UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

IMPRIMISRX, LLC,

Plaintiff,

v.

OSRX, INC.; OCULAR SCIENCE, INC.,

Defendants.

Case No. 21-cv-01305-BAS-DDL

ORDER:

(1) DENYING DEFENDANTS' MOTION TO EXCLUDE PLAINTIFF'S WITNESSSES (ECF No. 189-1);

(2) GRANTING DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT (ECF No. 168-1);

AND

(3) GRANTING IN PART AND DENYING IN PART PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT (ECF No. 171-1)

Before the Court are two motions for partial summary judgment by the parties and a motion by Defendants to exclude belatedly identified witnesses. (ECF Nos. 168-1, 171-1, 189-1.) Defendants OSRX, Inc. and Ocular Science, Inc. filed a motion for partial summary judgment with respect to Plaintiff ImprimisRx, LLC's false advertising claims and their affirmative defense of unclean hands. (ECF No. 168-1.) Plaintiff ImprimisRx filed a motion for cross summary judgment with respect to its false advertising claims

against Defendants and with respect to Defendants' false advertising counterclaims. (ECF No 171-1.) Defendants also filed a motion to exclude twelve witnesses identified in Plaintiff's amended witness disclosures following the close of fact discovery. (ECF No. 189-1).

For the following reasons, the Court **DENIES** Defendants' motion to exclude Plaintiff's belatedly identified witnesses and reopens fact discovery solely to allow for the deposition of these witnesses, **GRANTS** Defendants' motion for partial summary judgment, and **GRANTS IN PART AND DENIES IN PART** Plaintiff's motion for partial summary judgment.

BACKGROUND

I. Factual and Regulatory Background

Both Plaintiff and Defendants are compounding pharmacies that focus on medications used in optometry and ophthalmology. Compounding is the practice of combining, mixing, or altering ingredients of an existing drug to create a product tailored to the needs of a specific patient. (ECF No. 171-1 at 8.) Ordinarily, the Federal Food, Drug, and Cosmetic Act ("FDCA") requires drug-makers to obtain approval to sell pharmaceutical products under extended, rigorous approval guidelines. However, Sections 503A and 503B of the FDCA provide exceptions from those approval guidelines for compounded drugs under certain conditions. There are two versions of compounding pharmacies under these exceptions: Section 503A pharmacies fill prescriptions for individual patients and Section 503B pharmacies produce compounded products in large quantities that are not necessarily tied to a specific patient. Plaintiff ImprimisRx operates both a Section 503A pharmacy and a Section 503B pharmacy. (ECF No. 171 at 9.) Defendants OSRX and Ocular Science operate only a Section 503A pharmacy. (*Id.* at 10.)

Section 503A allows for drugs compounded "for an identified individual patient . . . [that are] necessary for the identified patient" to be exempted from the typical FDCA drug-approval requirements if certain conditions are met. 21 U.S.C. § 353a. This exemption

applies where: (1) the drug compounding occurs after the receipt of a valid, individual prescription; or (2) the drug compounding occurs before the receipt of a valid, individual prescription "based on a history of . . . receiving valid prescription orders for the compounding of the drug product" within an "established relationship" between the compounding pharmacy and the prescriber. *Id.*

Among other conditions, Section 503A also requires compliance with the "applicable United States Pharmacopeia ("USP") . . . monograph if one exists, and the [USP] chapter on pharmacy compounding." USP General Chapter 797 "describes the minimum standards to be followed when preparing compounded sterile human and animal drugs" including "ophthalmic dosage forms." USP Chapter 797 § 1. USP Chapter 797 provides numerous regulations and procedures that must be followed including garbing, labeling, cleaning, monitoring, and testing requirements. Violations of the sterile manufacturing requirements of USP Chapter 797 also imply non-compliance with Section 503A of the FDCA.

Section 503B provides an exception to the FDCA's drug approval guidelines for bulk compounded drug products sold to practitioners and hospitals as "office stock" to be available for use on an as-needed basis. 21 U.S.C. § 353b. These outsourcing facilities are exempted from the FDCA's premarket approval requirements if eleven statutory criteria are met. *Id.*

II. Procedural Background

The Court addresses Defendants' motion to exclude Plaintiff's belatedly identified witnesses and the parties' cross motions for summary judgment on false advertising claims brought under the Lanham Act, 15 U.S.C. §1125 (a). On July 20, 2021, Plaintiff commenced this action alleging claims of false advertising, trademark infringement, false designation of origin, common law unfair competition, copyright infringement, and violation of California's Unfair Competition Law. (ECF No. 1.) On April 14, 2023, ImprimisRx filed the operative Third Amended Complaint. (ECF No. 145.)

Relevant to the motions before the Court, Plaintiff asserts that Defendants engaged in false advertising in violation of the Lanham Act by: claiming they operate in compliance with Section 503A of the FDCA ("Section 503A Compliance Claims"); claiming their products "are safe and effective, and appropriate for the treatment of certain maladies" ("Safety and Efficacy Claims"); claiming studies show the safety and efficacy of their products ("Study Claims"); claiming their products can be used to treat certain diseases, such as glaucoma, or used as LASIK drops, when they cannot ("Disease Use Claims"); and failing to disclose contraindications associated with their drugs ("Contraindications Claims"). In its Opposition to Defendants' motion, Plaintiff clarified it does not intend to pursue its Safety and Efficacy Claims or Study Claims at trial but does intend to pursue its Section 503A Compliance, Disease Use, and Contraindications Claims at trial. (ECF No. 203 at 10.) Accordingly, the Court does not review Plaintiff's Safety and Efficacy Claims or Study Claims here.

On May 13, 2022, Defendants filed their Answer and Counterclaims to Plaintiff's Amended Complaint which asserted four false advertising counterclaims. (ECF No. 30.) Defendants contend Plaintiff engaged in false advertisements through: statements by Mark L. Baum, the CEO of ImprimisRx's parent company, claiming ImprimisRx is "compliant with highest quality standards" and is "100% dedicated to patient safety and regulatory compliance" ("Baum Claims"); statements in a video by John Saharek, ImprimisRx's president, that Plaintiff uses "strict sterile manufacturing processes" where "[e]ach formulation is properly labeled" and then "approved using validated and stringent testing requirements" ("Saharek Claims"); statements on ImprimisRx's website that ImprimisRx "provides sterile compounded formulations you can trust" ("Trust Claims"); and statements that ImprimisRx is compliant with USP standards for its sterility testing, beyond date use, pre-shipment quarantine, and endotoxin testing internal monitoring procedures ("USP Claims"). (ECF No. 152 at 21–22.)

