UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

CLAUDIO DE SIMONE,

Plaintiff/Counterclaim Defendant,

EXEGI PHARMA, LLC,

Plaintiff,

v.

VSL PHARMACEUTICALS, INC.,

Defendant/Counterclaim Plaintiff,

LEADIANT BIOSCIENCES, INC., and ALFASIGMA USA, INC.,

Defendants,

v.

DANISCO USA, INC.,

Counterclaim Defendant.

Civil Action No. TDC-15-1356

ORDER

For the reasons set forth in the accompanying Memorandum Opinion, the Motion for an Order of Civil Contempt, ECF No. 981, filed by Plaintiff and Counterclaim Defendant Claudio DeSimone and Plaintiff ExeGi Pharma, LLC ("ExeGi") (collectively, "the De Simone Parties") against Defendant and Counterclaim Plaintiff VSL Pharmaceuticals, Inc. ("VSL") and Defendant Alfasigma USA, Inc. ("Alfasigma") (collectively, "the VSL Parties") is GRANTED IN PART and DENIED IN PART.

The Motion is GRANTED to the extent that:

1. The Court FINDS the VSL Parties in CONTEMPT of the Court's June 20, 2019 Permanent Injunction based on online statements made by the VSL Parties and their representatives, specifically (a) the online accessibility until September 10, 2019 of the January 31, 2019 Healthcare Providers Letter, which stated that Italian VSL#3 was "equivalent to" the De Simone Formulation and that clinical studies of the De Simone Formulation could "be relied on to show the efficacy and safety" of Italian VSL#3; (b) responses by VSL#3 representatives on the VSL#3 Facebook page to consumer questions in which those representatives stated that the formulation of VSL#3 had "not changed," that manufacturing of VSL#3 was "moved back to its original site in Italy," and that "[n]o changes to the current formula have been made"; and (c) assertions on the VSL#3 Facebook page and in statements describing various VSL#3 YouTube videos, which continued to be available online after issuance of the Permanent Injunction, that VSL#3 was "clinically proven," "has more than a decade of patient support and use," and "is one of the most studied" probiotics of its kind.

2. The Court FINDS the VSL Parties in CONTEMPT of the Court's June 20, 2019 Permanent Injunction based on CEO Luca Guarna's statement in a September 2019 press release that Visbiome was the "generic" version of VSL#3.

3. The VSL Parties are ORDERED to: (a) remove the remaining contumacious statements from the relevant media within **5 days** of the date of this Order; (b) to review within **14 days** of the date of this Order all promotional materials and online postings, including the audio content of any YouTube videos referenced in the exhibits to the Motion, for the same or similar statements and remove any that contain statements that violate the Permanent injunction; and (c) instruct all relevant personnel to refrain from using the same or similar language going forward.

4. The VSL Parties are further ORDERED to pay the De Simone Parties' reasonable attorney's fees expended in advancing the Motion. The parties are directed to meet and confer on this issue with the aim of agreeing on the amount of attorney's fees without further intervention from the Court, and to file a Joint Status Report on the issue within **30 days** of the issuance of this Order.

5. The Court's reasoning and analysis in the accompanying Memorandum Opinion are incorporated into this Order and may be relied upon by the parties in assessing whether any future conduct violates this Order.

The Motion is otherwise DENIED.

Date: July 30, 2020

THEODORE D. CHUANG
United States District Judge

UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

CLAUDIO DE SIMONE,

Plaintiff/Counterclaim Defendant,

EXEGI PHARMA, LLC,

Plaintiff,

v.

VSL PHARMACEUTICALS, INC.,

Defendant/Counterclaim Plaintiff,

LEADIANT BIOSCIENCES, INC., and ALFASIGMA USA, INC.,

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DANISCO USA, INC.,

Counterclaim Defendant.

