UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

MACUHEALTH, LP,

Plaintiff,

v. Case No. 8:22-cv-199-VMC-JSS

VISION ELEMENTS, INC.,

Defendant.
_____/

ORDER

This matter is before the Court on consideration of Plaintiff MacuHealth, LP's Motion for Summary Judgment (Doc. # 63), filed on February 13, 2023, Defendant Vision Elements, Inc.'s Motion for Summary Judgment (Doc. # 66), filed on February 13, 2023, MacuHealth's Daubert Motion to exclude the testimony of one of Vision Elements' experts (Doc. # 68), filed on February 13, 2023, and Vision Elements' Motion to Exclude one of MacuHealth's expert's supplemental report (Doc. # 77), filed on February 16, 2023. Both parties responded to the summary judgment motions on March 13, 2023. (Doc. ## 81, 83). Vision Elements responded to MacuHealth's Daubert Motion and MacuHealth responded to Vision Elements' Motion to Exclude, also on March 13, 2023. (Doc. ## 82, 84). Both parties replied to the summary judgment motions. (Doc.

86, 87). For the reasons that follow, MacuHealth's Daubert Motion is denied, Vision Elements' Motion to Exclude is denied, Vision Elements' Motion for Summary Judgment is denied, and MacuHealth's Motion for Summary Judgment is granted in part and denied in part.

I. Background

A. The Parties

MacuHealth sells a nutritional supplement called "MacuHealth" that is intended to maintain or improve eye health. (Doc. # 78-6 at 24:13-22). Below is an image of the MacuHealth bottle:

(Doc. # 63-3 at 50). Each capsule of MacuHealth's product contains three active ingredients: lutein, zeaxanthin, and mesozeaxanthin ("LMZ carotenoids"). (Doc. # 78-6 at 24:13-22).

Vision Elements also sells a nutritional supplement, called "Early Defense," intended to maintain or improve eye health. (Doc. # 78-1 at 33:11-19). Early Defense is available

throughout the United States via its website and has been sold and shipped to customers in multiple states in interstate commerce. (Id. at 46:11-21). Vision Elements' only employees are its owners, Matthew Hinton and Jennifer Hinton. (Id. at 30:14-17). Approximately 1 percent of Early Defense product sales are direct to consumers and 99 percent are to eyecare physicians. (Doc. # 66-2 at ¶ 7). Vision Elements states that its supplement has the same LMZ carotenoids, in the same amount, as MacuHealth's supplement does. (Id. at 24:16-25). According to Mr. Hinton, Early Defense competes with MacuHealth:

> Q. Okay. So who are your competitors who sell product that includes the carotenoids lutein, zeaxanthin, and mesozeaxanthin?
> A. I would say almost any product on the market would contain some amount of mesozeaxanthin, even if it's not disclosed. Every product marketed for eyes would contain lutein, likely zeaxanthin. And I'm aware of just a couple that would have mesozeaxanthin claimed on the label.
> Q. And which are those?
> A. MacuHealth comes to mind first.

(Id. at 43:13-44:5).

The LMZ carotenoids used in MacuHealth and Early Defense are extracted and derived from marigold flower petals using solvents. (Doc. # 63-5 at 126:1-19). It is industry standard to use as solvents hexane or methanol to extract and derive the LMZ carotenoids. (Id. at 132:2-5; Doc. # 78-6 at 18:22-

19:3). The solvents are largely removed from the LMZ carotenoids during the production process, but residual amounts remain in the final product. (Doc. # 63-4 at 43).

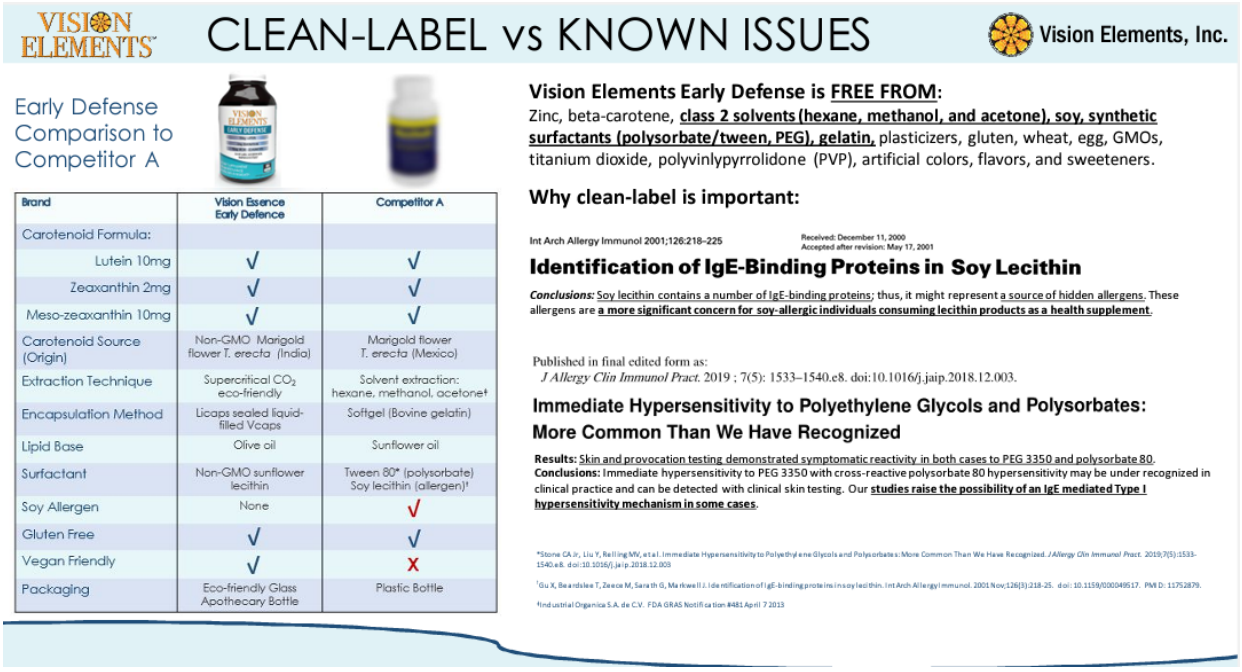
B. Vision Elements' Advertisements

When this suit commenced, Vision Elements' advertisements promoting Early Defense stated that it was (1) made without the use of Class 2 solvents, such as hexane, methanol, and acetone and (2) no residual solvents are present in Early Defense. (Doc. # 66-2 at ¶ 10). Specifically, Vision Elements claimed that Early Defense contained "Clean label ingredients: Solvent-free carotenoids derived from non-GMO marigold flowers through an eco-friendly super critical CO2 extraction process – No hexane, methanol, or acetone." (Doc. # 63-2 at 11). The Early Defense bottle states that Early Defense "contains **none** of the following: . . . Class 2 solvents – hexane, methanol, acetone[.]" (Id. at 15) (emphasis in original). The Food and Drug Administration states that Class 2 solvents "should be limited in pharmaceutical products because of their inherent toxicity." (Doc. # 63-4 at 15).