On June 2, 2023, Plaintiff and Defendants filed the present motions for partial summary judgment with respect to Plaintiff's false advertising claims and Defendants'

false advertising counterclaims. (ECF Nos. 168-1, 171-1.) In specific, Plaintiff moves for partial summary judgment on its Section 503 Compliance Claims. (ECF No. 171-1 at 10–11.) Defendants move for cross summary judgment on this claim and Plaintiff's Safety and Efficacy claims. (ECF No. 168-1 at 14.) Additionally, Defendants move for summary judgment on their unclean hands defense. (ECF No. 168-1 at 25–26.) Plaintiff also brings a motion for partial summary judgment on Defendants' false advertising counterclaims.

In addition to the parties' cross motions for summary judgment, the Court considers Defendants' motion to exclude Plaintiff's belatedly identified witnesses. (ECF No. 189-1.) On February 24, 2022, Plaintiff served Rule 26(a) initial disclosures on Defendants. (ECF No. 200 at 6.) On March 2, 2023, the fact discovery window closed. (ECF No. 91.) On April 28, 2023, Kelsey Deschamps, a former OSRX employee, left a voicemail for Plaintiff's counsel claiming she had information that would be pertinent to the litigation. (ECF No. 200 at 7.) Plaintiff was unaware of Deschamps prior to this voicemail. (*Id.*) Twenty days after Deschamps left her voicemail, on May 18, 2023, Plaintiff served amended disclosures adding twelve new witnesses, ten of which are former OSRX employees, including Deschamps. (*Id.* at 8.) Defendants now move to exclude the evidence to be offered by these twelve witnesses. (ECF No. 189-1.)

ANALYSIS

I. Defendants' Motion to Exclude Plaintiff's Witnesses

Defendants move to exclude the twelve witnesses newly identified in Plaintiff's Second Amended Initial Disclosures under Rules 26 and 37 of the Federal Rules of Civil Procedure. (ECF No. 189-1.) Fact discovery for this case was closed March 2, 2023. (ECF No. 91.) On May 18, 2023, Plaintiff served its Second Amended Initial Disclosures identifying the twelve new witnesses, who are all current or former OSRX employees. (ECF No. 189-1 at 6.) Plaintiff contends it was not previously aware of these witnesses or their testimony before Deschamps left a voicemail on April 28, 2023. (ECF No. 200 at 6.)

Federal Rule of Civil Procedure 26(a) requires "a party must, without awaiting a discovery request, provide to the other parties . . . the name and, if known, the address and

telephone number of each individual likely to have discoverable information—along with the subjects of that information—that the disclosing party may use to support its claims or defenses, unless the use would be solely for impeachment[.]" Fed. R. Civ. P. 26(a)(1)(A)(i). Additionally, Rule 26(e) requires:

> "[a] party who has made a disclosure under Rule 26(a)—or who has responded to an interrogatory, request for production, or request for admission—[to] supplement or correct its disclosure or response . . . in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing[.]"

Fed. R. Civ. P. 26(e)(1)(A).

Where "a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). "In addition to or instead of this sanction, the court on motion and after being given an opportunity to be heard" may instead "order payment of the reasonable expenses, including attorney's fees, caused by the failure[,] may inform the jury of the party's failure[,] and may impose other appropriate sanctions[.]" *Id.*

Plaintiff argues it did not violate its Rule 26(a) or (e) discovery obligations because it was previously unaware of Deschamps and amended its disclosures "in a timely manner" once it verified Deschamps's information. (ECF No. 200 at 11–12.) Defendants insist Plaintiff was dilatory by taking three weeks to investigate Deschamps's claims and should have been aware of Deschamps if ImprimisRx had exercised proper diligence in investigating the case. (ECF No. 189-1.)

Amended disclosures served after the close of discovery are presumptively untimely. *See, e.g.*, *Ashman v. Solectron, Inc.*, No. CV 08-1430 JF, 2010 WL 3069314, at *4 (N.D. Cal. Aug. 4, 2010). Here, however, Plaintiff was not aware of Deschamps or any of the belatedly disclosed witnesses and was not aware of the content of their testimony prior to Deschamps recording her voicemail. Rule 26(e) creates a "duty to supplement" but that

duty cannot attach before Plaintiff was aware of the information to be supplemented. *Cf. Luke v. Family Care and Urgent Med. Clinics*, 323 F. App'x 496, 500 (9th Cir. 2009) (noting "[s]upplementation under the Rules means correcting inaccuracies, or filling the interstices of an incomplete report based on information that was not available at the time of the initial disclosure") (quoting *Keener v. United States*, 181 F.R.D. 639, 640 (D. Mont. 1998)). As follows, Plaintiff was not "untimely" in disclosing Deschamps and the other identified witnesses after receipt of her voicemail. *See Dayton Valley Investors, LLC v. Union Pac. R. Co.*, No. 2:08-CV-00127-ECR, 2010 WL 3829219, at *3 (D. Nev. Sept. 24, 2010) (holding "[t]iming is better gauged in relation to the availability of the supplemental information" rather than the timing of the discovery cutoff date).

Even if Plaintiff's disclosure was untimely under Rule 26(e), the Court may decline to impose Rule 37(c)(1) exclusion where the discovery violation was either substantially justified or harmless. *See, e.g.*, *Erhart v. BofI Holding, Inc.*, No. 15-cv-02287-BAS, 2022 WL 84389, at *2 (S.D. Cal. Jan. 7, 2022). The Ninth Circuit "give[s] particularly wide latitude to the district court's discretion to issue sanctions under Rule 37(c)(1)." *Yeti by Molly, Ltd. v. Deckers Outdoor Corp.*, 259 F.3d 1101, 1106 (9th Cir. 2001). Courts consider several factors to determine whether substantial justification or harmlessness exists: (1) prejudice or surprise to the party against whom the evidence is offered; (2) the ability of that party to cure the prejudice; (3) the likelihood of disruption of trial; and (4) bad faith or willfulness in not timely disclosing the evidence. *See Lanard Toys Ltd. v. Novelty, Inc.*, 375 F. App'x 705, 713 (9th Cir. 2010).