Civil Action No. TDC-15-1356

MEMORANDUM OPINION

This case involved a dispute between former business partners as to the ownership of a proprietary formulation ("the De Simone Formulation") used in a probiotic previously known by the tradename VSL#3 and now known by the tradename Visbiome. In November 2018, a jury returned a verdict in favor of Plaintiff and Counterclaim Defendant Claudio DeSimone and Plaintiff ExeGi Pharma, LLC ("ExeGi") (collectively, "the De Simone Parties") on all counts against Defendant and Counterclaim Plaintiff VSL Pharmaceuticals, Inc. ("VSL"), Defendant Leadiant Biosciences, Inc. ("Leadiant") and Defendant Alfasigma USA, Inc. ("Alfasigma")

(collectively, "the VSL Parties"), including a verdict in favor of the De Simone Parties on their claim against Leadiant and Alfasigma for false advertising of VSL#3 in violation of the Lanham Act, 15 U.S.C. § 1125(a) (2018). In light of that verdict, and pursuant to a motion filed by the De Simone Parties, this Court issued a permanent injunction on June 20, 2019 barring the VSL Parties from making certain representations about VSL#3. The De Simone Parties now assert that the VSL Parties have violated the terms of that injunction and have thus filed a Motion for an Order of Civil Contempt against VSL and Alfasigma. The VSL Parties oppose the Motion. Having reviewed the briefs and submitted materials, the Court finds no hearing necessary. D. Md. Local R. 105.6. For the reasons set forth below, the De Simone Parties' Motion is GRANTED IN PART and DENIED IN PART.

BACKGROUND

Prior relevant factual background is set forth in the Court's September 23, 2015 Memorandum Opinion on the First Motion for a Preliminary Injunction, *De Simone v. VSL Pharm., Inc.*, 133 F. Supp. 3d 776, 780–88 (D. Md. 2015); its June 20, 2016 Memorandum Opinion on the Second Motion for a Preliminary Injunction, *De Simone v. VSL Pharm., Inc.*, No. TDC-15-1356, 2016 WL 3466033 at *1–12 (D. Md. June 20, 2016); its October 9, 2018 Memorandum Opinion on the Parties' Cross Motions for Summary Judgment, *De Simone v. VSL Pharm., Inc.*, 352 F. Supp. 3d 471 (D. Md. 2018); its June 20, 2019 Memorandum Opinion on the VSL Parties' Rule 50 and 59 Motions, *De Simone v. VSL Pharm., Inc.*, 395 F. Supp. 3d 617 (D. Md. 2019); and its June 20, 2019 Memorandum Opinion on the De Simone Parties' Motion for a Permanent Injunction, *De Simone v. VSL Pharm., Inc.*, No. TDC-15-1356, 2019 WL 2569574 (D. Md. June 20, 2019). Additional facts and procedural history are provided below as necessary.

I. The Permanent Injunction

On June 20, 2019, the Court issued an Order ("the Permanent Injunction") enjoining the VSL Parties from:

> (1) stating or suggesting in VSL#3 promotional materials directed at or readily accessible to United States consumers that that the present version of VSL#3 produced in Italy ("Italian VSL#3") continues to contain the same formulation found in versions of VSL#3 produced before January 31, 2016 ("the De Simone Formulation"), including but not limited to making statements that VSL#3 contains the "original proprietary blend" or the "same mix in the same proportions" as earlier versions of VSL#3; and
>
> (2) citing to or referring to any clinical studies performed on the De Simone Formulation or earlier versions of VSL#3 as relevant or applicable to Italian VSL#3.

June 20, 2019 Order at 2, ECF No. 930. The De Simone Parties contend that since the issuance of this Order, the VSL Parties have repeatedly violated its terms.

I. Online Media

On January 31, 2019, after the jury verdict, the VSL Parties posted on the VSL#3 website a letter to healthcare providers (the "Healthcare Providers Letter") that recounted the verdict but asserted that the trial evidence "confirmed that … Italian-made VSL#3 contains the same 8 strains of bacteria" as the De Simone Formulation and that "Italian-made VSL#3 is equivalent to" the De Simone Formulation. Healthcare Providers Letter, ECF No. 981-2. The Healthcare Providers Letter also stated that prior clinical studies of the De Simone Formulation could "be relied on to show the efficacy and safety" of Italian VSL#3. *Id.* Upon issuance of the Permanent Injunction, the VSL Parties took some steps to remove the Healthcare Providers Letter from the VSL#3 website, but it remained accessible until September 10, 2019.

In the same time frame, the VSL#3 Facebook page has contained the statement that VSL#3 is "clinically proven in the dietary management of IBS, ulcerative colitis and ileal pouch." VSL

Facebook Page, ECF No. 981-7. That assertion is repeated in the written summaries accompanying numerous VSL#3 YouTube videos, all of which remained accessible at least through November 4, 2019 but which were posted several years prior to this Court's Permanent Injunction. At least one posting connected to a YouTube video states that VSL#3 has "more than a decade of patient support and use" and that it "is one of the most studied" probiotics of its kind. VSL#3 & Me: Dr. Pat Raymond (Oct. 7, 2016) at 1, ECF No. 984-13.