Mr. Hinton also testified that Vision Elements conveyed that Early Defense did not use, and was free from, Class 2 solvents to customers at trade shows, in personal product

pitches, and in emails to potential customers. (Doc. # 78-1 at 198:21-199:2; Doc. # 78-4 at 292-93). Vision Elements claims that it has ceased publishing these claims on its website or brochures in order to avoid further litigation. (Doc. # 66-2 at ¶ 16).

Vision Elements also created the following advertisement:



Brand	Vision Essence Early Defence	Competitor A
Carotenoid Formula:		
Lutein 10mg	√	√
Zeaxanthin 2mg	√	√
Meso-zeaxanthin 10mg	√	√
Carotenoid Source (Origin)	Non-GMO Marigold flower T. erecta (India)	Marigold flower T. erecta (Mexico)
Extraction Technique	Supercritical CO_2 eco-friendly	Solvent extraction: hexane, methanol, acetone†
Encapsulation Method	Licaps sealed liquid-filled Vcaps	Softgel (Bovine gelatin)
Lipid Base	Olive oil	Sunflower oil
Surfactant	Non-GMO sunflower lecithin	Tween 80* (polysorbate) Soy lecithin (allergen)†
Soy Allergen	None	√
Gluten Free	√	√
Vegan Friendly	√	X
Packaging	Eco-friendly Glass Apothecary Bottle	Plastic Bottle

(Doc. # 78-3 at 299). Mr. Hinton acknowledges that he created the Competitor A bottle using a photo of the MacuHealth bottle. (Doc. # 78-2 at 139:6-21; 142:19-23). Frederic Jouhet, MacuHealth's CEO, testified that consumers would recognize the Competitor A bottle as that of MacuHealth. See (Doc. # 78-5 at 44:22-45:3) ("There is a marketing document that shows a . . . Vision Essence bottle side by side with a MacuHealth bottle that has been blurred slightly, but not enough to not convince the doctors what we're discussing.").

Additionally, Vision Elements also distributes a promotional document titled "Competitor Solvent Extraction Method" at trade shows. (Doc. # 78-2 at 147:11-148:2; Doc. # 78-4 at 311). It includes a cover page of a patent assigned to Industrial Orgánica, S.A. de C.V. ("IOSA"), MacuHealth's LMZ carotenoid supplier, and compares IOSA's use of hexane as an extraction solvent to the use of supercritical CO2 extraction techniques. (Doc. # 78-4 at 311). Vision Elements used this document to distinguish its product from MacuHealth, which uses hexane in the extraction process. (Doc. # 78-3 at 148:22-149:10). MacuHealth is the only competitor of Vision Elements that used IOSA as a supplier. (Id. at 150:15-19).

Vision Elements purchases its LMZ carotenoids from a a brokerage company from India called FT. (Doc. # 78-1 at 68:4-7). Vision Elements does not know the identity of the entity that extracts the LMZ carotenoids used in Early Defense, and Mr. Hinton was not curious about the third-party extraction. (Doc. # 78-3 at 17:1-8; 21:19-23). However, MacuHealth determined that FT, in turn, purchases the LMZ carotenoids from a third-party manufacturer, Bio-gen. (Doc. # 78-3 at 27:5-8; 32:20-33:6; 35:1-6). Bio-gen stated that it extracts LMZ carotenoids from marigolds using hexane as a solvent.

(Doc. # 78-8 at 2; Doc. # 63-9 at 82). It also confirmed that it did not use super critical CO2 extraction. (Doc. # 63-9 at 82). Mr. Hinton stated that he was not aware until the start of this litigation that FT did not do its own extraction. (Doc. # 78-3 at 17:1-8; 21:19-23). He also acknowledged that he never asked and FT never told him whether Class 2 solvents were used to extract the LMZ carotenoids it sold. (Doc. # 78-1 at 83:14-22; 84:10-14; 84:1-9).

The parties dispute whether a supercritical CO2 extraction process is commercially feasible and whether any commercial supplier uses it. Vision Elements relies on the certificates of analysis ("COAs") it received from FT to demonstrate that the supercritical CO2 extraction method was used on the batches it purchased. (Doc. # 66-2 at 8-9). MacuHealth's experts, Carlos Torres and Dr. James Stringham, on the other hand, testified that they are not aware of any suppliers who claim to be able to extract LMZ carotenoids without the use of Class 2 solvents. (Doc. # 63-5 at 163:9-18; Doc. # 63-8 at 95:23-96:1). However, the parties agree that Bio-gen does not offer LMZ carotenoids obtained using the supercritical CO2 extraction process. (Doc. # 78-5 at 160-61).

Vision Elements relies on two pieces of evidence to support its solvent claims: (1) the COAs provided by FT and (2) a Canadian Analytical Laboratories ("CAL") report on testing conducted on Early Defence, a different product sold in Canada by Mr. Hinton's company, Vision Essence. (Doc. # 78-1 at 109:6-16). Mr. Hinton admitted that all the FT COAs for mesozeaxanthin and two of the four FT COAs for lutein/zeaxanthin are silent as to the presence or absence of residual Class 2 solvents. (Id. at 157:17-158:2; 158:21-3; 159:23-160:3;161:23-162:10;162:17-163:4; 163:11-15). Mr. Hinton ultimately admitted that none of the COAs provide a basis for whether the Class 2 solvents were used. (Id. at 152:18-22). Mr. Hinton further acknowledged that the CAL report is irrelevant to the case, as the testing was not done on the American version of Early Defense at issue. (Id. at 101:13-23). Finally, Mr. Hinton admitted that the CAL report only determined whether the levels of the Class 2 solvents exceeded standard limits, and did not assess whether such solvents were present in any amount, and he acknowledged that the report "does not provide a factual foundation or basis" to claim that no Class 2 solvents were used in the extraction process. (Id. at 185:14-186:1).