In reviewing these factors, the Court does not find bad faith or willfulness in waiting three weeks to disclose these new witnesses. Plaintiff needed sufficient time to verify the new witnesses' proposed testimony and determine it intended to use this information at trial. A three week window to accomplish these tasks is not dilatory and does not amount to bad faith. Further, trial is unlikely to be disrupted as the trial schedule has been vacated in this matter. *Compare Soverns v. Delta Air Lines, Inc.*, No. 20-CV-06258-BLF, 2023 WL 2768431, at *2 (N.D. Cal. Apr. 3, 2023) (holding a belated disclosure harmless where

the disclosures were made months before trial), *with Montalvo v. Am. Family Mut. Ins. Co.*, No. CV-12-02297-PHX-JAT, 2014 WL 2986678, at *7 (D. Ariz. July 2, 2014) (holding disruption to the trial schedule was prejudicial to the moving party). Defendants will not be forced to make "last-minute preparations and decisions on the run" here. *See Ollier v. Sweetwater Union High Sch. Dist.*, 768 F.3d 843, 863 (9th Cir. 2014).

Defendants, however, will be prejudiced if they are unable to depose the newly identified witnesses to understand the extent of their knowledge and their testimony. *See Soverns*, 2023 WL 2768431, at *2. Accordingly, the Court finds that reopening discovery for the sole purpose of allowing Defendants to depose the twelve newly identified witnesses is appropriate. Defendants' motion to exclude these witnesses' testimony is therefore denied and discovery reopened to depose the new witnesses.

II. Summary Judgment

A. Legal Standard

Summary judgment is proper on "each claim or defense" "or the part of each claim or defense" when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is "material" if it might affect the outcome of the suit under the governing law, and a dispute is "genuine" if there is sufficient evidence for a reasonable trier of fact to decide in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

Summary judgment is appropriate if "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . admissions, interrogatory answers, or other materials" show that a "a fact cannot be." Fed. R. Civ. P. 56(c). "[T]he district court may limit its review to the documents submitted for the purposes 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) (quoting *Richards v. Combined Ins. Co. of Am.,* 55 F.3d 247, 251 (7th Cir. 1995)). When

resolving a motion for summary judgment, the court must view all inferences drawn from the underlying facts in the light most favorable to the nonmoving party. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). The court does not make credibility determinations or weigh conflicting evidence. *See Anderson*, 477 U.S. at 255. The court's role at summary judgment "is to isolate and dispose of factually unsupported claims" so that they are "prevented from going to trial with the attendant unwarranted consumption of public and private resources." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–24, 327 (1986). "Disputes over irrelevant or unnecessary facts will not preclude a grant of summary judgment." *T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987).

The party seeking summary judgment bears the initial burden of establishing the absence of a genuine issue of material fact. *Celotex Corp.*, 477 U.S. at 323. The moving party can satisfy its burden in two ways: (1) by presenting evidence that negates an essential element of the nonmoving party's case or (2) by demonstrating that the nonmoving party failed to make a showing sufficient to establish an element essential to that party's case on which that party will bear the burden of proof at trial. *Id.* at 322–23. If the moving party fails to discharge this initial burden, summary judgment must be denied and the court need not consider the nonmoving party's evidence. *Adickes v. S.H. Kress & Co.,* 398 U.S. 144, 159–60 (1970).

If the moving party meets its burden, the nonmoving party must go beyond the pleadings and, by its own evidence or by citing appropriate materials in the record, show by sufficient evidence that there is a genuine dispute for trial. *Celotex Corp.*, 477 U.S. at 324. The party "must do more than simply show that there is some metaphysical doubt as to the material facts . . . [w]here the record 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*, 475 U.S. at 587 (quoting *First Nat. Bank of Ariz. v. Cities Serv. Co.*, 391 U.S. 253, 289 (1968)). A "scintilla of evidence" in support of the nonmoving party's position is insufficient; "there must be evidence on which the jury could reasonably find for the [nonmoving party]."

Anderson, 477 U.S. at 252. *See also Triton Energy Corp. v. Square D Co.*, 68 F.3d 1216, 1221 (9th Cir. 1995). Nor can "a party . . . manufacture a genuine issue of material fact merely by making assertions in its legal memoranda." *S.A. Empresa de Viacao Aerea Rio Grandense (Varig Airlines) v. Walter Kidde & Co., Inc.*, 690 F.2d 1235, 1238 (9th Cir. 1982) (citations omitted).

B. Plaintiff's Lanham Act False Advertising Claims

Plaintiff moves for partial summary judgment on its claim that Defendants violate the false advertising provision of the Lanham Act by claiming that "OSRX operates in full compliance with Section 503A regarding compounded drugs as defined in the [FDCA]." (ECF No. 171-1 at 10–11.) Defendants also move for partial summary judgment on this claim and Plaintiff's other false advertising claims. (ECF No. 168-1 at 9.)

The elements of a Section 43(a) false advertising claim under the Lanham Act are:

> (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) (citing *Cook, Perkiss and Liehe, Inc. v. Northern Cal. Collection Serv., Inc.*, 911 F.2d 242, 244 (9th Cir. 1990)). The Court will analyze each element of ImprimisRx's false advertising claims in turn.

1. Falsity

Plaintiff contends the material facts establish that OSRX's claim it "operates in full compliance with Section 503A regarding compounded drugs as defined in the [FDCA]" is literally false. (ECF No. 171-1 at 24.) Plaintiff argues Defendants are not in compliance with Section 503A based on two theories: (1) Defendants instruct prescribers to place bulk

product orders, rather than for particular patients, and provide "office stock" for use by unspecified future patients; and (2) Defendants fail to compound drugs in a sterile manner in violation of USP Chapter 797. (*Id.*)

To demonstrate falsity under the Lanham Act, "a plaintiff may show that the statement was literally false, either on its face or by necessary implication, or that the statement was literally true but likely to mislead or confuse consumers." *Southland Sod Farms*, 108 F.3d at 1139. When evaluating whether a claim is literally false, the claim must always be analyzed in its full context. *Id.* "Literal falsity is a question of fact, and summary judgment should not be granted where a reasonable jury could conclude a statement is not false." *K&N Eng'g, Inc. v. Spectre Performance*, No. EDCV 09-01900-VAP, 2011 WL 4387094, at *9 (C.D. Cal. Sept. 20, 2011) (citing *Southland Sod Farms*, 108 F.3d at 1144–45).

i) Bulk Ordering

Plaintiff claims Defendants' statement is literally false because OSRX provides bulk order prescriptions and "office stock" in contravention of the requirements of Section 503A of the FDCA. Section 503A, as an exception to the FDCA's general drug approval requirements, is limited to products "compounded for an identified individual patient based on the receipt of a valid prescription order" or where a history of receiving valid prescriptions exists between the compounding pharmacy and the prescriber. 21 U.S.C. § 353a.

