magnolia to cite to the Rupp Study in support of its claims of 92% or 93% reduction in contamination rate.

A 92% reduction was also achieved in the clinical study performed at the San Antonio Military Medical Center in 2016. (*See* Roberts Rept. App'x C.) Out of 672 cultures collected using the standard method, 52 showed false positive results. (Kurin

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[11] This claim is not alleged in the complaint.

[12] Kurin confuses the references to 93% and 92%, which derive from separate sets of data. (*See* doc. no. 67 ("Magnolia Opp'n") at 9-10.) The testimony of Magnolia's Vice President of Sales is consistent with this distinction. When asked about a 93% reduction in *false positives*, he stated the percentage he uses is *92%* rather than 93%. (Doc. no. 64-19 ("Stuckert Dep.") at 130-32.) Excerpts are found in docs. no. 64-19, 65-24 and 67-2.

Ex. 24.)[13] Out of 784 cultures collected with Steripath during the same period, only five showed false positive results. (*Id.*) The resulting contamination rate reduction is 92%. (Kurin Ex. 2.)

Kurin has presented no evidence tending to show that no efficacy studies show a 93% reduction in contamination rates and that only one study showed a 92% reduction. Kurin's motion is denied to the extent it is based on literal falsity of Magnolia's claims of 92% or 93% reduction.

c. References to Average

Next, Kurin argues it is literally false for Magnolia to refer to the 92% and 93% reduction as averages.[14] The argument is rejected for the reasons stated below.

Based on its Exhibits 20 and 21, Kurin argues it was literally false for Magnolia to represent its single best study result as an average of 92%. (Kurin Mot. at 13; *see also* Kurin Opp'n at 14.) The exhibits, however, list 83.8% as the average, and not 92%.

Exhibit 20, a screenshot of Magnolia's website taken November 13, 2019, references eight independent clinical studies, only one of which reported a 92% reduction in the contamination rate, while the others reported lower reductions. The studies are individually listed with links to more information about each. The summary on the website states, "These institutions reduced their blood culture contamination rates by an average of *83.8%* when using Steripath vs. standard practice [baseline]." (Kurin Ex. 20 (emphasis added).) Magnolia's Vice President of Sales testified about Kurin's Exhibit 21, a screenshot of Magnolia's website taken May 31, 2019, which is in all relevant respects the same as Exhibit 20. (Stuckert Dep. at 210, 227-28 (Kurin Ex. 21 is Ex. 18 to

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[13] Kurin's exhibits are found in docs. no. 50-13, 50-22, 50-21, 59-14, 64-2 through 64-23, 66-10 and 66-11.

[14] The complaint does not allege any false advertising claims based on an average reduction of 92% or 93%.

the deposition transcript).) The testimony confirms that Exhibit 21 displays the average of *83.8%* rather than 92%.

Kurin also relies on its Exhibits 2, 9 and 11 to argue that the representation of 92% average is literally false. (Kurin Mot. at 13.) However, none of the exhibits refers to 92% as an average.

Exhibit 9 is Magnolia's email template to contact prospective customers. It reads in pertinent part:

> In eight (8) peer-reviewed published clinical trials and clinical trial poster presentations at major medical conferences, Steripath has demonstrated:
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> - 92% reduction in false positive culture results
> - 12-month sustained blood culture contamination rate of 0.2% (P=0.001)
> - Reduction in Vancomycin DOT of 37% (P=0.007)
> - Average cost savings of $103,000 per month or $1,236,000 annually
>
> [¶] I am attaching Steripath technical and clinical information and providing the below links for your reference.
>
> - [Rupp Study] (See attached).
> - View a video of Dr. Mark Rupp . . . discussing the clinical trial results. [hyperlink to a YouTube video]
> - An animation video on how and why Steripath works. [hyperlink to a YouTube video]
> - Additional information can be found on our website at [hyperlink to the website]

Neither the introductory sentence nor the bullet-point reference to a 92% reduction states that the percentage is an average. (Kurin Ex. 9.) Nothing about the bullet points suggests that each of them is based on all eight studies. Furthermore, the email attaches the Rupp Study and includes a link to Dr. Rupp's video discussing the results. The Rupp Study supports the 92% reduction and contamination rate of 0.2%. When emails based on this template were sent to Magnolia's prospective customers, they included the Rupp Article and Dr. Rupp's video. (*See* Magnolia Exs. 22-26.)

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Kurin's Exhibit 11, a September 13, 2017, screenshot of Magnolia's website, states in pertinent part, "Used by reputable hospitals around the country—and proven in countless clinical trials—Steripath has been clinically proven to sustain a blood culture rate of 0.2% and a reduction in false positives by 92%." The statement includes a link to "view evidence." (Kurin Ex. 11).[15] Again, contrary to Kurin's contention, Magnolia's statement does not refer to 92% as an average. The same is true of Kurin's Exhibit 2. As discussed in section b., above, the 92% reduction claim is not literally false because it is supported by two clinical studies. (*See also* Kurin Ex. 2 (Rupp Study and San Antonio Military Medical Center study).)

Some of Magnolia's advertising includes the claim of 93% average reduction. Kurin argues this is literally false (Kurin Mot. at 13-14). Magnolia counters it is not because "the 93% average is supported by both published and unpublished clinical data." (Magnolia Opp'n at 12.)

In many instances, the sources in support of Magnolia's claim are cited in its advertising. For example, Kurin's Exhibit 1 states that Steripath's efficacy was studied "within multiple healthcare systems" and in "large scale clinical trials and commercial customer deployment." Exhibit 2 states, "Average of 93% lower contamination rate with SteriPath" under the heading "20+ Gov. & Private Hospital Systems, Clinical Results." Exhibit 4, one of Magnolia's PowerPoint presentation slides, includes the 93% average under the heading "Reduction In Blood Culture Contamination Validated In Clinical Practice" above a chart summarizing thirteen clinical studies.

To the extent Kurin argues that Magnolia failed to provide sufficient evidence to negate literal falsity because it has not produced the cited study results in its opposition (*see* Kurin Reply at 5, 6 n.4), the argument is unavailing. Kurin is moving for summary adjudication of its own claims as to which it would bear the burden of proof at trial. It

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[15] Kurin did not provide a screenshot of the linked page.

therefore "must come forward with evidence which would entitle it to a directed verdict if the evidence went uncontroverted at trial." *C.A.R. Transp. Brokerage Co.*, 213 F.3d at 480. Kurin had the burden to produce evidence supporting its literal falsity claim. It has not met this burden.

However, Kurin cites two advertisements claiming that the 93% average is based on "multiple publications and peer-reviewed published studies." (Kurin Exs. 5, 7.) According to Magnolia, it "has . . . never represented that the 93% average reduction is derived from only published clinical trials." (Magnolia Opp'n at 12; *see also* doc. no. 83 ("Magnolia Reply") at 3 ("Magnolia has never represented that the 93% reduction statistic was based *exclusively* on published studies.") (emph. in orig,).) Based on this admission, the Court finds that Magnolia's claim of 93% average is literally false insofar as its advertising states the average is based on "multiple publications and peer-reviewed published studies."