C. Testing of MacuHealth and Early Defense

In December 2021 and September 2022, IOSA tested multiple batches of Early Defense for the presence of residual solvents. (Doc. # 63-5 at 47:4-19; Doc. # 63-6 at 119; Doc. # 63-8 at 214). IOSA issued certified reports for the tests, both of which reported the presence of hexane, methanol and acetone in the Early Defense capsules. (Doc. # 63-4 at ¶¶ 71-72 Doc. # 63-5 at 95:2-11). At MacuHealth's request, two additional independent laboratories, ACS Laboratories and UFAG Laboratorien, tested Early Defense for the presence of residual solvents. ACS issued a report indicating that of the four samples tested, three contained methanol and one contained both methanol and acetone. UFAG issued a report indicating that methanol was present in Early Defense. (Doc. # 63-7 at ¶ 23).

Two of MacuHealth's expert witnesses, Carlos Torres and Dr. James Stringham, opined on the presence of residual solvents in Early Defense. Dr. Stringham found that the chromatographs from the UFAG report indicated that methanol, acetone, and hexane were present in the sample. (Id. at ¶ 26). Both Mr. Torres and Dr. Stringham opined that the presence of the residual solvents in the samples indicated

that such solvents were used to manufacture Early Defense. (Doc. # 63-4 at ¶ 80; Doc. # 63-6 at ¶ 58).

Vision Elements chose not to test for the presence of solvents in Early Defense. (Doc. # 78-1 at 124:17-21; 188:23-189:7, 190:24-191:2; 194:24-195:5; 194:10-13). Mr. Hinton testified that he did not think such a test was necessary because he was "aware of where [his] product stands." (Id. at 194:14-23).

D. Impact of Vision Elements' Claims on Customers

Mr. Hinton testified that his solvent claims are "highly important" to customers when they are choosing a particular ocular supplement. (Doc. # 78-1 at 118:6-20). He also stated that Vision Elements distinguishes Early Defense from competitors like MacuHealth by advertising that Early Defense uses "solvent free" extraction of LMZ carotenoids (Id. at 196:23-197:2). He said that consumers look for products that use fewer chemicals. (Id. at 96:21-24; 97:3-4). An attendee at an industry conference asked Mr. Jouhet, "How is it that [MacuHealth] doesn't have a way to do things without solvents?" (Doc. # 63-9 at 136:21-24).

Dr. SK was a substantial customer and reseller of MacuHealth for many years – purchasing $66,351 and $68,496 worth of MacuHealth in 2019 and 2020 respectively. (Doc. #

78-5 at 216:6-7; Doc. # 78-7 at 109; Doc. # 78-2 at 2). She switched from MacuHealth to Early Defense in 2021, making purchases worth $45,020 and $86,040 in 2021 and 2022, respectively. (Doc. # 78-1 at 127:5-8; Doc. # 78-9). Dr. SK promoted Early Defense over MacuHealth to fellow doctors based in part on Vision Elements' "clean formulation," which includes manufacturing without Class 2 solvents. (Doc. # 78-1 at 128:6-129:7). Dr. SK pays attention to the use of solvents. (Doc. # 78-7 at 219:6-10). However, in her affidavit she stated that Vision Elements' advertisements promoting Early Defense as free from Class 2 solvents did not affect her decision to purchase Early Defense or recommend it to her patients. (Doc. # 67-3 at ¶¶ 10-11).

Dr. CA, along with his successor Dr. TM, switched from MacuHealth to Early Defense in 2021 after Mr. Hinton promoted Early Defense to him based on Vision Elements' claims that no class 2 solvents were used. (Doc. # 78-1 at 197:3-198:3). In his affidavit, however, Dr. CA, also stated that Vision Elements' advertisements promoting Early Defense as free from Class 2 solvents did not affect his decision to purchase Early Defense or recommend it to his patients. (Doc. # 67-2 at ¶¶ 11-12).

E. Procedural History

MacuHealth initiated this action on January 25, 2022. (Doc. # 1). In its complaint, MacuHealth alleges unfair competition under 15 U.S.C. § 1125(a)(1)(B) (Count I), negligent misrepresentation under Fla. Stat. § 817.41(1) (Count II), unfair competition under Florida common law (Count III), and deceptive and unfair trade practice under Fla. Stat. § 501.201 (Count IV). (Id. at ¶¶ 41-81).

Now, MacuHealth seeks final summary judgment in its favor. (Doc. # 63). Vision Elements also seeks final summary judgment in its favor on all counts. (Doc. # 66). Both MacuHealth and Vision Elements responded (Doc. ## 81, 83), and replied. (Doc. ## 86, 87). MacuHealth also filed a Daubert motion to exclude the expert report and testimony of Christopher Byrd (Doc. # 68), and Vision Elements responded. (Doc. # 84). Finally, Vision Elements filed a motion to strike Dr. Stringham's supplemental expert report (Doc. # 77), and MacuHealth responded. (Doc. # 82). The Motions are ripe for review.

II. Legal Standard

Summary judgment is appropriate "if the movant shows that 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 factual dispute alone is not enough to defeat a properly pled motion for summary judgment; only the existence of a genuine issue of material fact will preclude a grant of summary judgment. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247–48 (1986).