During September 2019, VSL#3 representatives responding to consumer questions about the composition of VSL#3 on the VSL#3 Facebook page repeatedly offered the assertions that "VSL#3 was not recalled or discontinued, there are no safety or efficacy concerns and the formulation has not changed," and that "In January 2016 manufacturing of VSL#3 was moved back to its original site in Italy and the lactose was removed from the product. No changes to the current formula have been made." Facebook Conversations, ECF Nos. 981-8–981-14.

II. Press Release

In a September 9, 2019 press release touting a victory for the VSL Parties in Italian litigation about VSL#3, Luca Guarna, the Chief Executive Officer of VSL, affirmed VSL's commitment to "making the VSL#3 probiotic available to our dedicated customers and healthcare providers notwithstanding De Simone and ExeGi's aggressive efforts to sell their competing, generic probiotic product." Sept. 9, 2019 Press Release at 2, ECF No. 981-6. That press release appeared on numerous websites, including markets.financialcontent.com, biospace.com, businesswire.com, citizentribune.com, finance.yahoo.com, and streetinsider.com.

III. Product Information Sheets

On July 26, 2019, the VSL Parties sent a letter to wholesalers and distributors of VSL#3 relaying the terms of the Permanent Injunction, asserting that it was not retroactive, and stating

that no recall of, or corrective advertising about, previously packaged VSL#3 was required. The VSL Parties advised that consistent with the Permanent Injunction, Alfasigma was removing product information sheets, which contained language in violation of the Permanent Injunction, from remaining VSL#3 packages still within its facilities. They also reported that future VSL#3 product information sheets would be revised to remove any comparison of Italian VSL#3 to the De Simone Formulation, and that the revised product information sheet would be posted on the VSL#3 website. On August 20, 2019, Alfasigma advised VSL#3 wholesalers and distributors that to comply with the Preliminary Injunction, they should either remove the old product information sheets from all VSL#3 packages remaining in their inventory before sale, or return the unsold product to Alfasigma for credit.

The revised product information sheet, first posted on the VSL#3 website on August 14, 2019, contains no citations to any clinical studies. However, it states multiple times that "VSL#3 is a probiotic medical food intended for the dietary management of Irritable Bowel Syndrome (IBS), Ulcerative Colitis (UC) or an ileal pouch," and that VSL#3 has been manufactured using ingredients "Generally Recognized as Safe" (GRAS) for their intended use." Revised Product Info. Sheet, ECF No. 981-5.

DISCUSSION

The De Simone Parties ask this Court to find VSL and Alfasigma in contempt of the Permanent Injunction based on statements in Italian VSL#3 promotional materials, statements of representatives of VSL#3, and statements in the Italian VSL#3 product information sheet. The VSL Parties argue primarily that the De Simone Parties are seeking an expansion of the Permanent Injunction rather than enforcement of it and that such expansion is beyond the power of this Court. They also argue that their challenged conduct did not violate the Permanent Injunction. Lastly,

the VSL Parties argue that to the extent any of their actions did violate the terms of the Permanent Injunction, such violations were inadvertent and swiftly corrected.

I. Legal Standard

To support a finding of civil contempt, each of the following elements must be established by clear and convincing evidence: (1) the existence of a valid decree of which the alleged contemnor had actual or constructive knowledge; (2) that the decree was in the movant's favor; (3) that the alleged contemnor by its conduct violated the terms of the decree and had knowledge or constructive knowledge of such violation; and (4) that the movant suffered harm as a result. *Ashcraft v. Conoco, Inc.*, 218 F.3d 288, 301 (4th Cir. 2000) (internal citation omitted). Here, there is no dispute that the first two elements are satisfied. Where the Court's analysis will focus only on whether the Permanent Injunction was violated and must be enforced, rather than on whether the Permanent Injunction should be expanded, the Court has the authority to rule on the Motion even while this case is on direct appeal.

