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

Counterclaim Plaintiffs VSL Pharmaceuticals, Inc. ("VSL") and Alfasigma USA, Inc. ("Alfasigma") (collectively, "the VSL Parties") have filed a Third Motion for a Preliminary Injunction seeking an order from this Court barring Plaintiffs Claudio De Simone and ExeGi Pharma, LLC ("ExeGi") (collectively, "the De Simone Parties") from certain activities that, they assert, constitute false advertising actionable under the Lanham Act, 15 U.S.C. § 1125(a)(1)(B) (2012). Having reviewed the submitted materials, the Court finds no hearing necessary. *See* D. Md. Local R. 105.6. For the reasons set forth below, the Third Motion for a Preliminary Injunction is DENIED.

BACKGROUND

The relevant factual background of this case 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), and 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). Additional facts and procedural history are provided below as necessary.

On January 16, 2018, De Simone published an abstract entitled "P884 No shared mechanisms among 'old' and 'new' VSL#3: Implication for claims and guidelines," ("the Abstract") in the *Journal of Crohn's and Colitis*. That volume of the *Journal of Crohn's and Colitis* compiled abstracts and presentations selected for the 2018 European Crohn's and Colitis Organization ("ECCO") Congress. The ECCO is a non-profit medical association focused on advancing research into and treatment of inflammatory bowel disease ("IBD") and describes itself as the largest association for IBD specialists in the world. Submissions for the 2018 Congress were reviewed by ECCO's Scientific Committee. Guidelines for submissions included that authors (1) accept responsibility for the scientific accuracy of the abstract, (2) disclose any financial interest in products or processes described in the abstract, (3) acknowledge that abstracts stating "data will be presented," rather than providing supporting data, would likely be rejected, and (4) acknowledge that acceptance of the abstract obligated them to present their work at the Congress. Guidelines for Abstract Submission at 1-2, Opp'n Mot. Prelim. Inj. ("Opp'n") Ex. 6, ECF No. 588-7. Abstracts were limited to 2750 characters, including spaces but excluding the title and author names, and were to be divided into four sections: Background, Methods, Results, and Conclusions. Approximately 77 percent of abstracts submitted by

scientists were accepted to the Congress. As part of his submission, De Simone disclosed that he owned one share of stock in VSL. He did not disclose his interest in ExeGi or Visbiome.

In the Abstract, De Simone asserts that the current probiotic branded as VSL#3, manufactured in Italy and which he dubs the "new" VSL#3, is "completely different" from the "old" VSL#3, manufactured in the United States. Abstract at 1–2, Mot. Prelim. Inj. Ex. A, ECF No. 573-3. The U.S.-produced version of the probiotic is sold under the brand name "Visbiome," but that brand name does not appear anywhere in the Abstract. As to "Methods," the Abstract states that the old and new VSL#3s were studied using "proteonomics, metabolomics and lipidomics," but provides no additional detail. *Id.* at 2. The "Results" state that "[c]ertain metabolic pathways and molecular mechanisms present in the 'original' VSL#3 are clearly no more present in the 'new' Italy-made VSL#3." *Id.* The "Results" section includes a complex diagram divided into five sections, labeled "Purine Metabolism," "Glycolysis," "Protein Fate," "Aminoacyl tRNA Biosynthesis," and "Ribosome." *Id.* The "Conclusion" of the Abstract is that the study data "confirm the need for clinical trials in IBD patients with the Italy-made formulation to establish the efficacy and safety of the 'new' VSL#3." *Id.* The Abstract also encourages the ECCO to revise its IBD treatment guidelines as to the "new" VSL#3. *Id.* The Abstract cites to what appear to be three peer-reviewed scientific articles.

In February 2018, De Simone attended the ECCO Congress, where he displayed the Abstract, formatted as a poster, in booth P884. De Simone's booth was situated next to booth P883, which also displayed a poster containing the text of an abstract.

Dr. Rodolphe Barrangou, an expert in microbiology retained by the VSL Parties, asserts in a Declaration that the Abstract is merely a summary of a conference presentation, not a published article, and therefore does not constitute a peer-reviewed publication. Dr. Barrangou

criticizes the Abstract for failing to provide data relating to the two VSL#3 formulations, data sufficient to support De Simone's broad conclusions, a legend on the diagram that would allow for interpretation of its significance, and a full accounting of the data and methods used that would allow for replication of the results. Consequently, he states that the Abstract does not provide enough information to allow for an assessment and interpretation of the study. He also theorizes that De Simone had a biased motive that caused him to select certain methodologies and criticizes the lack of any statement of how the research was funded or a disclaimer about conflicts of interest.