Kurin further argues that "[b]ased simply on the literal falsity of Magnolia's statements[, it] is entitled to injunctive relief." (Kurin Mot. at 15.) It requests to "enjoin Magnolia from repeating its false and misleading statements . . . and require Magnolia to make corrective statements." (Kurin Reply at 11.)

A showing of literal falsity alone is insufficient to warrant permanent injunctive relief for two reasons. First, the Lanham Act requires proof of likelihood of future injury. *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 135 (2014). Second,

> a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate: (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.

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eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006). Kurin has provided no evidence of either.[16]

For the foregoing reasons, to the extent Kurin moves for summary adjudication of literal falsity of Magnolia's claims that Steripath reduces blood culture contamination by an average of 92% or 93%, the motion is granted only insofar as Magnolia represented that the 93% average is based on "multiple publications and peer-reviewed published studies." The related request for summary adjudication of injunctive relief is denied.

d. References to 30,000 and 100,000 Blood Cultures

Last, Kurin argues that "[n]either a 93% nor 92% reduction was observed across 30,000 blood cultures or across 100,000 blood cultures collected with SteriPath."[17] (Kurin Mot. at 13.) This argument is based on the premise that the 92% and 93% reduction claims are based solely on the Rupp Study, which involved 1,808 blood cultures collected from 904 patients during the 12-month controlled study period. (*Id.* (citing Kurin Ex. 22 (discussing Rupp Study)).)

As discussed above in section c., the 93% average is based on data collected from published and unpublished clinical studies as well as from Magnolia's customers. (*See, e.g.*, Kurin Ex. 1 ("large scale clinical trials and commercial customer deployment comprised of over 30,000 blood cultures"), Kurin Ex. 2 ("Over 100,000 cultures collected with Steripath" under the heading "20+ Gov. & Private Hospital Systems, Clinical Results"), Kurin Ex. 4 ("more than 100,000 blood cultures collected with Steripath" next to a chart summarizing thirteen studies).)

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[16] *See* Kurin Reply at 10-11, providing argument but no evidence. Furthermore, Kurin addresses the elements of injunctive relief for the first time in its reply brief. It is inappropriate to raise new arguments in the reply, because it deprives the opposing party of an opportunity to respond. *See Zamani v. Carnes*, 491 F.3d 990, 997 (9th Cir. 2007) ("The district court need not consider arguments raised for the first time in a reply brief.")

[17] This claim is not alleged in the complaint.

Kurin has cited no evidence to show that Magnolia's references to 30,000 and 100,000 blood cultures are literally false. To the extent it moves for summary adjudication of this claim, Kurin's motion is denied.

2. Claims That Steripath (Virtually) Eliminates Contamination

Kurin also claims that Magnolia's statements that Steripath "eliminates" or "virtually eliminates" blood culture contamination are literally false. For the reasons discussed below, this contention is rejected.

Kurin argues the statements that Steripath "eliminates" contamination are literally false because none of Steripath's clinical trials show that Steripath eliminated 100% of contamination, and Magnolia's Vice President of Sales admitted as much. (Stuckert Dep. at 73-74.) The argument is rejected because, when viewed in context, none of the cited statements represent that Steripath eliminates 100% of contamination. Alternatively, to the extent any of the cited statements could reasonably be viewed as Kurin suggests, they were nonactionable puffery.

Kurin points to four exhibits. Kurin's Exhibit 12 is one slide out of Magnolia's PowerPoint presentation which contains only a topic heading "**ELIMINATE** BLOOD CULTURE CONTAMINATION" next to an image of Steripath. (Emphasis in original.) It is apparent that the statement is intended to introduce a topic rather than represent that Steripath eliminates all contamination. Kurin's Exhibit 13 is another isolated slide from a PowerPoint presentation with the heading "Eliminating Blood Culture Contamination," image of Steripath, and notation that it introduces an animation video. Kurin's Exhibits 12 and 13 are included in Magnolia's Exhibit 14, which includes additional slides from the same presentation and provides context. For example, the slide after Kurin's Exhibit 12 explains: "Only technology **CLINICALLY PROVEN** to virtually **ELIMINATE** the **PREVENTABLE ERROR** of blood culture contamination and false positive results." (Magnolia Ex. 14 at 3 (emphases in original).) The slide then summarizes the clinical results, including "**SUSTAINED** contamination rate of **0.2%**." (*Id.* (emphases in original).) Kurin's Exhibit 13 is included four slides later to introduce a video. (*Id.* at 7.)

Kurin's Exhibit 17 is another presentation slide with the heading "Eliminating False Positive Blood Cultures in Adult Emergency Department, Steripath GEN2 Initial 60-Day Pilot Results." The rest of the slide puts into context the reference to "eliminating" by showing that Steripath use during the pilot trial reduced the contamination rate to 0.19%. (*Id.*) The location and authors of the pilot trial are identified in the slide. (*Id.*)

Kurin's Exhibit 16 is a PowerPoint slide with a discussion of how the presence of some of the skin-residing organisms may be clinically relevant which ends with the statement: "When we eliminate blood culture contamination, we eliminate unnecessary PCR tests." When read in the context, the statement identifies a goal. (*See, e.g.,* Stuckert Dep. at 73 ("[E]liminate blood culture contamination" is "an aspirational statement to connect with what everybody is trying to accomplish."); Gerberich Dep. at 52 ("aspirational statement for what the technology is designed to do").) The slide does not state that Steripath eliminates all blood culture contamination.

To show that one potential customer understood Steripath to "eliminate" contamination, Kurin points to its Exhibit 24 (Kurin Opp'n at 11-12), a poster presentation of a study performed at the San Antonio Military Medical Center. Contrary to Kurin's contention, the study concluded that "[d]ata indicates use of Steripath significantly reduces contamination rates." Kurin points to the summary of "Steripath Methods," which includes a bullet point stating that Steripath "[e]liminates fragments from skin or contaminates introduced during initial intravenous access." (*Id.*) The bullet point does not speak to the relevant issue, much less raise a reasonable inference that San Antonio Military Medical Center was misled by Magnolia's advertising.

Alternatively, Magnolia argues the statement that Steripath eliminates blood culture contamination is nonactionable puffery. "Puffing is exaggerated advertising, blustering, and boasting" which is not actionable under the Lanham Act. *Southland Sod*, 108 F.3d at 1145.

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> A statement is considered puffery if the claim is extremely unlikely to induce consumer reliance. Ultimately, the difference between a statement of fact and mere puffery rests in the specificity or generality of the claim.