An issue is genuine if the evidence is such that a reasonable jury could return a verdict for the non-moving party. Mize v. Jefferson City Bd. of Educ., 93 F.3d 739, 742 (11th Cir. 1996) (citing Hairston v. Gainesville Sun Publ'g Co., 9 F.3d 913, 918 (11th Cir. 1993)). A fact is material if it may affect the outcome of the suit under the governing law. Allen v. Tyson Foods, Inc., 121 F.3d 642, 646 (11th Cir. 1997). The moving party bears the initial burden of showing the court, by reference to materials on file, that there are no genuine issues of material fact that should be decided at trial. Hickson Corp. v. N. Crossarm Co., 357 F.3d 1256, 1260 (11th Cir. 2004) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986)). "When a moving party has discharged its burden, the non-moving party must then 'go beyond the pleadings,' and by its own affidavits, or by 'depositions, answers to interrogatories, and admissions on file,' designate specific facts showing that there is a genuine issue

for trial." Jeffery v. Sarasota White Sox, Inc., 64 F.3d 590, 593–94 (11th Cir. 1995) (quoting Celotex, 477 U.S. at 324).

If there is a conflict between the parties' allegations or evidence, the non-moving party's evidence is presumed to be true and all reasonable inferences must be drawn in the non-moving party's favor. Shotz v. City of Plantation, 344 F.3d 1161, 1164 (11th Cir. 2003). If a reasonable fact finder evaluating the evidence could draw more than one inference from the facts, and if that inference introduces a genuine issue of material fact, the court should not grant summary judgment. Samples ex rel. Samples v. City of Atlanta, 846 F.2d 1328, 1330 (11th Cir. 1988). But, if the non-movant's response consists of nothing "more than a repetition of his conclusional allegations," summary judgment is not only proper, but required. Morris v. Ross, 663 F.2d 1032, 1034 (11th Cir. 1981).

Finally, the filing of cross-motions for summary judgment does not give rise to any presumption that no genuine issues of material fact exist. Rather, "[c]ross-motions must be considered separately, as each movant bears the burden of establishing that no genuine issue of material fact exists and that it is entitled to judgment as a matter of law." Shaw Constructors v. ICF Kaiser Eng'rs, Inc., 395 F.3d 533, 538-

39 (5th Cir. 2004); see also United States v. Oakley, 744 F.2d 1553, 1555 (11th Cir. 1984) ("Cross-motions for summary judgment will not, in themselves, warrant the court in granting summary judgment unless one of the parties is entitled to judgment as a matter of law on facts that are not genuinely disputed[.]" (citation omitted)).

III. Analysis

Before analyzing the parties' summary judgment motions, the Court will first address the issues regarding the parties' experts.

A. MacuHealth's Daubert Motion as to Dr. Byrd

MacuHealth seeks to exclude Dr. Christopher Byrd's expert testimony on the grounds that it fails to meet the qualifications, reliability, or helpfulness requirements of Rule 702. (Doc. # 112 at 1). Dr. Byrd opined that the Court should not rely on the levels of solvents detected by IOSA and ACS Laboratories in the Early Defense samples because the solvents were detected in different amounts depending on the sample. (Doc. # 68-2 at 12).

The Court need not rule on MacuHealth's Daubert Motion, however, as Dr. Byrd's testimony is not necessary to the resolution of the merits of this case. Dr. Byrd does not opine that the tests IOSA and ACS Laboratories performed were

unreliable in the detection of the presence of some amount of solvent – hexane, methanol, or acetone. Rather, he simply points out that the amount of solvent found varied depending on the sample. As such, his opinion does not create a genuine dispute of material fact as to the presence of some amount solvent in Early Defense. Therefore, the Court denies as moot MacuHealth's motion to exclude Dr. Byrd's testimony.

B. Vision Elements' Motion to Exclude Dr. Stringham's Supplemental Report

Vision Elements seeks to exclude the supplemental report of Dr. Stringham on the grounds that it includes two new lab tests that, according to Vision Elements, impermissibly bolster his initial report and opinion. (Doc. # 77 at 2). Additionally, Vision Elements claims that the supplemental report should be excluded because it was disclosed after MacuHealth's expert report deadline. (Id. at 3). In response, MacuHealth contends that Dr. Stringham's supplemental report was a timely supplementation under Rule 26(e) or, alternatively, even it was untimely, it was still substantially justified and harmless. (Doc. # 82 at 3).

Federal Rule of Civil Procedure 37(c)(1) states that when "a party fails to provide information or identify a witness as required by [Federal Rule of Civil Procedure] 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." Rule 37 allows a district court to exclude a witness as a sanction for a Rule 26 violation. Mitchell v. Ford Motor Co., 318 F. App'x 821, 824 (11th Cir. 2009). "In general, excluding expert testimony is viewed as a 'drastic sanction requiring careful consideration.'" SFR Services LLC v. Electric Insurance Company, No. 8:19-cv-2013-CPT, 2021 WL 1193284 at *5 (M.D. Fla. March 30, 2021).

Rule 26(e) supplementation exists for the purpose "of correcting inaccuracies or adding information that was not available at the time of the initial report." All-Tag Corp. v. Checkpoint Sys., Inc., No. 9:17-CV-81261, 2019 WL 5073499, at *3 (S.D. Fla. Oct. 9, 2019). Supplementation is not a device that allows experts to engage in additional work, correct weaknesses in the initial report, or produce information in a belated fashion. Great Lakes Ins. Se v. Rental Boat Corp., No. 20-60133-CIV, 2021 WL 1686926, at *2-3 (S.D. Fla. Mar. 1, 2021).

The Court entered a Case Management and Scheduling Order on March 28, 2022, setting August 19, 2022, as the deadline to disclose expert reports and September 16, 2022, as the

deadline for rebuttal reports. (Doc. # 29). The Court set the discovery deadline for October 21, 2022. (Id.). After the Court granted Vision Element's motion to extend several case deadlines (Doc. # 45), it extended the deadline to disclose rebuttal reports to December 14, 2022, and the discovery deadline to January 13, 2023. (Doc. # 50).

MacuHealth served Dr. Stringham's supplemental report on December 15, 2022. (Doc. # 77 at 1). The report noted two additional tests performed on Early Defense. Dr. Stringham determined that the two additional tests would be necessary after reviewing the CAL report regarding the Canadian product Early Defence produced by Vision Elements on October 12, 2022. (Doc. # 77-3 at ¶ 30). In that test, CAL used water as the dissolvent. (Doc. # 78-3). Water is typically used as a dissolvent for water soluble materials, while dimethylformamide ("DMF") is typically used for water-insoluble materials. (Doc. # 63-6 at 53). Early Defense is a water-insoluble product. (Doc. # 77-3 at ¶ 21). Dr. Stringham inquired with ACS, which performed a prior test of Early Defense, regarding what dissolvent it used. (Id. at ¶ 30). ACS indicated that it used triacetin and chloroform as dissolvents. (Id.).