Dr. Barrangou also contends that several of De Simone's conclusions are "scientifically impossible." Barrangou Decl. ¶¶ 12-13, 17, Mot. Prelim. Inj. Ex. 18, ECF No. 573-18. In support of this broad claim, he asserts, "Bacteria being unable to grow without glycolysis (to generate energy from carbohydrates) or purines (building blocks of DNA), it is scientifically impossible that these pathways are 'no longer present' in the 'new' Italy-made VSL#3." Barrangou Decl. ¶ 13. Dr. Barrangou also asserts that the Abstract's statements that "certain metabolic pathways are not present" and are "no more present in the new Italy-made VSL#3" are "fundamentally incorrect, and actually scientifically impossible" because according to various unnamed, peer-reviewed manuscripts, glycolysis is a pathway that is present in all strains of VSL#3, and his own research shows that purine pathways are universally occurring in all bacteria. *Id.* ¶ 17. Dr. Barrangou further asserts that the statement that the two versions of VSL#3 "do not have similar underlying core mechanisms" is "technically impossible" because other studies have found the bacteria in the two versions to be genetically equivalent. *Id.* ¶18. Dr. Barrangou also criticizes De Simone's failure "to mention or discuss widely accepted and state of the art genetics and genomics studies." *Id.* ¶ 20.

On February 8, 2018, Susan Linke, a dietician, sent a copy of the Abstract to several internet discussion boards or listservs for dieticians, specifically GastroRDs@ yahoogroups.com, DIFM_Listserv@yahoogroups.com, and NEDpg@yahoogroups.com. According to Linke, membership in various dietician professional organizations often comes with membership in one of these listservs. By her estimation, the discussions boards of which she is a part have anywhere from 10,000 to 15,000 members. Prior to November 2016, Linke had made positive posts about VSL#3 on the listservs of which she was a member, but had stopped those posts after she became "confused about the formulation change" and was no longer sure VSL#3 "was the same product." Linke Decl. ¶¶ 8-9, Opp'n Ex. 3, ECF No. 573-5.

In November 2016, Linke met Conrad Shepard, a Visbiome sales representative. From November 2016 to January 2017, Linke exchanged a series of emails with Shepard and with Marc Tewey, ExeGi's Chief Executive Officer, about Linke posting to listservs certain studies on the efficacy of the De Simone Formulation in treating various conditions. In a November 4, 2016 email to Tewey and Shepard, Linke offered to "start posting those research studies on a regular basis to increase [Visbiome's] name familiarity." 11/4/16 Email at 1, Mot. Prelim. Inj. Ex. F, ECF No. 573-8. Linke's posts appear to have been part of a broader conversation in the listservs about the differences between VSL#3 and Visbiome. In a November 13, 2016 email, Linke forwarded a listserv post from a VSL#3 representative to another dietician addressing that issue. Linke advised Shepard to schedule a call with that dietician, explaining that she was someone who was well-respected by her peers and that, "[r]ight now she's only hearing the VSL#3 side of things." 11/13/16 Email at 1, Mot. Prelim. Inj. Ex. K, ECF No. 573-13. Based on her posts, Linke received correspondence from at least one other dietician who planned to present the forwarded studies to doctors with whom she worked.

At no point was Linke paid to post any messages about Visbiome to any listserv. According to Linke, in February 2018 she found the Abstract on the internet on her own and posted it on the various listservs without direction from, or communication with, ExeGi. Linke was subsequently retained by the De Simone Parties as an expert witness in this litigation.

DISCUSSION

The VSL Parties assert that the Abstract contains false and misleading statements of fact and thus that its dissemination by Linke on various dietician listservs is actionable false advertising under the Lanham Act. They further assert that they are presently suffering irreparable harm from that alleged false advertising and so ask this Court to enjoin the De Simone Parties and their associates from circulating the Abstract and to require De Simone to retract the Abstract from the *Journal of Crohn's and Colitis* and all other places where it was published.