Office stock are prescriptions held by prescribers for use by future, unspecified patients. Section 503B outsourcing facilities are permitted to distribute compounded drugs without a valid prescription and provide office stock, but Section 503A compounding pharmacies are limited to only providing products for specific patients. *See Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry*, U.S. Department of Health and Human Services Food and Drug Administration (Dec. 2016), https://www.fda.gov/media/97347/download. Accordingly,

providing bulk supplies of compounded medications as office stock is prohibited under Section 503A.

In support of its office stock theory, Plaintiff offers email correspondence between Defendants' sales agents and various prescribers where Defendants advise customers to order four bottles of ophthalmological solution per patient. (ECF No. 171-1 at 13–16.) Plaintiff contends four bottles exceeds what is needed per patient and, because the bottles are not labeled with patient names, this strategy works to generate office stock in contravention of Section 503A. (*Id.*) Plaintiff's pharmacy operations expert, Dr. Kenneth Schell, opines this four bottle order strategy helps skirt Section 503A's bulk order prohibition. (*Id.*) In response, Defendants argue four bottles is an appropriate quantity of product per patient. (ECF No. 206 at 14.) Defendants offer deposition testimony by Dr. Damien Goldberg and Amy Frost that dosing regimens are patient and physician specific and that there is a range of plausible bottles per patient. (*Id.* at 14–15.)

In reviewing the evidence, the Court finds the question of whether four bottles per patient is excessive is contested. Plaintiff has offered the testimony of its medical experts and Defendant has countered with its own expert testimony and declarations. (ECF Nos. 171-1 at 12, 206 at 14–15.) Ultimately, the question of whether four bottles per patient is appropriate, and subsequently interpreting whether that sales tactic is a workaround for Section 503A's individual prescription requirements, is not undisputed given the evidence before the Court.

Further, even if there was no controversy over the appropriate amount of product dispensed per patient, there is a factual dispute over whether Defendants actually distributed the product discussed in their sales emails. Defendants assert the sales emails describe their sales and marketing communications rather than their dispensing practices. (*Id.* at 16.) Defendants assert the prescription data reviewed by Dr. Alyson Wooten shows bulk orders and office stock were not actually provided. (ECF No. 206 at 17.) To support its theory that these products were dispensed, Plaintiff provides the declarations of three former OSRX employees who all claim OSRX shipped large quantities of product without

individual patient prescriptions. (ECF No. 171-1 at 15.) In turn, Defendants present rebuttal declarations by current OSRX employees and claim the former employees are not credible. (*Id.*)

In assessing the evidence, the Court finds there is a dispute of material fact as to whether there were valid patient prescriptions for each bottle and whether office stock was actually dispensed. Summary judgment under this theory of falsity is not merited.

ii) Compliance with USP Chapter 797

Plaintiff argues OSRX's claim that it "operates in full compliance with Section 503A" is literally false because Plaintiff violates USP Chapter 797 and therefore Section 503A. (ECF No. 171-1 at 20–22.)

Section 503A of the FDCA requires compounding pharmacies comply with the "applicable United States Pharmacopeia ("USP") . . . monograph if one exists, and the [USP] chapter on pharmacy compounding." 21 U.S.C. § 353a(b)(1). USP Chapter 797 "describes the minimum standards to be followed when preparing compounded sterile human and animal drugs." USP Chapter 797, § 1. USP Chapter 797 provides a litany of standards applicable to Defendants' compliance with Section 503A.

Plaintiff contends OSRX violates USP Chater 797 because: OSRX personnel do not comply with garbing and cleaning requirements; OSRX equipment is not maintained or recertified; OSRX compounding procedures are not updated or recorded properly; OSRX failed sterility and visual tests are not corrected; OSRX reports of patients experiencing adverse side effects are not investigated; and OSRX standard operating procedures ("SOPs") are not maintained. (ECF No. 171-1 at 25–26.)

In support of these allegations, Plaintiff offers the declarations of two former OSRX employees, Deschamps and Zirko, who declare they personally observed the alleged manufacturing defects. (ECF No. 171-1 at 20–22.) Plaintiff does not adduce any additional evidence in support of its claim that Defendants violate the provisions of USP Chapter 797. In response, Defendants offer the declarations of Frost and Brian Holdorf that deny the facts observed by Deschamps and Zirko (ECF No. 206 at 18–19). For each alleged

violation observed by Deschamps and Zirko, Frost or Holdorf dispute and rebut the claims made. Defendants also present the job performance records of Deschamps and Zirko in an effort to undermine their credibility.

Neither party is entitled to partial summary judgment with respect to this claim. Defendants provide rebuttal declarations for each observed production violation offered in the declarations of Deschamps and Zirko. "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge, whether he [or she] is ruling on a motion for summary judgment or for a directed verdict." *Anderson*, 477 U.S. at 255 (1986). *See also Neely v. St. Paul Fire and Marine Ins. Co.*, 584 F.2d 341, 344 (9th Cir. 1978).

Given the competing declarations offered by former and current OSRX employees, there is a material factual dispute as to whether Defendants operate in full compliance with USP Chapter 797. It is the responsibility of the trier of fact to make the requisite credibility assessments to assess whether USP Chapter 797 has been violated.

Overall, because the evidence is disputed for both of Plaintiff's theories, summary judgment as to the issue of falsity is not warranted.

2. Deception

Plaintiff moves for summary judgment on the element of deception arguing Defendants' literally false statements are necessarily deceptive. Where a challenged statement is literally false, consumer confusion is presumed. *U-Haul Int'l, Inc. v. Jartran, Inc.*, 793 F.2d 1034, 1041 (9th Cir. 1986). Because falsity has not been established for Plaintiff's Section 503A compliance claim, a presumption of deception does not apply. Plaintiff has otherwise not provided any evidence as to deception. Accordingly, summary adjudication on the issue of deception is not merited.

3. Materiality

Plaintiff moves for partial summary judgment arguing the evidence is uncontroverted that Defendants' challenged Section 503A compliance claims are material. (ECF No. 171-1 at 27.) Defendants move for partial summary judgment arguing the

evidence is uncontroverted that the alleged misstatements were not material. (ECF No. 168-1 at 17–19.) Under the Lanham Act, false or deceptive advertising is material where "it is likely to influence the purchasing decision." *Rice v. Fox Broad. Co.*, 330 F.3d 1170, 1181 (9th Cir. 2003) (quoting *Cook, Perkiss, and Liehe*, 911 F.2d at 244).