Dr. Stringham then ordered a second test using DMF as the dissolvent. (Id. at ¶ 31). He believed that, while triacetin and chloroform adequately dissolved Early Defense to detect the presence of methanol, DMF would provide for more accurate detection of the level of methanol and would more effectively detect the presence of other Class 2 solvents. (Id.). Additionally, he ordered residual solvent testing using DMF by UFAG Laboratorien during the same time period. Dr. Stringham received the results from the second round of tests on December 6 and December 8, 2022. (Id. at 15, 23). Based on the results of the second round of tests, which he opined indicated the presence of methanol, acetone, and possibly hexane, Dr. Stringham reaffirmed his opinions in his initial report. (Id. at ¶ 41).

Here, Dr. Stringham's additional report was a supplemental report timely submitted under Rule 26(e). In the supplemental report, Dr. Stringham did not offer any new opinion, he merely opined on new evidence generated during discovery. See Tampa Bay Water v. HDR Eng'g, Inc., No. 8:08-cv-2446-JDW-TBM, 2011 WL 3475548, at *3 (M.D. Fla. Aug. 9, 2011), aff'd, 731 F.3d 1171 (11th Cir. 2013) (finding additional expert report was a timely served supplemental report because it "did not offer any new opinion or general

criticism not previously given" and was based on "an additional literature search" and "laboratory tests" conducted during discovery). He also ordered the additional tests in response to evidence produced by Vision Elements after he disclosed his initial report. The tests that Dr. Stringham relied on in his supplemental report were not available at the time he issued his first report, and the additional tests, demonstrating that both acetone and methanol were present, completed his initial report.

Even if Dr. Stringham's report was not a timely supplement under Rule 26(e), its submission after MacuHealth's expert disclosure deadline was substantially justified and harmless. "Prejudice generally occurs when late disclosure deprives the opposing party of a meaningful opportunity to perform discovery and depositions related to the documents or witnesses in question." Bowe v. Pub. Storage, 106 F. Supp. 3d 1252, 1260 (S.D. Fla. 2015). "Failure to timely make the required expert witness disclosures is harmless when the party entitled to the disclosure suffers no prejudice." Kleiman v. Wright, No. 18-CV-80176, 2020 WL 6729362, at *5 (S.D. Fla. Nov. 16, 2020).

Vision Elements contends that it would be prejudiced if the Court did not strike the supplemental report because

discovery is now closed. (Doc. # 77 at 7). However, Dr. Stringham submitted his supplemental report one month before the close of discovery. The Court notes that Vision Elements waited until February 16, 2023 – a month after discovery closed and two months after MacuHealth disclosed Dr. Stringham's supplemental report – to raise the issue of prejudice. Further, Dr. Stringham did not change any of his opinions; therefore, his supplemental report is wholly consistent with his initial report and did not create any surprise.

This is not a situation in which the Court will take the extreme measure of striking Dr. Stringham's supplemental report. The Court, thus, denies Vision Elements' Motion to Exclude Dr. Stringham's Supplemental Report.

C. Vision Elements' Motion for Summary Judgment

In its Motion for Summary Judgment, Vision Elements contends that MacuHealth is not entitled to injunctive relief because Vision Elements has "voluntarily removed the challenged advertisements and ceased representing its products as being free from class 2 solvents." (Doc. # 66 at 13). Vision Elements further states that it has no incentive to repeat these claims. (Id.). In its opposition, MacuHealth argues that Vision Elements has not met its burden for mooting

MacuHealth's request for injunctive relief. (Doc. # 81 at 19-20).

The Supreme Court has laid out the high standard for mooting a case by ceasing unlawful conduct:

> [A] defendant cannot automatically moot a case simply by ending its unlawful conduct once sued. Otherwise a defendant could engage in unlawful conduct, stop when sued to have the case declared moot, then pick up where he left off, repeating this cycle until he achieves all his unlawful ends. Given this concern, our cases have explained that a defendant claiming that its voluntary compliance moots a case bears the formidable burden of showing that it is absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur.

Already, LLC v. Nike, Inc., 568 U.S. 85, 91 (2013) (citations and internal quotations omitted). Similarly, the Eleventh Circuit has declared that "[a]n appeal is not moot where the defendant might exercise its discretion to change its policy back while continuing to press the old policy's validity." Norwegian Cruise Line Holdings, Ltd. v. State Surgeon General, Florida Dep't of Health, 55 F.4th 1312, 1315 (11th Cir. 2022) (internal quotations omitted).

Here, Vision Elements has not met its burden to moot the case. Vision Elements still contests the underlying facts, and the parties do not agree that Vision Elements' solvent claims were false. See Hatcher ex rel. Hatcher v. DeSoto Cnty. Sch. Dist. Bd. of Educ., No. 2:13-cv-138-JES-DNF, 2013 WL

1395829, at *3 (M.D. Fla. Apr. 5, 2013) (finding that there was still a live controversy where "[t]he parties contest[ed] the operative facts and d[id] not agree on whether plaintiff's First Amendment rights were violated in the past").

Further, Vision Elements contends that it is entitled to summary judgment on all of MacuHealth's claims because MacuHealth has not met its burden on any of the elements of its claims. For the reasons explained below, Vision Elements' Motion for Summary Judgment is denied.

D. MacuHealth's Motion for Summary Judgment

MacuHealth seeks summary judgment on all counts of the complaint: (1) unfair competition under the Lanham Act, (2) negligent misrepresentation, (3) unfair competition under Florida common law, and (4) deceptive and unfair trade practices. The Court will address each claim in turn.

