

**UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND**

CLAUDIO DE SIMONE and
EXEGI PHARMA, LLC,

Plaintiffs/Counterclaim Defendants,

v.

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

Defendants/Counterclaim Plaintiffs,

v.

DANISCO USA, INC.,

Counterclaim Defendant.

Civil Action No. TDC-15-1356

MEMORANDUM OPINION

Pending before the Court is the latest conflict in a long-standing dispute between former business partners about 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. Plaintiff ExeGi Pharma, LLC (“ExeGi”) has filed a Motion for an Order of Civil Contempt against Defendant and Counterclaim Plaintiff VSL Pharmaceuticals, Inc. (“VSL”) and Defendant Alfasigma USA, Inc. (“Alfasigma”) (collectively, “the VSL Parties”) asserting that they have violated this Court’s June 20, 2019 permanent injunction (“the Permanent Injunction”) barring the VSL Parties from making certain representations about their new version of VSL#3 manufactured in Italy (“new VSL#3” or “Italian VSL#3”). Defendant Lediand Biosciences, Inc. is not named in the Motion. 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 Motion will be DENIED.

BACKGROUND

Prior relevant factual background and rulings are 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 (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 (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); its June 20, 2019 Memorandum Opinion on Plaintiffs' Motion for a Permanent Injunction, *De Simone v. VSL Pharm., Inc.*, No. TDC-15-1356, 2019 WL 2569574 (D. Md. June 20, 2019); and its July 30, 2020 Memorandum Opinion on Plaintiffs' Motion for an Order of Civil Contempt, *De Simone v. VSL Pharm., Inc.*, No. TDC-15-1356, 2020 WL 4368103 (D. Md. July 30, 2020). Additional facts and procedural history are provided below as necessary.

In November 2018, a jury returned a verdict in favor of Claudio De Simone and ExeGi (collectively, "the De Simone Parties") on all counts against the VSL Parties, including a verdict finding Leadiant and Alfasigma liable 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, on June 20, 2019, the Court issued the Permanent Injunction, which enjoined the VSL Parties from:

- (1) stating or suggesting in VSL#3 promotional materials directed at or readily accessible to United States consumers 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.

Permanent Injunction at 2, ECF No. 930.

In *De Simone v. Alfasigma USA, Inc.*, 847 F. App’x 174 (4th Cir. 2021), the United States Court of Appeals for the Fourth Circuit affirmed the jury verdict and this Court’s rulings on post-trial motions, and it largely affirmed the Permanent Injunction, vacating its terms only as to the prohibition on “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.” *Id.* at 184.

In so narrowing the Preliminary Injunction, the Fourth Circuit clarified that:

To the extent that this language is intended to prohibit the VSL Parties from citing or referring to the clinical studies *as though* they were performed on Italian VSL#3 (rather than on the Danisco-made version), it’s superfluous to prohibiting claims of continuity between the products. But prohibiting the VSL Parties from citing or referring to the clinical studies as *even relevant* to Italian VSL#3 goes too far, as they could feasibly do so without claiming continuity between their old product and their new one.

Id.

DISCUSSION

In the wake of the Fourth Circuit’s opinion, ExeGi has filed a Second Motion for an Order of Contempt, asserting that the VSL Parties have continued to violate the Permanent Injunction. Specifically, ExeGi argues that the VSL Parties should be found in contempt based on (1) the December 2020 publication in a scientific journal of an article reporting results of a clinical study on Italian VSL#3 and citing to the prior clinical studies conducted on the De Simone Formulation;

(2) the posting on the VSL#3 website of a Fact Sheet that allegedly impermissibly implies continuity between Italian VSL#3 and Visbiome, and Alfasigma's responding to inquiries on Facebook about whether VSL#3 had changed by directing consumers to the Fact Sheet; and (3) an email from Luca Guarna, VSL's Chief Executive Officer, to various practitioners in the probiotic field asserting that the Fourth Circuit's decision allows prior clinical studies of VSL#3 to be cited without restriction in discussing Italian VSL#3.

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).

As to the third element, 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*, 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).

Here, there is no dispute that the first two elements are satisfied. The dispute centers only on whether the VSL Parties’ conduct violated the Permanent Injunction and, if so, if any such violations resulted in harm to ExeGi. Because the Court does not find that the conduct violated the Permanent Injunction, it need not, and so does not, address the issue of harm.