In determining whether there was a violation of a court order, there is no requirement that the violation was willful. "Civil as distinguished from criminal contempt is a sanction to enforce compliance with an order of the court or to compensate for losses or damages sustained by reason of noncompliance. Since the purpose is remedial, it matters not with what intent the defendant did the prohibited act." *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 191 (1949) (internal citations omitted). However, because intent is irrelevant, the order allegedly violated must be one that sets forth in "specific detail an unequivocal command." *In re General Motors Corp.*, 61 F.3d 256, 258–59 (4th Cir. 1995) (internal citation omitted). A party therefore should not be found in civil contempt where there is "a *fair ground of doubt* as to the wrongfulness of [their] conduct." *Taggart v. Lorenzen*, ___ U.S. ___, 139 S. Ct. 1795, 1801 (2019). However, civil contempt need

not be limited to addressing only activities that were "specifically enjoined," because such a narrow requirement "would give tremendous impetus to [a] program of experimentation with disobedience of the law." *McComb*, 336 U.S. at 192. Instead, "[i]t is enough protection for defendants if close questions of interpretation are resolved in the defendant's favor in order to prevent unfair surprise." *Schering Corp. v. Ill. Antibiotics Co.*, 62 F. 3d 903, 906 (7th Cir. 1995).

II. Violation of the Injunction

A. Online Statements

The De Simone Parties allege violations of the Permanent Injunction arising from online promotional statements, including (1) the January 31, 2019 letter on the VSL#3 website stating that, despite the jury verdict, Italian VSL#3 was equivalent to the De Simone Formulation; (2) repeated statements on Facebook by VSL#3 representatives in response to consumer questions that the formulation for VSL#3 has not changed; and (3) statements on Facebook and YouTube that VSL#3 is "clinically proven." The Court agrees that these statements violate the Permanent Injunction.

The VSL Parties do not seriously dispute that the continued presence of the January 31, 2019 letter on the VSL#3 website after the issuance of the Permanent Injunction on June 20, 2019 violated its terms. Although they argue that its continued presence was inadvertent, and point to a declaration in which an Alfasigma official attests to efforts to remove the Healthcare Providers Letter from the website after the issuance of the Permanent Injunction, only to be informed in September 2019 that it remained accessible, DiMarco Decl. ¶¶ 6, 14, ECF No. 983-3, a lack of intent does not preclude a finding of a violation of the Permanent Injunction or of civil contempt. *McComb*, 336 U.S. at 187.

Turning next to the September 2019 statements by VSL#3 representatives on Facebook, the VSL Parties have effectively conceded that the statements violated the Permanent Injunction and note that the content was removed soon after the De Simone Parties brought it to their attention. The statements that "the formulation has not changed," and that "the manufacturing of VSL#3 was moved back to its original site in Italy" but that "[n]o changes to the current formula have been made," either directly state, or plainly suggest, that the present version of VSL#3 continues to use the De Simone Formulation. Facebook Conversations, ECF Nos. 981-8–981-14. Whether, as the VSL Parties argue, the consumers were "plants" from the De Simone Parties is irrelevant: the repeated use of the same language reveals that the VSL Parties clearly had a script from which they were working, and that script specifically stated that the formulation of Italian VSL#3 had not changed, an assertion that violates the Permanent Injunction's requirement that the VSL Parties make no representations suggesting that the Italian VSL#3 continues to contain the De Simone Formulation. The Court thus finds that the statements made by VSL#3 Representatives in Facebook chats with consumers violated the Permanent Injunction.

As for the continued assertions on the VSL#3 Facebook page that VSL#3 is "clinically proven" to help in the treatment of various gastrointestinal disorders, and the continued presence of YouTube videos accompanied by the same representation, those statements plainly suggest that Italian VSL#3 has a history of clinical studies establishing its efficacy. The absence in the Italian VSL#3 product information sheet of any citations to any clinical studies, however, demonstrates that there is no robust history, or possibly any history, of clinical studies of Italian VSL#3 establishing its efficacy for treatment of irritable bowel syndrome, ulcerative colitis, and ileal pouch, nor have the VSL Parties identified in their brief or attached as exhibits any such studies. Accordingly, the reference to "clinically proven" can fairly be construed only as referring to the