As an initial matter, Plaintiff argues when statements are found to be literally false, materiality is presumed according to circuit precedent. (ECF No. 203 at 12.) The Court disagrees. In prior cases, the Ninth Circuit reviews for materiality even when the challenged statements were found to be literally false. *See Rice*, 330 F.3d at 1181; *Skydive Ariz., Inc. v. Quattrocchi*, 673 F.3d 1105, 1111–12 (9th Cir. 2012); *Obesity Research Inst., LLC v. Fiber Research Int'l, LLC*, 310 F. Supp. 3d 1089, 1125 (S.D. Cal. 2018) (discussing Ninth Circuit precedent). As follows, even if the evidence was uncontroverted that the challenged statements were literally false, Plaintiff must still provide some evidence in support of its materiality argument.

Second, Defendants contend the challenged statement could not be observed by consumers and therefore cannot be material. (*Id.*) In cases where the Ninth Circuit has found alleged false statements were immaterial because the statements were unobservable, there was no possible means by which purchasers could see the statements. *See Rice*, 330 F.3d at 1181 (holding statements were immaterial because the allegedly false video jackets were not sold in retail stores, were not part of broadcasted advertisements, and were not depicted in internet advertisements). That is not the case here. While the statements may be presented in a small font, possible purchasers could still see them on Defendants' website and order forms.

Turning to the evidence, Plaintiff cites declarations by four ImprimisRx customers that claim Section 503A compliance was an important factor in their purchasing decisions. Plaintiff also presents survey evidence by its expert Amanda Butler that 54.1% of surveyed prescribers indicate that whether a compounding pharmacy "operates in full compliance with Section 503A" is an important factor in selecting a compounding pharmacy. (ECF No. 171-1 at 27.) In response, Defendants offer their own survey expert testimony and

critique Butler's opinion arguing her survey does not test the importance of the challenged statements in this case and the results appear illogical. (ECF No. 206 at 29.)

Defendants' objections to Butler's proposed testimony do not make the evidence uncontroverted. As the Court discussed in evaluating the parties' motions to exclude expert testimony, while Butler's survey may have seemingly contradictory survey results, those results are not so illogical as to fully undermine the credibility of the survey. (ECF No. 257.) However, Plaintiff's evidence is not uncontroverted. Defendants present their own expert and survey evidence in direct conflict with Plaintiff's evidence. Given the conflicting expert testimony and evidence, the issue of materiality ultimately requires parsing the credibility and weight of evidence presented by both parties.

Accordingly, summary adjudication on the issue of materiality is not due.

4. Dissemination in Interstate Commerce

Plaintiff moves for summary judgment on the element of dissemination in interstate commerce. (ECF No. 168-1 at 27.) The Lanham Act proscribes misrepresentation of one's own goods or services in "commercial advertising or promotion." 15 U.S.C. § 1125(a)(1)(B). The Ninth Circuit has acknowledged that it is "virtually automatic" that statements on websites enter interstate commerce. *See TrafficSchool.com, Inc. v. Edriver Inc.*, 653 F.3d 820, 829 n.3 (9th Cir. 2011). Defendants placed the challenged statement on their website ordering pages and included the statement on many additional webpages and emails. (ECF No. 168-1 at 27–28.)

Accordingly, summary adjudication on the issue of dissemination in interstate commerce is appropriate.

5. Injury to Plaintiff

Plaintiff and Defendants move for summary judgment on the issue of injury. The required showing under the Lanham Act depends on the remedy sought. *See Obesity Research*, 310 F. Supp. 3d at 1126–28. Plaintiff seeks a preliminary and permanent injunction against Defendants from "engaging in any of the types of false and unlawful

advertising described herein," an award of unjustly obtained profits, compensatory damages, and statutory damages. (ECF No. 145 at 16–17.)

i) Monetary Damages & Unjust Enrichment

Under Section 43(a) of the Lanham Act, to obtain monetary damages and unjustly obtained profits, a plaintiff must have 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*, 108 F.3d at 1139. When suing for damages, "actual evidence of some injury resulting from the deception is an essential element of the plaintiff's case." *Harper House, Inc. v. Thomas Nelson, Inc.*, 889 F.2d 197, 210 (9th Cir. 1989).

Plaintiff contends under the Lanham Act injury can be presumed because Defendants are its direct competitors. (ECF No. 171-1 at 28.) The Court is not convinced that presumption applies here. In cases involving false comparative advertising, the Ninth Circuit has held that damages may be awarded without proof of injury because a competitor can be presumed harmed. *See TrafficSchool.com*, 653 F.3d at 831 (noting an award of profits is "appropriate in false comparative advertising cases, where it's reasonable to presume that every dollar defendant makes has come directly out of plaintiff's pocket"); *Nat'l Prod., Inc. v. Gamber-Johnson LLC*, 699 F. Supp. 2d 1232, 1241 (W.D. Wash. 2010). Similarly, in false advertising cases involving improper use of a competitor's mark, the Ninth Circuit holds injury can be presumed because the use of the mark violated the rights of the mark registrant. *See Lindy Pen Co., Inc. v. Bic Pen Corp.*, 982 F.2d 1400, 1403 (9th Cir. 1993). *See also Certified Nutraceuticals Inc. v. Clorox Co.*, No. 18-CV-0744 W (KSC), 2021 WL 4460806, at *7 (S.D. Cal. Sept. 29, 2021). Neither circumstance is applicable here.

Instead, Plaintiff must provide some proof of past injury or risk of future injury caused by Defendants' false statements. *See, e.g.*, *Quidel Corp. v. Siemens Med. Solutions USA, Inc.*, No. 16-CV-3059-BAS-AGS, 2020 WL 4747724, at *10 (S.D. Cal. Aug. 17, 2020), *aff'd*, No. 20-55933, 2021 WL 4622504 (9th Cir. Oct. 7, 2021); *Cascade Yarns, Inc.*

v. Knitting Fever, Inc., No. C10-861 RSM, 2015 WL 1735517, at *6 (W.D. Wash. Apr. 15, 2015). The Lanham Act requires this proof to avoid awarding damages or profits for speculative injuries. *See TrafficSchool.com*, 653 F.3d at 831 (noting without proof of past injury "the district court had no way to determine with any degree of certainty what award would be compensatory" and therefore not speculative) (citing *ALPO Petfoods, Inc. v. Ralston Purina Co.*, 913 F.2d 958, 969 (D.C. Cir. 1990)); *Porous Media Corp. v. Pall Corp.*, 110 F.3d 1329, 1334 (8th Cir. 1997) ("[W]here a defendant is guilty of misrepresenting its own product without targeting any other specific product, it is erroneous to apply a rebuttable presumption of harm in favor of a competitor. Otherwise, a plaintiff might enjoy a windfall from a speculative award of damages by simply being a competitor in the same market.").