Newcal Indus., Inc. v. Ikon Office Solutions, 513 F.3d 1038, 1053 (9th Cir. 2008). "[W]hether an alleged misrepresentation is a statement of fact or is instead mere puffery is a legal question." *Id.*

The statement that Steripath "eliminates" blood culture contamination is puffery. It is an exaggerated general statement on which medical professionals are unlikely to rely particularly when presented in the context of summarizing clinical study results.

Kurin next attacks as literally false the statements that Steripath "virtually eliminates" blood culture contamination. It argues the statement is literally false because Steripath eliminates blood culture contamination only by an average of 83.8%. (*See* Kurin Mot. at 16.)

The 83.8% is the average reduction in blood contamination rate based on eight clinical studies. (*See* Kurin Exs. 20, 21.) In the studies, the blood contamination rates without Steripath ranged between 2.6 and 7.7%, while the rates with Steripath ranged between 0.2% and 0.9%. The *difference* between the two ranges averaged 83.8%. With Steripath, the blood culture contamination rate was reduced in all instances to below 1%. Accordingly, the 83.8% average reduction is not the relevant reference point to evaluate the statements that Steripath virtually eliminates blood culture contamination.

In support of its argument Kurin also cites two examples. Exhibit 10, a PowerPoint slide, includes the statement that "Steripath can help you virtually eliminate false positive culture results." The statement is made at the bottom of the slide, following the representation that "Steripath has demonstrated: . . . 12-month sustained blood culture contamination rate of 0.2%." Exhibit 15, another slide, states next to a photo of Steripath, that it is "Only technology **CLINICALLY PROVEN** to virtually **ELIMINATE** the **PREVENTABLE ERROR** of blood culture contamination and false positive results for Sepsis." This is followed by the statement, "**SUSTAINED**

contamination rate of **0.2%**." (Emphases in original.) When read in context, both statements explain that "virtually eliminate" means to reduce contamination to 0.2%. This representation is supported by clinical studies as discussed in section 1. above.

Based on these examples, Kurin argues that "'virtually eliminates false positives' means 'almost completely removes or gets rid of false positives.'" (Kurin Mot. at 16.) Kurin's evidence shows that Steripath removed all but 0.9% of false positives. (*See* Kurin Exs. 20, 21.) Kurin has presented no evidence to suggest that eliminating all but less than 1% of false positives anything other than "virtually eliminating" them.

3. Conclusion

Kurin's motion for summary adjudication of its own claims against Magnolia is granted insofar as Kurin has established literal falsity of Magnolia's claim that the average 93% reduction in blood culture contamination is based on "multiple publications and peer-reviewed published studies." In all other respects, including the related request for summary adjudication of injunctive relief, the motion is denied.

B. <u>Magnolia's Motion for Summary Judgment on Kurin's Claims</u>

Magnolia moves for summary judgment on all of Kurin's claims, including claims for damages and injunctive relief. For the reasons stated below, the motion is granted.

1. Steripath Is Registered and Listed With the FDA

It is undisputed that Steripath is FDA registered and listed. (Joint Statement at 2.) Nevertheless, Kurin contends Magnolia's claim that Steripath is FDA registered and listed is false and misleading. (Compl. at 3.) Magnolia counters that "there is no record evidence that [it] even made statements about its FDA registration and listing in commercial advertisements" (Magnolia Mot. at 17) and that Kurin cannot show that the statement is false or misleading (*id*. at 15-16).

Kurin has not identified any promotional materials referencing FDA registration and listing, but points to two other documents. First, the Rupp Article notes in passing that Steripath is FDA registered and listed. (Rupp Article at 6.) Magnolia referenced the Rupp Study in its marketing materials to support not Steripath's FDA registration and

listing, but its efficacy. However, Magnolia's customers may have seen the reference to FDA registration and listing when they reviewed the Rupp Article.

Second, a slide from Magnolia's New Hire Training presentation states in pertinent part:

> **The Kurin Lock is FDA cleared, Steripath is not**
> [Steripath] is classified as a convenience kit and contains a patent-protected proprietary Class I exempt medical device that does not require a 510(k) clearance.
> - *Steripath is registered and listed with the FDA indicating compliance with all relevant QSR and GMP regulations*. This registration is publically [*sic*] available via the FDA website. We are happy to provide copies.
>
> [¶] The Kurin Lock product was designed to incorporate its own venipuncture needle which is a Class II non-exempt device requiring FDA 510(k) clearance.[18]

(Magnolia Ex. 8 at Bates no. MMT-0000227 (bold emphasis in original, italicized emphasis added).) Kurin objects to the italicized portion of the slide. Although Kurin has presented no evidence that the italicized statement was actually made to any prospective customer, the slide is sufficient to support a reasonable inference that it was. Kurin contends (1) the statement is misleading because it created a false impression

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[18] FDA regulates medical devices using a risk-based classification system. 21 U.S.C. § 360c. Class I, the lowest risk group, contains products that most often do not require FDA review before marketing and are exempt from premarket clearance. Registration and listing does not entail any premarket review, clearance, or approval of the device by the FDA; however, it is one of the necessary steps to legally market a medical device. (Shapiro Dep. at 132 (excerpts are found in doc. no. 65-5).) Class II devices present a higher level of risk than Class I devices. Unless exempt by regulation, 510(k) clearance is required before commercial distribution of the device. Class II devices are cleared for marketing by the FDA if they are substantially equivalent to one or more legally marketed products. Clearance does not entail an FDA approval. Class III devices present the highest level of risk and require FDA premarket approval. (*See generally* Magnolia Ex. 5 (Expert Report of Jeffrey K. Shapiro ("Shapiro Rept.")) at 7; (Magnolia Ex. 9 (Expert Report of David. W. Feigal, Jr. ("Feigal Rept.")) at 11-13.)

regarding Steripath's regulatory status, and (2) it was false to represent that registration and listing denotes compliance with QSR and GMP regulations. (Kurin Opp'n at 19, 22.)

a. False Impression Regarding Regulatory Status

Kurin claims the statement that Steripath is FDA registered and listed misled, or was likely to mislead, Magnolia's customers because they would not know that a registration and listing alone does not include FDA clearance or approval. In support of this contention, Kurin relies on three documents and the opinion of its expert Jeffrey Shapiro.

First, Kurin points to its Opposition Exhibit 13,[19] a poster presentation summary of a clinical study conducted at the Central Texas Veterans Health Care Systems ("Arenas Presentation"), which incorrectly states that the authors studied "two different types of FDA 510(k)-approved devices." (Kurin Opp'n Ex. 13.) The error is two-fold. First, neither registration and listing nor 510(k) certification entails FDA *approval* of a medical device. (Shapiro Rept. at 12; Magnolia Ex. 38 (Rebuttal Expert Report of David W. Feigal, Jr. ("Feigal Rebuttal")) at 7.) Second, Steripath was not 510(k)-cleared. However, the latter error is corrected in a footnote, "Correction: as of September 18, the Steripath device had not received 510(k) clearance." (Kurin Opp'n Ex. 13.)