clinical studies performed on the De Simone Formulation and thus suggesting that those prior studies are "relevant or applicable to Italian VSL#3." Permanent Injunction at 2. Indeed, where some of these statements appear on the YouTube video descriptions that remained posted after the Permanent Injunction but which were originally posted when VSL#3 still contained the De Simone Formulation, it is apparent that the clinical study language was first drafted to refer to the De Simone Formulation's history of clinical studies. Thus, by calling Italian VSL#3 "clinically proven" even after the Permanent Injunction, the VSL Parties are alluding to and invoking the clinical study history of the De Simone Formulation, thereby necessarily suggesting that Italian VSL#3 "continues to contain the same formulation" as the De Simone Formulation. *Id.* This conclusion is bolstered by the fact that one of the YouTube video descriptions improperly states that VSL#3 has "more than a decade of patient support and use" and that it "is one of the most studied" probiotics of its kind. VSL#3 & Me: Dr. Pat Raymond (Oct. 7, 2016) at 1, ECF No. 984-13. Although the VSL Parties argue that the Court has already addressed this language and found it acceptable, they misread the Court's earlier opinion. The Court's prior ruling stated only that there is no evidence establishing that Italian VSL#3 is "clinically ineffective." June 20, 2019 Mem. Op. at 4, ECF No. 929. A statement that Italian VSL#3 is not "clinically ineffective" is a far cry from a claim that it is "clinically proven" in that the former does not connote a history of successful clinical studies. The Court therefore finds that the various statements that Italian VSL#3 is "clinically proven" violate the Permanent Injunction.

B. Press Release

The De Simone Parties also argue that the press release statement by VSL CEO Luca Guarna describing Visbiome as the "generic" version of VSL#3 violated the Permanent Injunction. Press Releases at 2, ECF No. 981-6. In this statement, Guarna clearly suggested an equivalence

between the products' formulation and did so a way that signaled that Visbiome was the later copy while Italian VSL#3 was the original version. Guarna was thus passing off Italian VSL#3 as the authentic De Simone Formulation, an effort that squarely violates the Permanent Injunction's bar on "stating or suggesting" that Italian VSL#3 "continues to contain" the DeSimone Formulation. *See* Permanent Injunction at 2.

The VSL Parties, however, assert that labeling Visbiome as the generic version of Italian VSL#3 does not violate the order because, as a technical matter, Visbiome was never patented, and because earlier in this litigation Visbiome marketed itself as the VSL#3 generic. As to its first argument, the Court finds such semantics unpersuasive. Whether "generic" has a specific meaning in the patent context, the VSL Parties would be hard pressed to show that in a press release widely circulated to diverse media outlets, Guarna was using the term with such a specialized, intellectual property law meaning. Instead, Guarna used the term when discussing not the intellectual property status of VSL#3 and Visbiome, but their commercial availability, expressly emphasizing to customers that VSL#3 remained available for purchase despite its "aggressive," "generic" competitor. Sept. 9, 2019 Press Release at 2. That the term "generic" may have another, technical meaning is thus of no moment. *See Schering*, 62 F.3d at 907 (remarking that in determining whether conduct violates an injunction, the appropriate principle is "substance over form").

Recourse to context also dooms the VSL Parties' argument based on the De Simone Parties' prior marketing of Visbiome as a generic version of VSL#3. Those marketing statements were made in 2015, when VSL#3 was still, in fact, comprised of the De Simone Formulation manufactured by Danisco in the United States. Where VSL held the trademark to VSL#3, and this Court granted a preliminary injunction barring the DeSimone Parties from using the VSL#3 trademark in their promotional materials, their earlier references to a generic version of VSL#3

were logical and appropriate. However, when the VSL Parties lost access to that version of the product after January 2016 and began to manufacture their own version in Italy using a different formulation, it was no longer accurate to describe Visbiome as a generic version of VSL#3. Where the circumstances have materially changed and such a characterization suggests that Italian VSL#3 shares the same formulation with Visbiome, the Court finds that Guarna's statement in the September 2019 Press Release violates the Permanent Injunction.

C. Product Information Sheets

Although the De Simone Parties argue that the VSL Parties failed to take steps to ensure the removal before sale of the product information sheets previously inserted into VSL#3 packages prior to the Permanent Injunction, specifically those already on retail shelves, the Court will not find such an omission to amount to civil contempt. Where the Court did not specifically order such retroactive action, and the De Simone Parties have not submitted evidence establishing that such package inserts were actually distributed and caused harm, the Court finds that the VSL Parties' actions to direct the removal of package inserts still in the possession of wholesalers and distributors adequately addressed this issue.