1. Lanham Act (Count I)

In Count I, MacuHealth alleges that Vision Elements' claims that (1) Early Defense was free from Class 2 solvents and that (2) Class 2 solvents were not used in its production were false and made in violation of the Lanham Act. (Doc. # 1 at ¶¶ 41-57). MacuHealth argues that it is entitled to summary judgment on Count I because there is no genuine dispute as to the facts establishing liability for false

advertising. (Doc. # 63 at 16). In opposition, Vision Elements contends that MacuHealth has not demonstrated facts sufficient to prove any of the requisite elements of this claim. (Doc. # 83 at 10).

To prevail on a false advertising claim, a plaintiff must establish that: (1) the advertisements were false or misleading; (2) they deceived, or had the capacity to deceive, consumers; (3) the deception had a material effect on purchasing decisions; (4) the misrepresented product affects interstate commerce; and (5) the plaintiff has been injured because of the false advertising. Osmose, Inc. v. Viance, LLC, 612 F.3d 1298, 1319 (11th Cir. 2010).

"If the court deems an advertisement to be literally false, then the movant is not required to present evidence of consumer deception." Id. Even if an advertisement is literally false, the plaintiff must still establish materiality. Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc., 299 F.3d 1242, 1250 (11th Cir. 2002). In order to establish materiality, the plaintiff must demonstrate that "the defendant's deception is likely to influence the purchasing decision." Id. (internal quotation marks omitted). The plaintiff may demonstrate this by showing that "the defendants misrepresented an inherent quality or

characteristic of the product." Id. (internal quotation marks omitted). However, "the 'inherent quality or characteristic' formulation adopted by this Circuit does not replace the consumer-oriented nature of the materiality inquiry with a scientific one." J-B Weld Co., LLC v. Gorilla Glue Co., 978 F.3d 778, 797 (11th Cir. 2020).

"Where the challenged advertising makes a misleading comparison to a competitor's product, irreparable harm is presumed." North American Medical Corp. v. Axiom Worldwide, Inc., 522 F.3d 1211, 1227 (11th Cir. 2008). "[C]ourts have also adopted a presumption, in cases where money damages are sought, that willfully deceptive, comparative advertisements cause financial injury to the party whose product the advertisement targets." Trilink Saw Chain, LLC v. Blount, Inc., 583 F. Supp. 2d 1293, 1321 (N.D. Ga. 2008).

Here, there is no genuine dispute as to the first four elements of MacuHealth's false advertising claim. First, MacuHealth has presented multiple residual solvent tests demonstrating that Class 2 solvents are present in samples of Early Defense – rendering false Vision Elements' claim that Early Defense is free from Class 2 solvents. It also offers the testimony of Mr. Torres and Dr. Stringham, who opine that the presence of Class 2 solvents in the samples demonstrates

that such solvents are used in the production of Early Defense. The evidence Vision Elements put forth in its defense does not contradict these tests. The COAs from FT are silent as to whether Class 2 solvents are present in the batches of LMZ carotenoids. Further, the CAL reports demonstrate only that the tested samples contained no more than the standard limit of Class 2 solvents – not that Class 2 solvents are absent from the samples. Not to mention the CAL reports tested Early Defence, a Canadian version of the product not at issue in this litigation. Therefore, there is no genuine factual dispute that Vision Elements' claims that Early Defense did not contain Class 2 solvents and that such solvents were not used in the production process were literally false.

Second, because Vision Elements' advertisements are literally false, MacuHealth does not need to present evidence regarding consumer deception. See Club Exploria, LLC v. Austin, No. 6:18-cv-576-JA-DCI, 2020 WL 6585802, at *11 (M.D. Fla. Nov. 10, 2020) (quoting Border Collie Rescue, Inc. v. Ryan, 418 F. Supp. 2d 1330, 1347 (M.D. Fla. 2006)) ("If an advertisement is literally false, the plaintiff need not present evidence of consumer deception."). Thus, MacuHealth has satisfied the deception element of its Lanham Act claim.

Third, MacuHealth has demonstrated that Vision Elements' false claims were material to consumers' purchasing decisions. In his deposition, Mr. Hinton admitted that Vision Elements' claims regarding Class 2 solvents were "highly important" to consumers' purchasing decisions. (Doc. # 78-1 at 118:6-20). Mr. Jouhet has also been approached by potential consumers who query why MacuHealth is not able to produce its LMZ carotenoids without Class 2 solvents. (Doc. # 63-9 at 136:21-24). The prevalence of Vision Elements' solvent claims is also relevant. Vision Elements made its solvent claims on its website, its bottle, and its oral and email pitches to potential consumers. Through its own actions, Vision Elements has demonstrated that its solvent claims are material. See U.S. Structural Plywood Integrity Coal. v. PFS Corp., No. 19-62225-CIV, 2022 WL 953150, at *30 (S.D. Fla. Mar. 30, 2022) (finding defendant's false claims were material where defendant stated that "consumers rely" on the claim and where customers had noted concern with the company's compliance with the relevant industry standard). Therefore, MacuHealth has satisfied the material element of its Lanham Act claim.

Fourth, MacuHealth has demonstrated that Vision Elements' claims affect interstate commerce. Vision Elements acknowledged that Early Defense is available for sale

throughout the United States and has been sold in multiple states. (Doc. # 78-1 at 46:11-21).

Fifth, there is a genuine dispute of material fact as to whether MacuHealth was injured due to Vision Elements' false claims. MacuHealth does present evidence of two lost customers based on Vision Elements' false claims. Dr. SK and Dr. CA both switched from purchasing MacuHealth to Early Defense after reviewing advertisements regarding the lack of solvents in Early Defense. (Doc. # 78-1 at 127:5-8; 197:3-198:3). Additionally, Dr. SK mentioned the lack of solvents in Early Defense and noted that she pays attention to the presence of solvents. (Doc. # 78-1 at 128:6-129:7; 219:6-10). This is appropriate evidence demonstrating loss. See Fed. Trade Comm'n v. Fleetcor Techs., Inc., 620 F. Supp. 3d 1268, 1277 (N.D. Ga. 2022) ("One way for a plaintiff to prove causation for damages under [the Lanham Act] is to show diversion of customers. This does not place upon the plaintiff a burden of proving detailed individualization of loss of sales but only a showing of some customer reliance on the false advertisement."). However, Vision Elements has presented affidavits from both customers in which the customers state that they did not switch to Early Defense because of Vision Elements' advertisements. There is,

therefore, a factual dispute as to whether Vision Elements' false claims injured MacuHealth.