II. The Journal Article

ExeGi asserts that the publication in the scientific journal *Inflammatory Bowel Diseases* of an article entitled “Impact of the Trophic Effect of the Secretome From a Multistrain Probiotic Preparation on the Intestinal Epithelia” (“the Journal Article”), authored by 15 scholars including Valentina Petito, Antonio Gasbarrini, and Lucrezia Laterza, violated the Permanent Injunction. The article reports the results of a clinical study conducted on Italian VSL#3 and cites to prior clinical studies conducted on the De Simone Formulation. Petito and Gasbarrini are on the Scientific Advisory Board of Actial, a company owned by the Cavazza family, which also owns VSL. Laterza is a consultant for Actial. Based on these connections, ExeGi asserts that the article is a VSL#3 “promotional piece masquerading as a scientific study,” and that because it cites to the prior clinical studies, it runs afoul of the Permanent Injunction. Mot. at 5, ECF No. 1015.

Without reaching the question of whether the citations improperly suggest a continuity between Italian VSL#3 and the De Simone Formulation, the Court finds that the Journal Article cannot support a finding of contempt. Federal Rule of Civil Procedure 65(d) defines the persons

bound by a federal court injunction as “parties; the parties’ officers, agents, servants, employees, and attorneys; and other persons who are in active concert or participation with [any of the parties named above]” if they have received “actual notice” of the injunction by “personal service or otherwise.” Fed. R. Civ. P. 65(d)(2)(A)–(C). The named authors of the Journal Article are not parties to this action, nor is there any allegation that they are officers, agents, servants, or employees of VSL or Alfasigma. Nor can they be characterized as persons in active concert with VSL or Alfasigma. “Active concert” encompasses parties “identified with [the enjoined party] in interest, in ‘privity’ with them, represented by them or subject to their control.” *Regal Knitwear Co. v. N.L.R.B.*, 324 U.S. 9, 14 (1945). There is no allegation or evidence that any of the named authors has any direct relationship with VSL or Alfasigma or is in any way controlled by them. ExeGi instead identifies some of the authors as affiliated with Actial. But Actial cannot simply stand in for VSL. “[A] court must legally identify the participant with the named party before enjoining both persons.” *Little v. Associated Tech. Training Servs., Inc.*, 12 F.3d 205, 1993 WL 498282, at *4 (4th Cir. 1993) (unpublished table decision). Where this Court has never made a finding that would extend the Permanent Injunction to Actial, and the Motion provides no evidence to support such a determination, there is no basis to stretch the Permanent Injunction’s scope even further to include individuals with some affiliation with Actial. Finally, even if there were support for a finding that the identified authors could be deemed to be subject to the Permanent Injunction, Rule 65 imposes the further requirement of “actual notice.” Fed. R. Civ. P. 65(d)(2). There is no evidence that Actial or the identified authors have received actual notice of the Permanent Injunction. The Journal Article thus provides no basis for a finding of contempt.

III. The Fact Sheet

As to the online VSL#3 Fact Sheet and responses to inquiries on VSL#3's Facebook page, ExeGi takes issue with the statement on the Fact Sheet that "VSL#3 continues to be sold under the same brand." Mot. Ex. E, ECF No. 1015-6. In particular, ExeGi asserts that Alfasigma violated the Permanent Injunction by responding to a consumer Facebook posting stating "Original formula? I had heard there was a dispute with another company. Just wanted to make sure nothing has changed" by directing the consumer to that Fact Sheet. Mot. Ex. D, ECF No. 1015-5. ExeGi argues that Alfasigma representatives needed to affirmatively inform consumers that the new VSL#3 no longer contains the De Simone Formulation.

On these facts, the Court finds no violation of the Permanent Injunction. As to the Fact Sheet brand assertion, the Court appreciates ExeGi's argument that the statement, "VSL#3 continues to be sold under the same brand ..." might potentially be construed as an assertion that Italian VSL#3 is the same product as the prior VSL#3, which contained the De Simone Formulation. Mot. Ex. E. But where the Fact Sheet statement makes no reference to the contents or composition of Italian VSL#3, does not claim that it has the same formulation as prior versions, and instead arguably asserts only a continuity of use of the VSL#3 trademark, the Court finds that the statement, while it dangerously skirts the line of the Permanent Injunction, does not cross it. Nevertheless, the Court reminds the VSL Parties that this Court has already considered, and found unpersuasive, the argument that the VSL#3 trademark necessarily brings with it other intellectual property rights. *See De Simone*, 133 F. Supp. 3d at 791-92. The Court cautions them against future efforts to evade the strictures of the Permanent Injunction by hiding behind the shield of the VSL#3 trademark.

As to whether the VSL Parties can be held in contempt because their representatives are not affirmatively informing customers that VSL#3 no longer contains the De Simone Formulation, ExeGi is reminded that as part of the De Simone Parties' Motion for a Permanent Injunction, the Court denied their request that the VSL Parties be required to issue affirmative, corrective advertising. *De Simone*, 2019 WL 2569574, at *4. Because the VSL Parties are not required to issue affirmative, corrective advertising, they cannot be held in contempt for failing to do so.