Plaintiff offers a litany of evidence showing it was in competition with Defendants including: an email where Defendants describe ImprimisRx as their "direct competition" (Ex. 11, ECF No. 170 at 265); deposition testimony that Defendants "generally don't lose customers to Imprimis" and that customers "generally flow the other direction" (Ex. 4, ECF No. 170-1 at 68); and email correspondence where Defendants attempt to poach Plaintiff's customers (Exs. 21, 23, 31, 32, 33, ECF No. 170-2 at 28–31, 37, 127–36). This evidence of competition alone, however, is insufficient given the type of market and the false advertising at issue here.

In prior instances, courts have found false advertisements that injured the entire market's reputation were sufficient to presume injury. *See, e.g.*, *Sandoz Inc. v. Amgen Inc.*, No. 2:22-CV-05326-RGK-MARX, 2023 WL 4681569, at *4 (C.D. Cal. June 29, 2023). And in prior instances, courts have found injury can be presumed in a market consisting of only two major players. *Cf. TrafficSchool.com*, 653 F.3d at 831 (holding a showing of injury was not necessary where "it's reasonable to presume that every dollar defendant makes has come directly out of plaintiff's pocket). Here, unlike those cases, there is appreciable competition in the market, and Defendants' false statements did not harm the entire market. While ImprimisRx and Defendants are two of the largest compounding

pharmacies within the post-operative ophthalmological market, other U.S. Food and Drug Administration ("FDA") approved pharmaceutical companies compete with them. For example, Allergan, Novartis, and Bio Tissue manufacture competing products. Defendants' investment overview reflects this understanding of the market:

> "There are large and small companies offering post-operative surgical medications for the care of vision correction patients and the management of glaucoma and dry eye disease. The list of Big Pharma name brands and generic providers includes household names like Novartis/Alcon, Allergan, Shire, Bausch & Lomb, Bio Tissue and BioD. However, Ocular Science only has two significant competitors in the compounded medication and biologics space, Imprimis and Bio-Tissue."

(Ex. 25, ECF No. 170-2 at 96–97.) Because prescribers have many options in selecting post-operation ophthalmological drugs, the Court cannot assume Plaintiff's sales were necessarily reduced by any increases to Defendants' sales due to the false statements. Instead, Plaintiff must provide some evidence it was harmed to meet its burden.[1] It has not done so.

Plaintiff provides evidence that prescribers *could* care about Defendants' Section 503A compliance, but this evidence goes to the materiality of the alleged statements rather than injury. Plaintiff submits the declaration of Dr. Kevin Barber who asserts if "[he] discovered that the supplier claimed to be compliant but was in fact intentionally circumventing the applicable laws and regulations, [he] would stop prescribing from that prescriber." (ECF No. 170-4 at 17). However, Dr. Barber has only ever been an ImprimisRx customer. In other instances cited by Plaintiff, an ophthalmologist was concerned about Defendants' representations as a Section 503A pharmacy (ECF No. 170-4 at 144), a prescriber "currently using the Imprimis combination drops" requested information from Defendants including whether they were a 503a facility (Ex. 21, ECF No.

[1] The Court is not persuaded by Plaintiff's citation to *Allergan USA, Inc. v. Imprimis Pharm., Inc.*, 2019 WL 4545960 (C.D. Cal. Mar. 27, 2019), or other cases where, absent any evidence of injury, courts have denied summary judgment because the parties were competitors. The Ninth Circuit has described awarding profits or damages in circumstances without evidence of harm as "an uncommon remedy in a false advertising suit." *TrafficSchool.com*, 653 F.3d at 831.

170-2 at 31), and another prescriber "was not happy [Defendants] weren't a 503B [compounding pharmacy]." (Ex. 22, ECF No. 170-2 at 33). This evidence, again, goes to materiality rather than injury. Plaintiff submits evidence showing Defendants poached Plaintiff's customers but does not show that these customers were poached as a result of Defendants' alleged false statements. (ECF No. 203 at 16.) To wit, Plaintiff has not provided the name of or a declaration from any customers that purchased from Defendants and would have purchased from Plaintiff but for Defendants' misstatements. As such, Plaintiff ultimately offers no evidence it was actually injured by Defendants' alleged misstatements.

Plaintiff is correct that a precise calculation of damages is not required under the Lanham Act. *See DSPT Int'l, Inc. v. Nahum*, 624 F.3d 1213, 1223 (9th Cir. 2010) (holding a "crude" measure of damages was acceptable to survive a directed verdict for a suit involving intentional trademark infringement). But a showing of some injury is required. *See Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 562 (1931) (noting "there is a clear distinction between the measure of proof necessary to establish the fact that petitioner had sustained some damage and the measure of proof necessary to enable the jury to fix the amount"). *See also Harper House*, 889 F.2d at 210. To hold contrary "would enable every Lanham Act plaintiff to survive summary judgment, which is not correct." *VBS Distrib., Inc. v. Nutrivita Laby's*, 811 F. App'x 1005, 1008 (9th Cir. 2020). Plaintiff has not met its burden because it has not provided any evidence of actual injury.

Accordingly, Defendants' motion for summary judgment is granted with respect to injury for Plaintiff's monetary damages and unjust enrichment claims.

ii) Injunctive Relief

Because a competitor may suffer future injury, competitors "need not prove injury when suing to enjoin conduct that violates section 43(a)." *Harper House*, 889 F.2d at 210. It is uncontested that Plaintiff and Defendants are competitors in the post-care ophthalmological drug compounding market. While it does not need to provide proof of

injury to seek injunctive relief under the Lanham Act, Plaintiff must still meet all the prongs for a permanent injunction. *See Obesity Research*, 310 F. Supp. 3d at 1128. A plaintiff seeking a permanent injunction must establish:

> (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay Inc. v. MercExchange, LLC, 547 U.S. 388, 391 (2006).