This factual dispute prevents the Court from determine whether MacuHealth is entitled to either money damages or injunctive relief. While MacuHealth argues that the Court should employ a more lenient standard to determine whether it is entitled to injunctive relief (Doc. # 63 at 22; Doc. # 86 at 4), the Court is not persuaded. MacuHealth relies on Wika Instrument I, LP v. Ashcroft, Inc., No. 1:13-CV-43-CAP, 2015 WL 11199059 (N.D. Ga. July 10, 2015) for the proposition that proof of actual injury is not required for a plaintiff to receive injunctive relief. (Doc. # 86 at 4). However, the court in Wika relied, in turn, only on a District of Minnesota case when it made this statement. See Wika, 2015 WL 11199059 at *7 (citing Ott v. Target Corp., 153 F. Supp. 2d 1055, 1072-73 (D. Minn. 2001)) ("However, proof of actual injury is not required for WIKA to receive injunctive relief."). The Eleventh Circuit has not addressed whether it is appropriate to apply a different standard for permanent injunctive relief and money damages with respect to Lanham Act claims; therefore, the Court declines to apply differing standards for the relief sought by MacuHealth.

2. Negligent Misrepresentation (Count II)

In Count II, MacuHealth claims that Vision Elements' solvent claims were negligent misrepresentations in violation of Fla. Stat. § 817.41(1). (Doc. # 1 at ¶¶ 58-67). MacuHealth contends that there is no genuine dispute of fact as to any of the elements of Count II. (Doc. # 63 at 24-27). Vision Elements disputes only that it knew or should have known that its claims were false and that there is no evidence that anyone relied on its claims. (Doc. # 83 at 16-17).

"To state a cause of action for negligent misrepresentation in Florida, a plaintiff must allege: '(1) the defendant made a misrepresentation of material fact that [it] believed to be true but which was in fact false; (2) the defendant was negligent in making the statement because [it] should have known the representation was false; (3) the defendant intended to induce the plaintiff to rely . . . on the misrepresentation; and (4) injury resulted to the plaintiff acting in justifiable reliance upon the misrepresentation.'" McGee v. JP Morgan Chase Bank, NA, 520 Fed. App'x. 829, 831 (11th Cir. 2013) (quoting Simon v. Celebration Co., 883 So.2d 826, 832 (Fla. 5th DCA 2004)).

Under Florida law, "misleading advertising" includes "any statements made . . . which are known, or through the

exercise of reasonable care or investigation, might have been ascertained, to be untrue or misleading." Fla. Stat. § 817.40(5). When the plaintiff alleging misleading advertising is a competitor of the defendant, an allegation of competition satisfies the element of direct reliance that a consumer is obligated to plead. Third Party Verification, Inc. v. Signaturelink, Inc., 492 F. Supp. 2d 1314, 1322 (M.D. Fla. 2007).

Here, there is no genuine dispute as to the first three elements of negligent misrepresentation. As to the first, as discussed above, MacuHealth has demonstrated that Vision Elements' solvent claims were false. Second, there is no genuine dispute that Vision Elements should have known that its solvent claims were false. Mr. Hinton acknowledged that he was not curious about the third party performing the LMZ carotenoid extraction, that he did not ask and was never told by FT that the carotenoids were extracted without solvents, and never tested Early Defense for the presence of solvents because he was "aware of where our product stands." (Doc. # 78-1 at 194:14-23). Simply put, these actions indicate that Vision Elements did not exercise the reasonable care or investigation required under Florida law. See Joseph v. Liberty Nat. Bank, 873 So. 2d 384, 388 (Fla. 5th DCA 2004)

(reversing grant of summary judgment where bank unreasonably relied on six-year-old appraisal when it specifically advertised that real estate was in a significantly more valuable classification than it actually was).

Third, Vision Elements' solvent claims were intended to induce consumers to purchase Early Defense. Mr. Hinton stated that the solvent claims were important to consumers, and Vision Elements included those claims in nearly all of its advertisements. Vision Elements was promoting favorable information about its product in order to persuade potential consumers to purchase its product. See Gilchrist Timber Co. v. ITT Rayonier, Inc., 127 F.3d 1390, 1396 (11th Cir. 1997) ("[T]he only logical purpose for a seller to provide a potential buyer with favorable information about the land would be to persuade that potential buyer to buy the property."). Finally, MacuHealth has demonstrated that it is a competitor of Vision Elements; therefore, it has satisfied the reliance aspect of the fourth element.

As with Count I, there is still a genuine dispute of fact as to injury. MacuHealth argues that it "need not prove actual harm" because it is a competitor of Vision Elements. (Doc. # 86 at 6). However, it does not cite to any case law on point, and, through its independent research, the Court

did not find any cases in which a competitor seeking both injunctive relief and money damages was granted such relief without a showing of actual damages.

Therefore, the Court finds that there is no genuine dispute of fact as to any element of Count II, except the issue of whether MacuHealth has suffered injury.

3. Unfair Competition and FDUPTA (Counts III and IV)

In Counts III and IV, MacuHealth asserts that Vision Elements engaged in unfair competition, in violation of Florida common law and the Florida Deceptive and Unfair Trade Practices Act ("FDUPTA"), respectively. (Doc. # 1 at ¶¶ 68-81). Like MacuHealth's Lanham Act claim, Counts III and IV are based on Vision Elements' solvent claims. (Id. at ¶ 79) ("By making the False Advertisements, Vision Elements engaged in a deceptive act and an unfair practice").

"Under Florida common law, unfair competition is an umbrella for all statutory and nonstatutory causes of action arising out of business conduct which is contrary to honest practice in industrial or commercial matters." Third Party Verification, 492 F. Supp. 2d at 1324.