IV. Guarna Email

Lastly, ExeGi argues that a February 19, 2021 email from Luca Guarna to unspecified recipients, which ExeGi asserts has made its way to doctors and publishers of probiotic publications in the United States, violates the Permanent Injunction. The email, sent in the wake of the Fourth Circuit's limited modification of the Permanent Injunction, asserts that the Fourth Circuit's opinion means that "citing to historical clinical studies, even those performed on earlier versions of VSL#3, was permissible." Mot. Ex. C, ECF No. 1015-4. Guarna further claimed that the Fourth Circuit ruled that the prior clinical studies "can be cited without restriction or threat of contempt." *Id.*

Although Guarna egregiously misstated the Fourth Circuit's holding, the Court finds that his statement does not fall within the ambit of the Permanent Injunction because it does not itself assert continuity between Italian VSL#3 and the De Simone Formulation but instead claims only that references to prior studies of the De Simone Formulation, for whatever purpose, would be permissible under the Permanent Injunction as modified by the Fourth Circuit.

While the Court will not find that the email violates the Permanent Injunction, the substance of Guarna's email makes it necessary to state that his assertion is completely incorrect. The Fourth Circuit did not hold that prior clinical studies of VSL#3 could be cited, as Guarna

claimed, “without restriction” in relation to Italian VSL#3. *Id.* Rather, the Fourth Circuit narrowed the injunction because it concluded that the VSL Parties’ “citing or referring to the clinical studies” could be permissible to the extent that it could be done “without claiming continuity between their old product and their new one.” *De Simone*, 847 F. App’x at 184. It specifically stated, however, that “citing or referring to the clinical studies *as though* they were performed on Italian VSL#3 (rather than on the Danisco-made version)” remained barred because the Permanent Injunction more broadly prohibited the VSL Parties from making claims of “continuity between the products.” *Id.* Where “citing or referring to the clinical studies as though they were performed on Italian VSL#3” remains barred by the Permanent Injunction, Guarna’s claim that the Fourth Circuit held that the prior clinical studies “can be cited without restriction or threat of contempt,” Mot. Ex. C, grossly misrepresents the Fourth Circuit’s holding and invites future violations of the Permanent Injunction.

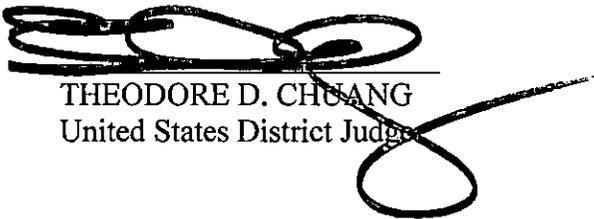
Because Guarna’s statement is such a gross misrepresentation of the law, the Court finds that it is reasonable to infer that Guarna’s statement was made in bad faith, and that to the extent it was drafted with the advice and approval of counsel, counsel acted in bad faith in advising that the statement correctly characterized the Fourth Circuit’s ruling. As a result, Guarna and the VSL Parties are strongly encouraged to issue a corrective statement to the recipients of the Guarna email informing them that citing or referring to the clinical studies “as though they were performed on Italian VSL#3” remains barred by the Permanent Injunction. *See De Simone*, 847 F. App’x at 184. If they fail to do so, they will be held responsible for any subsequent citations or references to the prior clinical studies “as though they were performed on Italian VSL#3” that are made directly or indirectly by the recipients of the Guarna email, even if not made by VSL or Alfasigma itself.

Moreover, the Court forewarns Guarna, the VSL Parties, and their counsel that any future, similar mischaracterizations of court rulings could result in a finding of contempt and imposition of sanctions, and that given the uniquely legal nature of such statements, the Court will specifically hold counsel for the VSL Parties directly responsible for any such mischaracterizations, including potentially referring counsel of record to this Court's Disciplinary and Admissions Committee. *See* Md. Rule Professional Conduct 19-304.1 (West 2020) (prohibiting attorneys from knowingly making false statements of material fact or law to a third person); D. Md. Local R. 704 (adopting the Maryland Rules of Professional Conduct); D. Md. Local R. 705 (setting forth this Court's disciplinary process). On this point, the Court also reminds counsel for the VSL Parties that by the terms of Rule 65, they, too, are subject to the constraints of the Permanent Injunction. Fed. R. Civ. P. 65(d)(2)(B).

CONCLUSION

For the reasons set forth above, ExeGi's Motion for an Order of Civil Contempt, ECF No. 1015, will be DENIED. A separate Order shall issue.

Date: July 15, 2021


THEODORE D. CHUANG
United States District Judge