Viewing the Arenas Presentation in the light most favorable to Kurin, it does not support a reasonable inference that the study authors' error was due to their confusion about the significance of FDA registration and listing, although they may have been confused about the significance of 510(k) clearance. Further, Kurin has presented no evidence that Magnolia disseminated this document or referenced it any of its advertising, or that the error was based on Magnolia's representation of any kind.

Second, Magnolia's Vice President of Sales testified that a customer purchased Steripath and later returned it (Kurin Opp'n at 20):

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[19] Kurin's Opposition Exhibits can be found at doc. nos. 59-1, 59-14, and 66-2 through 66-11.

> Q . . . Is Crouse currently purchasing Steripath devices?
>
> A No. They purchased the Kurin devices. . . . They made one initial purchase. It was returned[b]ecause they had a question about the 510(k) clearance status.
>
> [¶ The purchasing agent] communicated to me that a question had been raised by their current vendor, Kurin about our 510(k) clearance status, and it has gone to their risk management for discussion.
>
> And they had concluded that only 510(k) cleared devices would be used in the hospital and that it was risky for them to bring in Steripath, so they were not going to move forward.
>
> Q . . . Did you have any understanding as to why they thought it was risky?
>
> A She had made a statement that only 510(k) cleared devices are used within their hospital . . ..

(Stuckert Dep. at 112-13.) The testimony shows the customer wanted to purchase a 510(k)-cleared product. Reading the testimony in the light most favorable to Kurin, it does not suggest the customer was confused about the significance of FDA registration and listing as opposed to 510(k) clearance.

Third, Kurin cites to the Rupp Article. In the context of discussing the UNMC Institutional Review Board's requirement of informed consent to participate in the study, the article states, "It could be argued that in a nonsignificant risk study, informed consent should not be required to employ an FDA-registered and listed device." (Rupp Article at 6 (including link to Steripath's registration and listing).) Kurin argues this statement "impl[ies] that such registration and listing indicated a lack of risk to the patient" and that the authors concluded the study involved "nonsignificant risk" because Steripath was FDA registered and listed. (Kurin Opp'n at 21.) The link to Steripath's registration and listing in the article enables the reader to review what is entailed by the registration and listing. To support Kurin's argument, the jury would have to find that the authors misunderstood FDA registration and listing to include an assurance of medical device safety, and that they based their statement about nonsignificant risk on this erroneous

understanding. Viewed in the light most favorable to Kurin, the Rupp Article does not support these inferences.

Kurin also relies on Mr. Shapiro's expert opinion that Magnolia's statement of Steripath's FDA registration and listing was misleading because the average Steripath purchaser, although generally familiar with FDA regulation of devices, would not be familiar with the limited significance of registration and listing, and would therefore likely have understood the statement to mean that the FDA evaluated and accepted Magnolia's significant claims regarding Steripath's performance. (Shapiro Rept. at 4-5, 12, 16.) Mr. Shapiro's opinion is not based on a customer survey, which is how "[r]eactions of the public are typically tested" in Lanham Act cases, *see Southland Sod Farms*, 108 F.3d at 1140, but on his experience as an attorney representing medical device manufacturers before the FDA. (Shapiro Dep. at 122-23, 137-38, 140, 162-65.)

Magnolia moves to strike Mr. Shapiro's opinion as unreliable and unsupported pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Kurin, as the proponent of expert testimony, bears the burden to establish its admissibility. *United States v. 87.98 Acres*, 530 F.3d 899, 904 (9th Cir. 2008).

Rule 702 provides the following requirements for admissibility of opinion testimony:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

"An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed." Fed. R. of Evid. 703. "Federal Rules 702 and 703 grant expert witnesses testimonial latitude unavailable to other witnesses on the 'assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline.'" *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 148 (1999) (quoting *Daubert*, 509 U.S. at 592).

Daubert held that Rule 702 "imposes a special obligation upon a trial judge to 'ensure that any and all scientific testimony . . . is not only relevant, but reliable.'" *Kumho Tire*, 526 U.S. at 147 (quoting *Daubert*, 509 U.S. at 589). This inquiry "must be 'tied to the facts' of a particular 'case.'" *Kumho Tire*, 526 U.S. at 150 (quoting *Daubert*, 509 U.S. at 591).

Daubert articulated four factors to evaluate the reasoning or methodology underlying scientific testimony:

-- Whether a theory or technique can be (and has been) tested;

-- Whether it has been subjected to peer review and publication;

-- Whether, in respect to a particular technique, there is a high known or potential rate of error and whether there are standards controlling the technique's operation; and

-- Whether the theory or technique enjoys general acceptance within a relevant scientific community.

Kumho Tire, 526 U.S. at 149-50. This inquiry is flexible, and the list of factors was not intended to be exhaustive. *Daubert*, 509 U.S. at 593, 594-95; *Kumho Tire*, 526 U.S. at 151. "[T]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony. *Kumho Tire*, 526 U.S. at 150. Nevertheless, "*Daubert's* general principles" apply to all expert testimony, including experience-based testimony. *Id.* at 149, 151.

Kurin argues that Mr. Shapiro's opinion need not be based on scientific knowledge to be admissible because an expert's opinion can be properly based on relevant experience. *See Fortune Dynamic, Inc. v. Victoria's Secret Stores Brand Mgt, Inc.,* 618 F.3d 1025, 1043 (9th Cir. 2010). According to Kurin, Mr. Shapiro's opinion is admissible because he "has 25 years of experience regarding FDA compliance." (Kurin Opp'n at 34.) As a result, he has "become expert in FDA's medical device regulations as applied to the device industry and device users, as well as FDA's administrative practice and industry custom with regard to such regulations." (Shapiro Rept. at 3.) However, "compliance with FDA requirements is not at issue in this litigation." (Magnolia Ex. 7 (Expert Rebuttal Report of Jeffrey K. Shapiro ("Shapiro Rebuttal")) at 7.)

Mr. Shapiro is "offered to opine on the impact of [Magnolia's] statements." (Kurin Opp'n at 34.) He has no experience or expertise in market research or marketing and did not review any market surveys to form his opinion. (Shapiro Dep. at 137-38, 140, 164-65.) His experience and exposure to the relevant market comes from his work as an "attorney in private practice . . . focused on representing medical device manufacturers before the [FDA]." (Shapiro Rept. at 3.) His opinion is about the perception and reaction of Magnolia's customers and "average purchaser[s] of Steripath." (*See* Shapiro Rept. at 12, 16.) However, Mr. Shapiro only infrequently interacts with purchasers of medical devices. (Shapiro Dep. at 164; *see also id.* at 47.) His opinion about Steripath purchasers' perception therefore cannot reliably be based on his experience.