As for the content of the revised VSL#3 product information sheets, the De Simone Parties assert that the representations that VSL#3 has been manufactured with ingredients that have been deemed "Generally Recognized as Safe," ("GRAS"), and that it is "a probiotic medical food intended for the dietary management of Irritable Bowel Syndrome (IBS), Ulcerative Colitis (UC) or an ileal pouch," run afoul of the Permanent Injunction's requirement that the VSL Parties not cite to or refer to clinical studies as relevant or applicable to Italian VSL#3. Revised Product Info. Sheet, ECF No. 981-5. The Court does not find that these statements violate the Permanent Injunction. The assertions that Italian VSL#3 is manufactured with GRAS ingredients and is a

"medical food" do not, on their face, suggest or imply any continuity between Italian VSL#3 and the De Simone Formulation. There is no mention in the product information sheet of Visbiome or the De Simone Formulation, no statement about any long history of the effectiveness of VSL#3, and no citation to clinical studies of the De Simone Formulation.

The De Simone Parties argue that the GRAS designation implies equivalence with the De Simone Formulation because it was granted after an analysis that included consideration of the De Simone Formulation's history of clinical studies. The GRAS report, however, actually related to a review of Italian VSL#3, not the De Simone Formulation, and it does not conclude that Italian VSL#3 actually contains the exact same formulation as the De Simone Formulation but instead focuses on the safety of its ingredients, which substantially overlap with those of the De Simone Formulation, and appears to rely on such studies to conclude that those ingredients are safe. Under these facts, the Court finds that the chain of reasoning connecting the use of the term GRAS with the conclusion that Italian VSL#3 was the product reviewed in the earlier clinical studies is too attenuated to support a violation of the Permanent Injunction.

Likewise, the Court finds that the characterization of Italian VSL#3 as a "medical food" does not violate the Permanent Injunction. The De Simone Parties argue that "medical food" is a statutorily defined term that may be applied only when there is significant scientific agreement that it is clinically effective, and that where Italian VSL#3 has never been tested clinically to determine its effectiveness, the use of the term implies that prior clinical studies on the De Simone Formulation may be appropriately considered as applicable to Italian VSL#3. Again, this chain of reasoning is too indirect to establish a violation of the Permanent Injunction from the mere use of the term "medical food." To be sure, in using these terms, the VSL Parties run the risk that they may not be able to adequately respond to any consumer inquiries into the GRAS or medical food

designations without violating the Permanent Injunction. For example, if asked to provide support for these designations, they would be unable to provide or even refer to either the earlier clinical studies or the GRAS report, which references those studies in a way that would make them "relevant" to Italian VSL#3. Permanent Injunction at 2. But on the limited question of whether references to GRAS and "medical food" in the product information sheet violate the Permanent Injunction, the Court finds that they do not. Where the actual representations on the product information sheet make no direct or indirect reference to the De Simone Formulation or Visbiome, continuity with earlier versions of VSL#3, or the prior clinical studies on the De Simone Formulation, the Court finds no violation of the Permanent Injunction arising from the product information sheets. *Taggart*, 139 S. Ct. at 1801.

III. Harm

The Court finds that the identified violations, which were designed to create a false continuity between Italian VSL#3 and the De Simone Formulation so that VSL#3 could keep its prior customers and potentially poach new ones, caused harm to the De Simone Parties for the reasons set forth in this Court's Memorandum Opinions on the VSL Parties' Rule 50 and 59 Motions and the De Simone Parties' Motion for a Permanent Injunction. *See De Simone*, 395 F. Supp. 3d at 628–30; *De Simone*, No. TDC-15-1356, 2019 WL 2569574, at *2. These findings are further bolstered by the declarations of Debra Rexroat and Janet McGready which, while not identifying a direct link between the violations of the Permanent Injunction and lost sales to ExeGi, establish that customer confusion over whether VSL#3 still contains the De Simone Formulation has caused ExeGi to lose business because customers who rely on the De Simone Formulation continued to purchase VSL#3 for a period of time until they realized that Italian VSL#3 no longer

contained that formulation. *See* Rexroat Decl. ¶¶ 9-11, ECF No. 981-19; McGready Decl. ¶11, ECF No. 981-20. Accordingly, all requirements for civil contempt have been satisfied.