The Eleventh Circuit has determined that the legal analysis is the same for violations of the Lanham Act, FDUPTA,

and Florida common law for unfair competition. See Suntree Techs., Inc. v. Ecosense Int'l, Inc., 693 F.3d 1338, 1345 (11th Cir. 2012) ("Courts may use an analysis of federal infringement claims as a 'measuring stick' in evaluating the merits of state law claims of unfair competition."); see also Nat. Answers, Inc. v. SmithKline Beecham Corp., 529 F.3d 1325, 1332–33 (11th Cir. 2008) ("Since Natural Answers is unable to bring an unfair competition claim under the Lanham Act under the theory of either false advertising or trademark infringement, it follows that the common law claims based on unfair competition and trademark infringement must fail as well.").

Because MacuHealth bases its FDUPTA and common law unfair competition claims on the theory of false advertising, the Court evaluates Counts III and IV through the lens of the Lanham Act. Based on the Court's prior conclusion at to Count I, the Court finds that MacuHealth has demonstrated that there is no genuine dispute of fact on any element of Counts III and IV, other than whether Vision Elements' false claims injured MacuHealth.

4. Vision Elements' Affirmative Defenses

Finally, MacuHealth asserts that it is entitled to summary judgment on Vision Elements' affirmative defenses. Vision Elements includes the five following defenses in its answer:

> 1. MacuHealth's claims fail for unclean hands.
> 2. Vision Elements' advertisements were true.
> 3. If Vision Elements' advertisements were untrue, Vision Elements did not know, nor could it have known, of the advertisements' purported falsity.
> 4. MacuHealth fails to state claims for relief.
> 5. Vision Elements' advertisements did not materially impact a consumer's decision to purchase the product.

(Doc. # 25 at 10-11).

In its first defense, Vision Elements asserts that MacuHealth's claim fails for unclean hands because MacuHealth (1) has previously sued other competitors and (2) has misled consumers by claiming that its product is "natural" when it uses polysorbate 80, a synthetic surfactant. (Id. at 10). This defense fails as a matter of law.

In asserting an unclean hands defense, the defendant must show (1) the plaintiff's wrongdoing is directly related to the claim, and (2) the defendant was personally injured by the wrongdoing. Bailey v. TitleMax of Georgia, Inc., 776 F.3d 797, 801 (11th Cir. 2015). "[C]ourts require the connection

between the unclean-hands conduct and the matter in litigation to be very close." Bowe v. Pub. Storage, No. 1:14-CV-21559-UU, 2015 WL 11233137, at *3 (S.D. Fla. June 26, 2015).

As to Vision Elements' assertion that MacuHealth has "defame[d] competitors under the cloak of the litigation privilege" (Doc. # 25 at 10), Vision Elements does not explain why prior lawsuits filed by MacuHealth would prevent it from pursuing its claims against Vision Elements. Without more, Vision Elements cannot sustain this portion of its unclean hands defense. See Therapeutics MD, Inc. v. Evofem Biosciences, Inc., No. 20-CV-82296, 2022 WL 1013278, at *15 (S.D. Fla. Mar. 30, 2022), report and recommendation adopted sub nom. TherapeuticsMD, Inc. v. Evofem Biosciences, Inc., No. 20-CV-82296-RAR, 2022 WL 1262118 (S.D. Fla. Apr. 28, 2022) ("As for Defendant's allegation that this lawsuit was brought for anticompetition purposes, as opposed to a legitimate concern about the similarity of the PHEXXI and IMVEXXY marks, I find that is speculative, and that in any event, it rests on the faulty premise that this litigation is 'baseless.'"). Vision Elements has demonstrated neither that MacuHealth's previous lawsuits against third parties are directly related to its claims in this case nor that Vision Elements was

personally injured by those prior suits. Therefore, Vision Elements' unclean hands defense fails on this ground.

Vision Elements' unclean hands defense also fails based on its assertion that MacuHealth has misled consumers. Whether either MacuHealth or Early Defense contains polysorbate 80 is not the focus of this litigation. Instead this case is focused on the use of solvents in the production of LMZ carotenoids. Vision Elements makes no accusation that MacuHealth misrepresents its supplement's solvent content or the use of solvents in its production. Compare Royal Palm Properties, LLC v. Premier Est. Properties, Inc., No. 10-80232-CV, 2010 WL 3941745, at *2 (S.D. Fla. Oct. 6, 2010) (declining to strike unclean hands defense where defendant alleged that "Plaintiffs have engaged in exactly the same allegedly unlawful copying of advertising and marketing materials that are the basis of Plaintiffs' own claims") with Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dunn, 191 F. Supp. 2d 1346, 1355 (M.D. Fla. 2002) (rejecting unclean hands defense in case where plaintiff accused former-employee defendants of unlawfully soliciting employer's clients and defendants contended "that Plaintiff encourages its employees to help it recruit its competitors' financial advisors in order to obtain their customer lists"). Further, Vision

Elements makes no attempt to explain why it is injured by MacuHealth's "natural" claim.

Thus, MacuHealth is entitled to summary judgment on Vision Elements' first affirmative defense. Vision Elements' second, third, fourth, and fifth defenses do not impact the Court's analysis of MacuHealth's claims. These are not true affirmative defenses, but are instead simply contentions that, in various ways, MacuHealth, has failed to prove its case. The Court need not address these defenses further.

IV. Conclusion

The Court denies MacuHealth's Motion for Summary Judgment as to Counts I, II, III, and IV. However, the Court notes that the only issue left to litigate at trial as to each count is whether MacuHealth suffered injury, as the Court has determined that there is no genuine dispute of fact as to any other element of Count I, II, III, or IV.

Accordingly, it is now

ORDERED, **ADJUDGED**, and **DECREED:**

(1) Plaintiff MacuHealth, LP's Motion for Summary Judgment (Doc. # 63) is **GRANTED** as to Vision Elements' unclean hands defense and otherwise **DENIED.**

(2) Plaintiff MacuHealth's Daubert Motion to strike Christopher Byrd's testimony (Doc. # 68) is **DENIED as moot.**

(3) Defendant Vision's Motion to exclude the supplemental report of James Stringham (Doc. # 77) is **DENIED.**

(4) Defendant Vision Elements' Motion for Summary Judgment (Doc. # 66) is **DENIED.**

DONE and **ORDERED** in Chambers in Tampa, Florida, this 7th day of June, 2023.

Virginia M. Hernandez Covington

VIRGINIA M. HERNANDEZ COVINGTON
UNITED STATES DISTRICT JUDGE