Kurin further argues that an expert's opinion does not have to be based on personally-conducted surveys to be admissible but can be based on review of "incident reports and the literature on a particular topic." (Kurin Opp'n at 36 (citing *Metabolife Int'l, Inc. v. Wornick*, 264 F.3d 832, 841 n.13 (9th Cir. 2001).) Mr. Shapiro has not reviewed any literature on the topic of medical device purchasers' perception of statements about FDA regulatory status, or any "incident reports." His report does not identify any examples of Magnolia's advertising regarding Steripath's FDA registration and listing. (Shapiro Dep. at 107.) His opinion is based on review of the references to

Steripath's regulatory status in the Rupp Article and the Arenas Presentation, which are discussed above. (Shapiro Rept. at 11-12.) From these documents, Mr. Shapiro concluded that "even experts in blood culture contamination field do not understand that the Steripath has not been reviewed or evaluated by the FDA." (Shapiro Rept. at 12.) He did not know whether Drs. Rupp or Arenas would be involved in purchasing a device like Steripath. (Shapiro Dep. at 137-38.) He reasoned, "based on human nature, my knowledge of the industry, . . . what was said in the articles," that "if they are confused, I would imagine that there are many, many others who would be confused, as well." (Shapiro Dep. at 138-39.) As discussed above, neither article suggests that the authors were confused about the limited significance of FDA registration and listing. Accordingly, Mr. Shapiro's opinion that Steripath purchasers were confused is not based on sufficient facts or experience.

For the foregoing reasons, Mr. Shapiro's opinion is not admissible. Magnolia's motion to exclude it is granted. Kurin has not presented sufficient evidence to raise a genuine issue of material fact on its contention that Magnolia's representation of Steripath's FDA registration and listing is misleading because it creates a false impression regarding Steripath's regulatory status

b. <u>False Impression Regarding Compliance with QSR and GMP Regulations</u>

While not a part of his report or rebuttal report (*see also* Shapiro Dep. at 142), Mr. Shapiro opined at his deposition that the statement in one of the slides in Magnolia's new hire training presentation, that Steripath's FDA registration and listing "indicat[es] compliance with all relevant QSR and GMP regulations" (Magnolia Ex. 8 at Bates no. MMT-0000227), is false and misleading. "While it is possible that a registered and listed product is manufactured in a QSR/GMP compliant manner" (Kurin Opp'n at 22), registration and listing does not necessarily mean that the device is compliant. (Shapiro Dep. at 292-93.) Magnolia counters that the registration and listing indicates compliance with the regulations because it means that "the manufacturer has accepted the

responsibility to comply." (Magnolia Mot. at 18.) It further argues that in this case, Steripath was in fact compliant because it passed FDA inspection.

It is undisputed that, unless exempted by the FDA, marketed medical devices, regardless of their classification as Class I, II or III, must comply with FDA's General Controls. (Feigal Rept. at 11-12, 14.) General Controls require, among other things, registering the company and listing the product, as well as compliance with the manufacturing quality system regulations ("QSR"), including Good Manufacturing Practices requirements ("QSR" and "GMP," respectively). (*Id.* at 12, 14; *see also* 21 C.F.R. § 820.1 (GMP requirements included in the QSR).) Medical device manufacturers must develop procedures that address the various elements of these requirements for their specific devices and facilities. (Feigal Rept. at 14-15; Shapiro Dep. at 131 (medical device manufacturers responsible for full compliance).)

At most, in the abstract, the statement that registration and listing "indicat[es]" compliance (Magnolia Ex. 8 at Bates no. MMT-0000227) is ambiguous in the regulatory context where compliance is required. However, it is undisputed that the FDA inspected Magnolia for compliance. Manufacturing facilities are periodically inspected by the FDA. (Feigal Rept. at 22.) The inspections are one way the FDA ensures compliance with the QSR. (Shapiro Dep. at 130.) Magnolia was subject to two inspections focused on procedures for compliance with FDA's [QSRs]," including a comprehensive inspection in 2017. (Shapiro Rebuttal at 5-6.) Mr. Shapiro opined that this does not mean that the FDA "closely evaluated Magnolia's compliance," but only that "they looked at compliance with some applicable regulations" and that, in any event, the FDA's "position" is that "if we don't find something objectionable, that doesn't mean you're in compliance." (Shapiro Dep. at 130-31.)

Mr. Shapiro is not offered to testify about Magnolia's compliance with FDA requirements (*see* Kurin Opp'n at 34), and he offered no opinion on that point in his report, rebuttal or testimony (*see, e.g.*, Shapiro Rebuttal at 7). To successfully oppose Magnolia's motion on the issue whether the statement in the training materials was false

or misleading in the context of the facts of this case, Kurin must come forward with evidence to raise a genuine issue of material fact regarding Magnolia's noncompliance. Mr. Shapiro's opinion that a comprehensive inspection with no finding of violations does not *necessarily* mean compliance does not meet this burden. Magnolia's motion is therefore granted with respect to this issue.

c. Misbranding Under FDA Regulations

Finally, Kurin points to 21 C.F.R. § 807.39 in support of its argument that the statements in the Rupp Article, Arenas Presentation and the new hire training slide are misleading. The regulation provides:

> Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding.

As discussed above, none of the three statements Kurin relies upon create an impression of FDA approval. Accordingly, Kurin has not raised a genuine issue of material fact.

d. Conclusion

Magnolia's motion is granted as to Kurin's claims of false advertising based on statements that Steripath was registered and listed with the FDA.

2. Reliability of Controlled Clinical Study Results

Kurin alleges that Magnolia's use of controlled clinical study results, including the Rupp Study results, in its advertising is false because controlled clinical studies do not reflect "real-world conditions." (*See, e.g.*, Compl. at 6.) For the reasons discussed in section A.1.a. above, Kurin has not presented sufficient evidence to raise a genuine issue of fact regarding its claim that referencing controlled clinical study results is literally false or misleading. Kurin agrees that Magnolia's controlled clinical study results are "good data in verifying the efficacy of the device." (*See* Heindel Dep. at 119-23.) Accordingly, Kurin cannot proceed with its false advertising claims on this theory.

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3. 92% Reduction in Blood Culture Contamination

Kurin's allegation of falsity of Magnolia's claims that Steripath has been clinically proven to decrease false positives by 92% with a sustained contamination rate of 0.2% are based on the fact that some of Steripath efficacy studies report less favorable results. (Compl. at 5-6.) As discussed in section A.1.b. above, the statement is supported by clinical studies and Magnolia does not claim that *all* of its clinical studies achieved these results. Kurin has presented no evidence to the contrary in support of its own motion or in opposition to Magnolia's motion. It has therefore not raised a genuine issue regarding literal falsity of this claim.