The Court finds Plaintiff has not offered any evidence that it has suffered an irreparable injury and is therefore entitled to injunctive relief. *See Obesity Research*, 310 F. Supp. 3d at 1128; *Williams & Cochrane, LLP v. Rosette*, 631 F. Supp. 3d 884, 918 (S.D. Cal. 2022); *Kurin, Inc. v. Magnolia Med. Techs., Inc.*, 473 F. Supp. 3d 1117, 1146 (S.D. Cal. 2020). As discussed above, Plaintiff has failed to provide any evidence it was actually injured by Defendants' alleged false advertisements and therefore has not met its burden of showing it has suffered an irreparable injury or that non-monetary damages are inadequate to compensate it for its injury.

Because Plaintiff has not met its evidentiary burden with respect to its claim for injunctive relief, Defendants' motion for summary judgment on injunctive relief is granted.

C. Preemption/Preclusion Under the FDCA

Defendants move for summary judgment on Plaintiff's false advertising claims arguing that ImprimisRx is engaging in "impermissible private enforcement of the FDCA." (ECF No. 168-1 at 20–21.) The Court has previously addressed this question and denied Defendants' motion for partial judgment on the pleadings. (ECF No. 144.) The Court need not renew discussion of this argument because it is moot given the Court's ruling with respect to injury.

D. Unclean Hands Defense

Defendants move for partial summary judgment on their equitable defense of unclean hands. (ECF No. 168-1 at 25.) Because the Court granted Defendants' motion for

summary judgment on the issue of injury, this affirmative defense as it relates to Plaintiff's false advertising claims is moot. Accordingly, the Court does not reach this issue.

E. Defendants' Counterclaims

In their answer to Plaintiff's Third Amended Complaint, Defendants assert four false advertising counterclaims against ImprimisRx. (ECF No. 152 at 21–22.) Plaintiff moves for summary judgment on Defendants' false advertising counterclaims under a variety of arguments.

1. Claims Outside of the Pleadings

In their opposition to Plaintiff's motion for partial summary judgment, Defendants claim Plaintiff falsely advertises that it "compl[ies] with all cGMP requirements which are the most stringent standards in the nation." (ECF No. 206 at 21). Plaintiff asserts this claim is suitable for summary judgment because it was not pled in Defendants' counterclaims. (ECF No. 218 at 9.)

Where a complaint "does not include the necessary factual allegations to state a claim, raising such claim in a summary judgment motion is insufficient to present the claim to the district court." *Navajo Nation v. U.S. Forest Serv.*, 535 F.3d 1058, 1080 (9th Cir. 2008). Defendants do not identify ImprimisRx's cGMP compliance claim as a challenged claim in its their answer and counterclaims to Plaintiff's Third Amended Complaint. However, ImprimisRx's cGMP compliance is factually related to its Baum Claim that ImprimisRx is "compliant with highest quality standards." (ECF No. 152.) Defendants are not asserting an entirely new claim in their motion for partial summary judgment but rather are identifying a particular standard by which to evaluate their previously pled Baum Claim. Accordingly, the Court considers Plaintiff's cGMP compliance in that context.

2. Statute of Limitations

Plaintiff argues that Defendants' false advertising counterclaims are barred by the statute of limitations on the claims. (ECF No. 171-1 at 30.) Plaintiff insists the claims made by CEO Baum occurred in February and August 2017 while the remaining claims were all first made before 2019. (*Id.*) Because Defendants brought their counterclaims in

May 2022, Plaintiff contends these claims are barred by the Lanham Act's three-year limitations period. (*Id.*)

"The Lanham Act contains no explicit statute of limitations." *Jarrow Formulas, Inc. v. Nutrition Now, Inc.*, 304 F.3d 829, 836 (9th Cir. 2002). It is unclear whether the Lanham Act is governed by a limitations period, as opposed to laches. *See Yeager v. Bowlin*, 495 F. App'x 780, 781–82 (9th Cir. 2012) ("We have not resolved whether a statute of limitations defense applies to claims under the Lanham Act, which are of equitable character.") (quotation omitted). Regardless, laches is a well-established equitable defense to Lanham Act claims. *See Jarrow*, 304 F.3d at 835.

To assess a laches defense, the Court first examines whether a delay occurred and then decides whether that delay was reasonable. *See Jarrow*, 304 F.3d at 838. To assess delay, courts reference the analogous state law limitations period. *Id.* If the plaintiff filed suit outside the relevant limitations period, courts apply a strong presumption that laches bars the claims. *See Shouse v. Pierce Cnty.*, 559 F.2d 1142, 1147 (9th Cir. 1977). The presumption of laches is triggered if any part of the alleged wrongful conduct occurred beyond the limitations period. *See Jarrow*, 304 F.3d at 837. The limitations period is not reset even if the offensive conduct continues. *See id.*

The limitations period for Lanham Act claims begins to run when a party knew or should have known about a cause of action. *See Jarrow*, 304 F.3d at 838. The start date, however, is tolled by the discovery rule which pauses accrual "until the plaintiff discovers, or has reason to discover, the cause of action." *Grisham v. Phillip Morris U.S.A., Inc.*, 40 Cal. 4th 623, 634 (Cal. 2007). To invoke this rule, plaintiffs must plead and prove facts showing: (1) lack of knowledge; (2) lack of means of obtaining knowledge; and (3) how and when plaintiff actually discovered the fraud. *Gen. Bedding Corp. v. Echevarria*, 947 F.2d 1395, 1397 (9th Cir. 1991).

The parties agree that California's limitations period for fraud is most analogous such that a three-year limitations period applies here. *See* Cal. Civ. Proc. Code § 338(d). Plaintiff insists the challenged claims were made three years before Defendants filed their

counterclaims. With respect to the Baum Claims, the parties appear to agree those claims were made in February 2017. For the Saharek, USP, and Trust Claims, Defendants appear to dispute the date of publication but do not provide any evidence or counter Plaintiff's declaration by Andrew Boll that the statements were made and published prior to 2019. (ECF No. 171-3 at 289.) In sum, all four challenged claims were publicly available three years before Defendants lodged their counterclaims.

Defendants insist, however, that their claims are not time-barred because Plaintiff "fails to present any evidence that establishes when Defendants became aware, or should have become aware, that the challenged statements were made, nor why Defendants should have been aware that those statements were false by 2019." (ECF No. 206 at 31.) This, however, is not Plaintiff's burden. It is Defendants' responsibility to make a showing for why they lacked the means to discover Plaintiff's statements to invoke the tolling of the discovery rule. They have not done so. Indeed, because Plaintiff is a main competitor for Defendants, one assumes Defendants would be aware of the content hosted on Plaintiff's website or the claims Plaintiff makes regarding its products. *Cf. Baby Trend, Inc. v. Playtex Prod., LLC*, No. 5:13-CV-647-ODW RZX, 2013 WL 4039451, at *4 (C.D. Cal. Aug. 7, 2013) (finding the plaintiff should have been aware of claims made on its main competitor's packaging). Therefore, a presumption of laches applies.