I. Legal Standard

To obtain a preliminary injunction, moving parties must establish that (1) they are likely to succeed on the merits, (2) they are likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of equities tips in their favor, and (4) an injunction is in the public interest. *Winter v. Natural Res. Defense Council, Inc.*, 555 U.S. 7, 20 (2008); *see Dewhurst v. Century Aluminum Co.*, 649 F.3d 287, 290 (4th Cir. 2011). A moving party must satisfy each requirement as articulated. *Real Truth About Obama, Inc. v. Fed. Election Comm'n*, 575 F.3d 342, 347 (4th Cir. 2009), *judgment vacated on other grounds*, 559 U.S. 1089 (2010). To obtain a preliminary injunction, the moving parties must "clearly demonstrate" that they "will *likely succeed* on the merits," rather than present a mere "grave or serious question for litigation." *Id.* at 346-347. Because a preliminary injunction is "an extraordinary remedy," it

"may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter*, 555 U.S. at 22.

II. Likelihood of Success on the Merits

Under the Lanham Act, a cause of action for false advertising arises when "[a]ny person who, on or in connection with any goods or services . . . uses in commerce any . . . false or misleading representation of fact which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods services, or commercial activities." 15 U.S.C. § 1125(a)(1)(B).

To prevail on a claim of false advertising relating to the Abstract, the VSL Parties must establish that:

(1) The De Simone Parties made a false or misleading description of fact or representation of fact in a commercial advertisement about VSL#3;
(2) The misrepresentation is material, in that it is likely to influence the purchasing decision;
(3) The misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience;
(4) The De Simone Parties placed the false or misleading statement in interstate commerce; and
(5) The VSL Parties have been or are likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with their product.

Scotts Co. v. United Indus. Corp., 315 F.3d 264, 272 (4th Cir. 2002). The contested statement may either be "false on its face" or "although literally true, likely to mislead and to confuse consumers given the merchandising context." *Id.* (quoting *C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare L.P.*, 131 F.3d 430, 434 (4th Cir. 1997)). If an advertisement is literally false, a party can succeed on a false advertising claim without evidence of any consumer deception. *Scotts Co.*, 315 F.3d at 273 (internal citation omitted). However, "if a [party's] theory of recovery is premised upon a claim of implied falsehood, [that party] must demonstrate,

by extrinsic evidence, that the challenged advertisements tend to mislead or confuse consumers." *Id.*

A. Statements of Scientific Research

As an initial matter, the De Simone Parties, relying on *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490 (2d Cir. 2013), argue that the Abstract cannot constitute false advertising under the Lanham Act because it is the results of a scientific study, not advertising. In *ONY*, the United States Court of Appeals for the Second Circuit held that a Lanham Act claim cannot be based on alleged false statements "on subjects about which there is legitimate ongoing scientific disagreement," as long as the statements at issue are based on non-fraudulent data and accurately describe the nature of the data and the methodologies used to produce or analyze it. *Id.* at 498. *ONY* involved two companies selling competing versions of a product used to treat infants with lung conditions. *Id.* at 493. The defendant company financed a study, the results of which suggested that the defendant's product had a 20 percent lower mortality rate than competing products and reduced the length of infants' hospital stays by 15 percent. *Id.* Physicians hired by the defendant company presented these results at multiple conferences and published an article about the findings, which was later distributed by the company with promotional materials. *Id.* at 493–94. Although that article appeared in a peer-reviewed journal, the plaintiffs asserted that there were incorrect statements in the article and irregularities in the review process, including that one of the physicians hired by the defendant company was an editor of the journal and another was on the journal's editorial board. *Id.* at 494. In dismissing a Lanham Act claim based on statements in the article, the court held that statements on subjects about which there is "legitimate ongoing scientific disagreement" cannot support a Lanham Act claim, provided that the statement was based on non-fraudulent data and accurate descriptions of

the data and methodology underlying the conclusions. *Id.* at 498. The court reasoned that conclusions based on scientific research, while theoretically subject to objective verification, "are more closely akin to matters of opinion, and are so understood by the relevant scientific communities." *Id.* at 497. Although *ONY* is not controlling authority for this Court, the Court finds its reasoning persuasive.

As in *ONY*, De Simone's conclusions in the Abstract are based on scientific analysis on an issue about which there is ongoing disagreement. Although VSL challenges the conclusions of the Abstract and criticizes the lack of presentation of the underlying data, it offers no basis to conclude that the data used in the study was fraudulent. Notably, in *ONY*, the facts that the article in question was funded by a product manufacturer, was conducted by researchers hired by that company, reached conclusions favorable to its product, was published in a journal with which there were arguable conflicts of interest, and was later disseminated to the consumer public did not prevent the court from finding that no Lanham Act claim was available. *See id.* at 493–95. Thus, the fact that De Simone conducted and funded the study himself, and plainly did so to bolster his commercial product, Visbiome, does not render the reasoning of *ONY* inapplicable to the statements in the Abstract.