Kurin argues alternatively that if not literally false, the claim is misleading because it reasonably could be misunderstood as representative of the results of other studies. (*See* Kurin Opp'n at 16.) "Even if an advertisement is not literally false, relief is available under Lanham Act §43(a) if it can be shown that the advertisement has misled, confused, or deceived the consuming public" *Southland Sod*, 108 F.3d at 1140. Kurin has presented no evidence that its customers were, or were likely to be, misled by Magnolia's claim of 92% reduction. This is particularly unlikely given the customers' sophistication and access to clinical studies themselves. (*See* discussion in section 1., *supra*.) Accordingly, Kurin has not raised a genuine issue of material fact with respect to this claim.

4. Average Reduction of 93%

Kurin attacks Magnolia's claims of 93% average reduction in blood culture contamination,[20] and argues such claims are literally false.[21] (Kurin Opp'n at 9.) As discussed in section A.1.c. above, Kurin presented sufficient evidence to establish literal

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[20] This claim is not alleged in the complaint.

[21] Although Kurin begins its opposition with a heading that the statement is "Literally False and Misleading," it only argues literal falsity. (*See* Kurin Opp'n at 9-10.)

falsity insofar as Magnolia advertised that the 93% average was based on "multiple publications and peer-reviewed published studies." Magnolia argues for summary judgment in its favor because Kurin cannot raise a genuine issue of material fact with regard to every element of this claim, including causation.

To prevail on a false advertising claim under the Lanham Act, a plaintiff must prove proximate cause, *i.e.*, injury "flowing directly from the deception wrought by the defendant's advertising." *Lexmark.*, 572 U.S. at 133; *see also id.* at 140. This "occurs when deception of consumers causes them to withhold trade from the plaintiff." *Id.* at 133. Unlike "actual cause or cause in fact," proximate cause denotes a cause with "some direct relation between the injury asserted and the injurious conduct alleged." *Paroline v. United States*, 572 U.S. 434, 445 (2014). It must flow directly from the advertisements which are shown to be false. *See Lindy Pen Co., Inc. v. Bic Pen Corp.*, 982 F.2d 1400, 1407 (9th Cir. 1993), *abrogated on other grounds by SunEarth, Inc. v. Sun Earth Solar Power Co.*, 839 F.3d 1179 (2016); *Harper House, Inc. v. Thomas Nelson, Inc.*, 889 F.2d 197, 210 (9th Cir. 1989), *William H. Morris Co. v. Group W, Inc.*, 67 F.3d 310 (9th Cir. 1995) (unpub. disp.).

Kurin argues a deceptive effect is presumed when a statement is literally false. (Kurin Opp'n at 27 n.11.) A presumption applies when a defendant *intentionally* misleads consumers. *William H. Morris*, 66 F.3d at 258; *Harper House,* 889 F.2d at 209. Kurin has presented no evidence or argument relating to Magnolia's intent. Alternatively, Kurin argues a presumption may apply if the parties are direct competitors. (Kurin Opp'n at 27.) Such presumption applies 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.com, Inc. v. Edriver, Inc.*, 653 F.3d 820, 831 (9th Cir. 2011) (emphasis in orig.). The presumption does not apply "when advertising does not directly compare defendant's and plaintiff's products." *Id.* None of Kurin's evidence involving Magnolia's claim of average 93% reduction makes the claim in a comparative advertising context. (*See* Kurin Exs. 1-7.) Accordingly, neither presumption applies.

Kurin also relies on the testimony of its CEO Bob Rogers and its damages expert Patrick Kennedy.[22] (Kurin Opp'n at 28.) Mr. Rogers testified generally that Magnolia's marketing harmed Kurin's sales. (Rogers Dep. at 107.)[23] He did not state a basis for his implied opinion that Magnolia's marketing caused any lost sales and did not establish a causal connection between Magnolia's representation of 93% average reduction and lost sales. It is therefore insufficient to raise a genuine issue of fact regarding causation.

Mr. Kennedy, an economist, was offered on the issue of Kurin's lost profits and corrective advertising. (Magnolia Ex. 4 ("Kennedy Rept.") at 14; Kurin Opp'n at 28.) He offered no opinions regarding the causal link between Magnolia's advertising and Kurin's claimed damage, but instead relied on Kurin's assertions in this regard. (*Id.* at 14-18.)

For example, Mr. Kennedy prefaced his opinion about lost profits with, "Kurin asserts that the impact of Magnolia's false advertising is demonstrated in Kurin's inability to achieve its sales projections." (*Id.* at 15.) His lost profits opinion is premised on Kurin's representation that Kurin "felt it was unable to obtain [certain sales] *because of* Magnolia's false advertising," and that "its ability to obtain [certain] customers was impaired, and it suffered a delay in obtaining customers *due to* the alleged false advertising." (*Id.* at 16-17 (emph. added).) Mr. Kennedy's corrective advertising opinions appear to be based on the same representations, as he offers no other basis for causation. (*See id.* at 17-18 (implying that "market perceptions about Magnolia's testing and FDA status [were] caused by alleged false advertising").) Kurin has presented no evidence to support the assertions Mr. Kennedy relied upon in his report. Mr. Kennedy did not rely on any consumer surveys or speak to any Kurin or Magnolia customers to

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[22] Although Kurin also references Mr. Shapiro (Kurin Opp'n at 29), no citation to evidence or discussion of Mr. Shapiro's opinions is provided.

[23] Excerpts are found in docs. no. 65-23 and 66-11.

establish a nexus between Kurin's claimed lost sales and Magnolia's advertising. (Kennedy Dep. at 50-53.)[24]

Mr. Kennedy also did not form an opinion whether Magnolia's representations regarding reduction in contamination or false positives increased Steripath sales. (Kennedy Dep. at 137-38.) Further, he was unable to evaluate if any of Kurin's potential customers who declined to purchase Kurin Lock did so, not in favor of Magnolia, but because they decided not to change their existing practice (Kennedy Dep. at 61-64), or if they declined before Magnolia circulated any false advertising or after Magnolia ceased (*id.* at 79-81). Although he acknowledged that Magnolia's advertising claims changed over time, Dr. Kennedy's opinions do not attribute Kurin's claimed lost sales or corrective advertising to any particular claim, but to all alleged false claims combined. (Kennedy Dep. at 77-84; *see also id.* at 82-83 (did not isolate specific misrepresentations or "determine[] the period of time during which they were utilized by Magnolia"), 84 ("I haven't made an apportionment to carve out any of those misrepresentations," "that's a deeper factual inquiry").)

At most, Mr. Kennedy offers to make a temporal correlation between Kurin's sales and Magnolia's advertising. In this regard, he stated, for example, that "in 2018, when Magnolia was most widely asserting the disputed rates of reduction in false positives, Kurin fell materially below its sales projections," and "I understand that since Magnolia changed some of its advertising, Kurin has been able to . . . gain sales." (Kennedy Rept. at 15-16; *see also* Kennedy Dep. at 77-79.) He could make lost profits calculations based on the temporal connection provided he had Magnolia's financial records. (Kennedy Rept. at 16; Kennedy Dep. at 79-80 (he had not been able to do it).) However, a temporal relationship alone is insufficient to establish proximate cause. *Rexall Drug Co. v. Nihill*,

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[24] Excerpts are found in doc nos. 65-29 and 67-3.