Finding a delay, the Court then assesses whether Defendants' delay was unreasonable and whether Plaintiff would suffer prejudice caused by the delay. To assess whether the delay was unreasonable, courts look to the length of the delay and the reasonableness of that delay in light of the analogous limitations period. Plaintiff first made some of the challenged claims in 2017 and the other claims before 2019. Defendants did not bring their counterclaims until 2022. Defendants' delay is almost twice the time available to file suit under the analogous state limitations period. *See Jarrow*, 304 F.3d at 839. Defendants have not offered any reasons excusing the delay aside from waiting until Plaintiff filed suit, which is an insufficient justification. Defendants' delay was then unreasonable.

However, Plaintiff does not appear prejudiced by the delay. Courts generally recognize two forms of prejudice in the laches context: evidentiary and expectations-based. *See Danjaq LLC v. Sony Corp.*, 263 F.3d 942, 955 (9th Cir. 2001). Expectations-based prejudice occurs where defendants take actions or suffer consequences they would not have if plaintiff had brought suit promptly. *Id.* ImprimisRx has not offered any evidence to support a finding of prejudice due to Defendants' delay. In other cases, courts have found prejudice where a party invests labor and capital to build on its advertising goodwill or expanded its business in line with its presumed rights. *See, e.g.*, *NAACP v. NAACP Legal Def. & Educ. Fund, Inc.*, 753 F.2d 131, 138 (D.C. Cir. 1985). Neither appear to have happened here. In weighing the equities, without any support for a finding of prejudice at the posture before the Court, application of laches is inappropriate.

Accordingly, the Court denies Plaintiff's motion to summarily adjudicate Defendants' counterclaims on the basis of laches.

3. Elements of Lanham Act Counterclaims

Plaintiff moves for summary judgment on Defendants' false advertising counterclaims contending there is no evidence to support their claims. (ECF No. 171-1 at 29–30.) The Court examines whether summary judgment is appropriate by addressing each Lanham Act element in turn.

i) Falsity

Plaintiff asserts that there is no evidence from which a reasonable juror could conclude that the challenged statements were literally false at the time they were made. (ECF No. 171-1 at 29.) With respect to the Saharek claims, Defendants present a letter from the FDA that ImprimisRx does not test every batch of product. (ECF No. 206 at 24.) With respect to the USP Claims, Defendants provide an FDA inspection report that the ImprimisRx's sterility, endotoxin, and potency testing lacks sufficient sampling protocols, which would violate USP standards. (*Id.* at 25.) With respect to the Trust Claims, Defendants provide a number of issues related to sterility through employee declarations,

third party audits, and FDA letters. (*Id.* at 22–26.) As such, Defendants present sufficient facts to meet its burden as to the falsity of Plaintiff's advertising claims.

Accordingly, summary adjudication on the issue of falsity is not merited.

ii) Materiality

Plaintiff argues there is no evidence that a reasonable juror could find the challenged statements were material. (ECF No. 171-1 at 29.) It contends OSRX did not survey any customers to determine whether its statements are material and has not provided any customers who saw or relied on its advertising claims. (*Id.*) In support of their claim that Plaintiff's statements are material, Defendants note Plaintiff's marketing strategy centers around its sterility and reliability concerns, Plaintiff trains its sales representatives to use its sterility and reliability in their sales pitches, and Plaintiff compares its products to Defendants' products based on these claims. (ECF No. 206 at 21–22.)

The evidence here is disputed. While Defendants have not presented survey evidence in support of their claim, a reasonable jury could find Plaintiff's claims were material to prescribers. Accordingly, summary judgment as to materiality is not warranted.

iii) Injury to Defendants

Plaintiff contends that no reasonable jury could find the challenged statements harmed Defendants. (ECF No. 171-1 at 29.) As before, injury is examined according to the relief sought. Defendants seek injunctive and monetary relief in pursuing their counterclaims. (ECF No. 152 at 29.) Like Plaintiff's false advertising claims, the undisputed facts only show ImprimisRx and Defendants are competitors. Defendants do not submit any documentary evidence or deposition evidence demonstrating they lost customers due to Plaintiff's alleged false advertisements. Without evidence of actual injury, this is insufficient to survive a motion for summary judgment. *See TrafficSchool.com*, 653 F.3d at 831. Accordingly, the Court grants Plaintiff's motion for summary judgment with respect to injury for monetary damages.

With respect to injunctive relief, Defendants also have not provided evidence to survive a motion for summary judgment with respect to the *eBay* elements for injunctive

relief. *See eBay*, 547 U.S. at 391. Defendants have not submitted any evidence showing they were actually harmed by ImprimisRx's alleged false statements and therefore have not made a sufficient showing of irreparable harm. Accordingly, the Court grants Plaintiff's motion for summary judgment with respect to injunctive relief.

CONCLUSION

Based on the foregoing, the Court **DENIES** Defendants' motion to exclude Plaintiff's belatedly identified witnesses (ECF No. 189-1). The Court reopens discovery solely for the purpose of obtaining the depositions of the twelve newly identified witnesses in Plaintiff's amended disclosures.

The Court **GRANTS** Defendants' motion for partial summary judgment (ECF No. 168-1) with respect to Plaintiff's false advertising claims under the Lanham Act (Cause of Action 1). This does not, however, dispose of this case. Plaintiff maintains its remaining causes of action, namely trademark infringement in violation of the Lanham Act, false designation of origin in violation of the Lanham Act, common law unfair competition, copyright infringement, and violation of California's unfair competition law.

The Court **DENIES** Plaintiff's motion for partial summary judgment with respect to its false advertising claims under the Lanham Act and **GRANTS** Plaintiff's motion for summary judgment with respect to Defendants' false advertising counterclaims. (ECF No. 171-1).

The Court orders the parties to contact the Magistrate Judge's chambers within fourteen days of today's date to coordinate the deposition of Plaintiff's newly identified witnesses and to set new dates for a pretrial conference and trial.

IT IS SO ORDERED.

DATED: December 12, 2023

Hon. Cynthia Bashant
United States District Judge