The VSL Parties' citation of *Semco, Inc. v. Amcast, Inc.*, 52 F.3d 108 (6th Cir. 1995), is unpersuasive. In *Semco*, the Lanham Act claim related to an article in a trade journal about manufacturing plunger tips that generally praised one company's products, without any claim that the article constituted, or was even based upon, a scientific study published in a scientific journal. *Id.* at 110-11. Likewise, *Eastman Chemical Company v. Plastipure, Inc.*, 775 F.3d 230 (5th Cir. 2014), also relied on by the VSL Parties, involved a commercial brochure disparaging a

competitor's product as having a scientifically harmful condition and specifically acknowledged that the publication was in a different category from the scientific paper in *ONY*. *Id.* at 236.

There are, however, several distinguishing factors relating to the Abstract. Unlike the study in *ONY*, the Abstract, while reviewed by the Scientific Committee of ECCO, was not a formal, peer-reviewed study. The information contained in the Abstract is so sparse—limited by ECCO guidelines to 2750 characters including spaces—that one cannot fairly assess the quality of the data or the analysis. Further, while the sponsoring company's interest in the study in *ONY* was fully disclosed, De Simone, having cleverly framed the Abstract as a comparison of "old" and "new" VSL#3, disclosed only his affiliation with VSL, not his ownership of the competing product, Visbiome. Although the *ONY* court did not expressly limit its holding to statements made in peer-reviewed journals with fully disclosed data, its rationale was based in part on the importance of the peer review process and the presentation of sufficient information for other scientists to attempt to replicate the research, so that the scientific community, rather than a court, could resolve the dispute. *Id.* at 497. It also relied in part on the fact that the authors "readily disclosed the potential shortcomings of their methodology and their potential conflicts of interest." *Id.* at 498.

The Abstract appears to fall short of these standards to a sufficient degree that the Court will not conclude, on the present record, that it qualifies as a scientific statement protected from a Lanham Act claim as a matter of law. *See Eastman Chem. Co.*, 775 F.3d at 236 (distinguishing a commercial publication from the study in *ONY* because it was not made in a peer-reviewed journal with a description of the data, methodology, and potential conflicts of interest). Nevertheless, the Court finds that based on the standard of *ONY* and the evidence that the statements in the Abstract are conclusions made in a scientific publication, reviewed by the

ECCO Scientific Committee, and drawn on subjects about which there is "legitimate ongoing scientific disagreement," *id.* at 498, the VSL Parties have not clearly demonstrated that they are likely to succeed on the merits of their Lanham Act claim.

B. Falsity

In addition, the Court finds that even if the Abstract were found to be so lacking in scientific rigor that it could serve as the basis of a Lanham Act false advertising claim, the VSL Parties have failed to make a showing that they are likely to succeed on that claim because they have not provided sufficient basis to conclude that the Abstract contains false statements. The VSL Parties do not plainly state whether they are contending that the Abstract is literally false or likely to mislead. However, as noted above, a claim of false advertising based on implied falsehood requires a showing "by extrinsic evidence, that the challenged advertisements tend to mislead or confuse consumers." *Scotts Co.*, 315 F. 3d at 273. The VSL Parties have provided no evidence of consumer confusion and so cannot succeed on a theory of implied falsehood. The Court therefore assumes that they proceed under a theory of literal falsity.

As to literal falsity:

> In analyzing whether an advertisement is literally false, a court must determine, first, the unambiguous claims made by the advertisement, and second, whether those claims are false. A literally false message may be either explicit or conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated.

Id. at 274 (citations omitted).

Many of the claims in the Abstract are equivocal, such as the statement that the "change of the processing or product formulation may lead to a different outcome in terms of efficacy and safety" and the conclusion that additional studies are needed to establish the efficacy and safety of the new VSL#3. Abstract at 1–2. The more specific statements identified by the VSL Parties

as false include the "Result" that "[c]ertain metabolic pathways and molecular mechanisms present in the 'original' VSL#3 are clearly no more present in the 'new' Italy-made VSL#3" and the "Conclusion" that "[r]ecent data have shown that the 'new' Italy-made VSL#3 is different from the 'original' formulation. The proteomics, metabolomics and lipidomics confirm that the two formulations do not have similar underlying core mechanisms." *Id.* at 2.