276 F.2d 637, 643-44 (9th Cir. 1960); *see also Verisgn Inc. v. XYZ.COM LLC*, 848 F.3d 292, 300-01 (4th Cir. 2017).

Kurin maintains causation is established because its actual sales approximated sales projections in 2017, but significantly diverged in 2018 after Magnolia's inception of its allegedly misleading advertising. (Kurin Opp'n at 29, citing Kennedy Rept. at 15-16.) However, Kurin's Chief Financial Officer conceded that financial projections, particularly for a start-up company like Kurin, "change all the time. The minute you put them down on paper, they are wrong." (Covington Dep. at 78-80.)[25] The relationship between the admittedly unreliable projections and actual sales therefore does not provide a sufficient basis for causation to raise a genuine issue of fact.

Because Mr. Kennedy has not provided any opinions regarding causation, and Kurin's other evidence is insufficient to raise a genuine issue of material fact regarding causation, the Court need not address Magnolia's request to partially exclude Mr. Kennedy's opinions pursuant to Federal Rule of Evidence 702 and *Daubert.* (*See* Magnolia Mot. at 37.)

Finally, Kurin maintains that even if it cannot raise a genuine issue of fact regarding causation necessary for monetary relief, it is nevertheless entitled to injunctive relief. For the reasons discussed in section A.1.c., above, Kurin has not presented sufficient evidence to raise a genuine issue of fact regarding its entitlement to injunctive relief.

Kurin has failed to raise a genuine issue of material fact with respect to proximate cause or injunctive relief. Magnolia's motion for summary adjudication is therefore granted with regard to the false advertising claim arising from the claim that Steripath reduced the contamination rate by an average of 93%.

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[25] Excerpts are found in doc. no. 65-27.

5. Steripath (Virtually) Eliminates Contamination

Kurin contends Magnolia's claims that Steripath eliminates or virtually eliminates false positive results are literally false.[26] (Kurin Opp'n at 11-12.) For the reasons stated in section A.2. above, the statement that Steripath "eliminates" false positives or blood culture contamination is nonactionable puffery. In addition, Kurin has presented no evidence either in support of its own motion or in opposition to Magnolia's motion to contradict the evidence of studies showing that Steripath reduces blood culture contamination rate below 1% or tending to show that representing these results as "virtually eliminating" contamination is literally false. Accordingly, Kurin has failed to raise a genuine issue of material fact on this issue.

6. Statements About Kurin Lock

Kurin argues that in its employee training materials Magnolia made literally false statements about Kurin Lock's effectiveness.[27] (Kurin Opp'n at 13.) Kurin does not argue the statements were misleading and has presented no evidence of actual deception or likelihood of deception. (*See id*. at 12-13.)

It is undisputed that Kurin Lock diverts 0.15mL and Steripath diverts 1.5–2.0 mL of blood into a separate chamber before a second, sterile blood flow path is opened as the blood sample collected for testing. In its employee training materials, Magnolia states:

> **Effective Diversion Volume**
>
> - **Steripath**: Diverts initial 1.5-2.0 mL of blood, which is known to commonly contain contaminants. This diversion volume has been clinically proven in peer-reviewed published studies to virtually eliminate blood culture contamination. All peer-reviewed published data on the use of Initial Specimen Diversion for reducing blood culture contamination supports a

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[26] In its complaint, Kurin claims that the statements are "false and misleading" (Compl. at 6-7); however, the theory that the statements were misleading is not argued in opposition to summary judgment.

[27] This claim is not alleged in Kurin's complaint.

required diversion volume of 1.5-2.0 mL, as with Steripath.

- **Kurin Lock**: Redirecting such a minute volume (0.15 mL) of blood is not clinically proven effective.

(Magnolia Ex. 3 (emphases in original).) The training materials also include a statement that there is "[n]o peer-reviewed published or presented clinical trial data supporting a significant sustained reduction in blood culture contamination" relative to the Kurin Lock. (*Id.*)

Magnolia contends its statements are supported by a study published in 2010 in the *Journal of Clinical Microbiology*, which demonstrated that between 0.5mL and 2.0 mL "is adequate diversion volume to significantly reduce" blood culture contamination. (Magnolia Ex. 32 (Richard G. Patton et al., Innovation for Reducing Blood Culture Contamination: Initial Specimen Diversion Technique); Roberts Rept. at 14.) Magnolia's Vice President of Sales testified that at the time the training materials were created he was not aware of any "published peer-reviewed evidence" supporting the effectiveness of 0.15 mL diversion volume. (Stuckert Dep. at 143-44.)

Magnolia's Chief Commercial Officer Robert Gerberich testified to the same effect. (Gerberich Dep. at 139-40, 143-44.) He was aware of a poster study from the June 2018 Association for Professionals in Infection Control and Epidemiology Annual Conference, which was not peer-reviewed and only posted, not presented. (*Id.* at 140; *see also* Roberts Rept. Appx C.) It was conducted at Bayfront Health in St. Petersburg, Florida and was not a controlled clinical study. (Gerberich Dep. at 140-41; *see also* Roberts Rept. Appx C.) There was also a poster study from Crouse Hospital in Syracuse, New York shown at a regional conference in Louisiana, however, poster studies at such meetings are not reviewed before acceptance for presentation. (*Id.* at 142-43.)

To the extent Kurin relies on Mr. Gerberich's testimony, it does not raise a genuine issue of material fact. It shows, consistent with Magnolia's statement, that Mr. Gerberich was not aware of any "peer-reviewed published or presented clinical data" or any

"clinical" studies supporting Kurin Lock's effectiveness when the training materials were created, because the summer 2018 poster was not presented, and the presentation in Louisiana was not reviewed.

In February 2019, a Kurin Lock effectiveness study from Hartford Healthcare in Hartford, Connecticut was published in *Connecticut Medicine*, a peer-reviewed journal. (Roberts Rept. at 17 & App'x C.) It was published nearly a year after the commencement of this action. Kurin has not presented any evidence to show that the training presentation slide was still in use at that time, or that any of the statements in the slide were made to a potential customer at any time. Accordingly, the article does not raise a genuine issue of material fact regarding Magnolia's statements about Kurin Lock.

7. Product Superiority Claims

Kurin attacks a number of Magnolia's product superiority claims as literally false and misleading. (*See* Compl. at 6-7.) Magnolia argues it is entitled to summary judgment on four of these claims because they are non-actionable puffery.