IV. Remedies

For the reasons set forth above, the Court finds VSL and Alfasigma in contempt of court for violating the Permanent Injunction by (1) leaving the Healthcare Providers Letter accessible on the VSL#3 website for approximately three months after the issuance of the Permanent Injunction; (2) having VSL#3 representatives state in Facebook postings that VSL#3's formula had not changed; (3) maintaining statements on Facebook and YouTube that VSL#3 was "clinically proven"; and (4) having VSL's CEO refer to Visbiome as a "generic" of VSL#3. As to a remedy, the De Simone Parties ask for some or all of the profits derived from the sale of VSL#3 during the relevant time period. The Court declines to impose such a sanction. First, although harm can be inferred from these violations, the De Simone Parties have not put forth evidence of quantifiable damages of such a magnitude as would warrant such a remedy. Moreover, where the Facebook statements by VSL#3 representatives were removed shortly after they were posted, the Healthcare Providers Letter and some of the statements that VSL#3 is "clinically proven" appear to predate the Permanent Injunction and may have been left in place inadvertently, and Guarna's statement was limited to a single occasion in a press release not focused on establishing an equivalence between VSL#3 and the De Simone Formulation, the nature of the violations is not so egregious as to justify a transfer of profits. Accordingly, the Court will instead sanction the contempt by ordering VSL and Alfasigma to (1) remove the remaining contumacious statements from the relevant media, review all promotional materials and online postings, including the audio content of any YouTube videos referenced in the exhibits to the Motion, for the same or similar statements and to remove them, and instruct all relevant personnel to refrain

from using the same or similar language going forward; and (2) pay the De Simone Parties' reasonable attorney's fees expended in advancing the Motion. These limited sanctions, including the attorney's fees, are warranted because certain violations, such as the September 2019 Facebook statements, were blatant violations of the Permanent Injunction, and other violations, such as the claims that VSL#3 is "clinically proven" persisted over an extended period of time. Moreover, the number of different violations demonstrates that the VSL Parties' efforts to avoid violations of the Permanent Injunction were notably deficient.

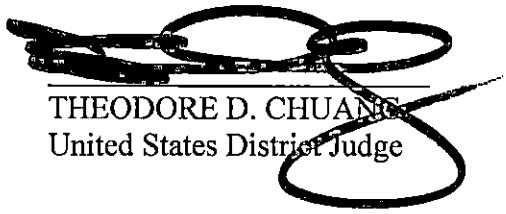
The VSL Parties' assertion that attorneys' fees may be awarded only when the contempt rises to the level of obstinance overstates the law. While in an unpublished case, the United States Court of Appeals for the Fourth Circuit stated that courts "may" award attorney's fees where a party has willfully disobeyed a court order, it did not expressly limit the awarding of attorney's fees to such an instance. *Omega Travel, Inc. v. Omega Travel and Shipping Agencies, Inc.*, 905 F.2d 1530, at *4 (4th Cir. 1990) (unpublished). Instead, the Fourth Circuit has since emphasized that "[t]he appropriate remedy for civil contempt is within the court's broad discretion," limited only in that any sanctions should be remedial and compensatory rather than punitive. *In re General Motors*, 61 F.3d at 259. In *In re General Motors Corp.*, parts of a prior court order had been stricken and the parties ordered not to cite them as authority, but one party submitted filings in other courts that continued to quote the stricken language, later characterizing the error as a "careless blunder." *Id.* at 258. After a finding of contempt that contained no discussion of willful disobedience or obstinacy, the court awarded damages and attorney's fees. *Id.* at 259. Based on this later, published case law, the Court concludes that there is no requirement of a showing of willful disobedience or obstinacy for the awarding of attorney's fees upon a finding of civil contempt.

Lastly, where the VSL Parties are on notice of the identified violations and of potential violations that could arise from the use of the clinical studies in support of the GRAS and medical food claims, any such violations occurring in the future will likely result in more severe sanctions. *See Cromer v. Kraft Foods, N.A., Inc.*, 390 F.3d 812, 821–22 (4th Cir. 2004) (stating that sanctions can be imposed on a finding of civil contempt if the sanctions are "remedial and intended to coerce the contemnor into compliance with court orders").

CONCLUSION

For the reasons set forth above, the De Simone Parties' Motion for an Order of Civil Contempt is GRANTED IN PART and DENIED IN PART. A separate Order shall issue.

Date: July 30, 2020



THEODORE D. CHUANG
United States District Judge