In asserting that these statements are false, the VSL Parties offer no contrary, peer-reviewed studies that specifically establish that old and new VSL#3 are the same and that the Abstract's claims of differences are false. Rather, the VSL Parties' only evidence on the falsity of these statements is the Declaration of Dr. Barrangou. Although Dr. Barrangou is certainly an accomplished scientist, he offers few facts to support his broad assertions that these statements in the Abstract are "scientifically impossible." Barrangou Decl. ¶ 12. Taking issue with the statement that "[c]ertain metabolic pathways and molecular mechanisms present in the 'original' VSL#3 are clearly no more present in the 'new' Italy-made VSL#3," Abstract at 2, Dr. Barrangou generally states that "[b]acteria being unable to grow without glycolysis (to generate energy from carbohydrates) or purines (building blocks of DNA), it is scientifically impossible that these pathways are 'no longer "present" in the "new" Italy-made VSL#3." Barrangou Decl. ¶ 13. He further asserts, citing unnamed peer-reviewed manuscripts, that the glycolysis pathway is present in all bacterial strains of VSL#3, and that the purine pathway is present in all bacteria in general. Dr. Barrangou's assertions fail to establish falsity because nowhere in the Abstract is there a statement that either the glycolysis pathway or the purine pathway is not present. Although the Abstract's diagram references "Glycolysis" and "Purine Metabolism," it is not readily discernible from the diagram that the Abstract is claiming that those particular pathways do not exist. Indeed, Dr. Barrangou asserts in his Declaration that the diagram cannot be

interpreted because there is no legend and no explanation of the colors used. Thus, while the Abstract's assertions that "certain metabolic pathways" are no longer present in the new VSL#3 are admittedly vague and not clearly supported by data contained in the Abstract, the VSL Parties have not offered evidence that convincingly refutes them and exposes them as false.

Likewise, as support for his claim that the statement that old and new VSL#3 "do not have similar underlying core mechanisms" is false, Dr. Barrangou generally references studies showing that the bacteria in new VSL#3 and old VSL#3 are "genomically and genetically equivalent" and that they share core mechanisms "such as glycolysis." Barrangou Decl. ¶ 18. Once again, Dr. Barrangou's purported evidence of falsity lacks specificity and consists of assertions about genetic equivalence and the presence of glycolysis that do not actually contradict any statements in the Abstract.

Dr. Barrangou's remaining critiques of the Abstract address the lack of data or information about De Simone's methodology and thus do not establish that the statements in the Abstract are literally false, only that they are inadequately supported. To be sure, Dr. Barrangou points to tangible deficiencies in the Abstract that may cast doubt on the reliability of its conclusions. But "the test for literal falsity is simpler; if a defendant's claim is untrue, it must be deemed literally false." *Castrol, Inc. v. Pennzoil Co.*, 987 F.2d 939, 944 (3rd Cir. 1993). That the Abstract contains only limited information about the data set and testing methodologies of the underlying study does not render the results of that study untrue, particularly where, as here, that brevity was required by ECCO's parameters for Abstract submissions.

With nothing more than Dr. Barrangou's Declaration to establish that the Abstract, reviewed by the Scientific Committee of a multi-national organization of IBD specialists, presented at a scientific conference, and published in a scientific journal, is untrue, the VSL

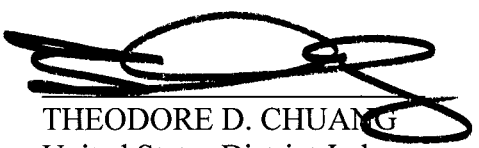
Parties have failed to persuasively establish that the Abstract is literally false. *Scotts Co.*, 315 F.3d at 272; *Castrol*, 987 F.2d at 943–44 (relying on a record "replete with Castrol's affirmative evidence proving the literal falsity of Pennzoil's claims"). They have thus failed to clearly demonstrate they are likely to succeed on their false advertising claim. The Court therefore need not address whether the later dissemination of the Abstract by Linke constituted advertising within the meaning of the Lanham Act.

Because the VSL Parties have failed to clearly demonstrate a likelihood of success on this claim, there is no need to address the remaining *Winter* factors. *See Winter*, 555 U.S. at 20. The Third Motion for a Preliminary Injunction will therefore be denied.

CONCLUSION

For the foregoing reasons, the VSL Parties' Third Motion for a Preliminary Injunction is DENIED. A separate Order shall issue.

Date: September 24, 2018



THEODORE D. CHUANG
United States District Judge