"While product superiority claims that are vague or highly subjective often amount to nonactionable puffery, misdescriptions of specific or absolute characteristics of a product are actionable." *Southland Sod*, 108 F.3d at 1145. Kurin argues that Magnolia's statements are not puffery because they contain misdescriptions of specific product characteristics which are objectively verifiable. (Kurin Opp'n at 18.)

First, Kurin alleges falsity of Magnolia's claim that "the use of Steripath represents simple and effective 'forced compliance.' With built-in best practices that require minimal training to implement, Steripath provides quality assurance 'in-a-box.'" (Magnolia Mot. at 27 (quoting Compl. ¶42(c)).) Magnolia argues this statement is puffery because the reference to "simple and effective" is general and subjective. (Magnolia Mot. at 27-28.) However, Kurin's claim is directed to another part of the statement. It claims the statement is false because Steripath does not "force compliance." (Compl. at 6-7.) This appears to be a description of Steripath's specific characteristic and is therefore not puffery.

Second, Kurin alleges falsity of advertising that "Steripath will '. . . significantly improve specimen integrity and the accuracy, consistency, and predictability of critical laboratory tests.'" (Magnolia Mot. at 27 (quoting Compl. ¶42(d)).) Contrary to Kurin's contention (*see* Compl. at 7), the statement does not refer to the accuracy of the lab work, but the integrity of the blood sample and the resulting accuracy of the test results. Magnolia argues the statement is puffery because stating that Steripath will "significantly improve" the accuracy of test results is vague and general. The Court agrees.

Third, Kurin alleges falsity of the claim that "Steripath's proprietary vein to bottle system technology is the fastest, most effective, and economical solution that marries technique and technology." (Magnolia Mot. at 27 (quoting Compl. ¶43(b)).) Kurin argues that the use of a superlative, *i.e.*, that Steripath is "the fastest, most effective, and economical solution" converts the statement from bluster by exaggeration to an absolute description of product characteristics. (Kurin Opp'n at 18 ("the manufacturer cannot advertise that the product is the fastest, unless it actually is").) This argument is precluded by *Cook, Perkiss and Liehe, Inc. v. Northern California Collection Service, Inc.*, 911 F.2d 242, 246 (9th Cir. 1990) ("the best technology, lower rates, and better customer service" and implied claim of "lower costs and superiority over" competitor held to be puffery). Magnolia's statement in this instance is a general and exaggerated claim constituting puffery.

Finally, Kurin alleges falsity of advertising that "Steripath is the 'only vein-to-bottle closed blood culture collection system that is proven to virtually eliminate preventable error of blood culture contamination and false-positive results for sepsis.'" (Magnolia Mot. at 27 (quoting Compl. ¶43(c)).) Kurin alleges this statement is false because Steripath is not a "closed system." (Compl. at 7.) Because the claim is directed to a specific product characteristic, it is not puffery.

Magnolia's motion with respect to the falsity of the product superiority claims is granted as to Paragraphs 42(d) and 43(b) of the complaint because the statements were nonactionable puffery. Although the statements in Paragraphs 42(c) and 43(c) are not

puffery, the motion is granted because Kurin has failed to raise a genuine issue of material fact regarding proximate cause or injunctive relief. (*See* discussion in section 4., *supra*.)

8. Conclusion

Based on the foregoing, Magnolia's motion for summary judgment is granted.

C. Kurin's Motion for Summary Judgment on Magnolia's Counterclaims

In its counterclaim Magnolia alleges that several categories of Kurin's advertising claims violated the Lanham Act and California's FAL. (*See* Countercl. at 12-18 (for example, statements that Kurin was first to market, product superiority claims, claims regarding Kurin Lock's capabilities, clinical data representations).) Kurin moves for summary judgment on all claims. For the reasons stated below, the motion is denied.

There is a marked difference in this case between the summary judgment briefing of the claims alleged in the complaint and the counterclaims. Kurin's motion pivots on the conclusion that none of its advertising claims is literally false. (Kurin Mot. at 18.) The argument is made in one paragraph without citation to any exhibits or quotation of the actual advertising language in context. *Southland Sod*, 108 F.3d at 1139 ("When evaluating whether an advertising claim is literally false, the claim must always be analyzed in its full context."). From there, Kurin reasons that all alleged false advertising statements are at best misleading, thus requiring Magnolia to come forward with sufficient evidence to raise a genuine issue of material fact on every element of false advertising as to every advertising claim alleged to be false. (Kurin Mot. at 18.) Kurin concludes it is entitled to summary judgment because Magnolia has no evidence. (*Id.* at 18-23.)

In its opposition, Magnolia offers only argument supported by citations to its counterclaims. Under normal circumstances, this is insufficient to oppose a summary judgment motion. *See Nissan Fire & Marine Ins.*, 210 F.3d at 1103 ("If . . . a moving party carries its burden of production, the nonmoving party must produce evidence to support its claim or defense."); *see also Celotex*, 477 U.S. at 324 (the nonmoving party

must "go beyond the pleadings and by [its] own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial.").

However, Kurin has not carried its burden as the moving party. Its conclusion that none of the alleged false advertising claims are literally false is unsupported. Although at trial Kurin would not bear the burden of proof on the counterclaims, as the moving party on summary judgment it must "produce affirmative evidence . . . negating an essential element of the nonmoving party's case." *Nissan Fire & Marine Ins.*, 210 F.3d at 1105-06. Kurin has offered none. "If a moving party fails to carry its initial burden of production, the nonmoving party has no obligation to produce anything, even if the nonmoving party would have the ultimate burden of persuasion at trial." *Id.* at 1102-03; *see also Adickes*, 398 U.S. at 160. Accordingly, Magnolia may defeat Kurin's motion without producing anything in opposition.

The rest of Kurin's motion is based on the assertion that Magnolia has no evidence. (Kurin Mot. at 18-23; *see also id.* at 19.) Although the moving party may meet its initial burden by "pointing out to the district court . . . that there is an absence of evidence to support the nonmoving party's case," "simply . . . saying that the nonmoving party has no such evidence" is not enough. *Nissan Fire & Marine Ins.*, 210 F.3d at 1106. What is required is evidence that the opposing party has no evidence, for example, attaching the non-moving party's answer to interrogatories admitting that he or she has no witnesses or other evidence to prove a material issue. *See id.* at 1105 (discussing *Celotex*, 477 U.S. at 320). Kurin has provided no evidence in support of its summary judgment motion, and therefore cannot force Magnolia to produce evidence in opposition. *Nissan Fire & Marine Ins.*, 210 F.3d at 1102-03. "In such a case, the nonmoving party may defeat the motion for summary judgment without producing anything." *Id.* at 1103.

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For the reasons stated above, Kurin's motion for summary judgment on Magnolia's counterclaims is denied.

IT IS SO ORDERED.

Dated: July 20, 2020

Hon. M. James Lorenz
United States District Judge