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 Defendants.

Civil Action No. TDC-15-1356

MEMORANDUM ORDER

Plaintiffs Claudio De Simone and ExeGi Pharma, LLC (collectively, "the De Simone Parties") have filed a Motion to Modify Preliminary Injunction in which they seek modifications to two Orders issued by this Court: a February 4, 2016 Order (the "February 2016 Order") and a June 20, 2016 Preliminary Injunction (the "June 2016 Order"). Specifically, the De Simone Parties seek a modification to the February 2016 Order to allow them to make statements about the present composition of VSL#3 and the current status of the license agreement between VSL Pharmaceuticals, Inc. ("VSL") and De Simone. They also seek a change to the June 2016 Order to allow them (1) to state in advertising that ExeGi Pharma, LLC ("ExeGi") is the exclusive provider of the "De Simone Formulation," the term they have coined for the combination of

probiotic strains developed by De Simone and first commercialized in the United States as VSL#3; (2) to cite to clinical studies with the term "VSL#3" in the title as part of their promotional materials; and (3) to engage in other speech critical of VSL#3. The De Simone Parties also seek, without objection, to have any injunctions as to Defendant Leadiant Biosciences, Inc. ("Leadiant"), formerly known as Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau"), rescinded because, during the course of this litigation, Leadiant transferred its rights to distribute VSL#3 in the United States and thus no longer has a stake in claims arising from any future false advertising or trademark infringement relating to VSL#3. The parties have fully briefed the Motion. Having reviewed the submitted materials, the Court finds no hearing necessary. *See* D. Md. Local R. 105.6. For the following reasons, the Motion to Modify is GRANTED IN PART and DENIED IN PART.

BACKGROUND

The February 2016 Order was entered by consent of the parties in response to VSL's stated intent to file a Motion for a Preliminary Injunction based on VSL's contention that the De Simone Parties were engaged in false advertising in violation of the Lanham Act. In support of that contention, VSL provided the Court with Visbiome promotional materials that, it argued, suggested that VSL#3 had been re-branded as Visbiome or that Visbiome was the generic version of VSL#3. As relevant here, the February 2016 Order required ExeGi to refrain from "stating or suggesting that the license agreement" between De Simone and VSL had "expired," or asserting that "VSL#3 will no longer be on the market." Feb. 2016 Order at 1, ECF No. 126.

The June 2016 Order was issued after full briefing and a hearing on VSL's Second Motion for a Preliminary Injunction, in which VSL sought preliminary injunctive relief based on its Lanham Act false advertising and trademark claims. In relevant part, VSL asserted that the

claim on the Visbiome website that ExeGi was the "exclusive provider" of the De Simone Formulation was false advertising. VSL 2d Mot. Prelim. Inj. at 32-35, ECF No. 144-1. At the time the Motion was litigated, the parties agreed, and the evidence on the Motion established, that the VSL#3 product then sold in the U.S. market was manufactured by Danisco using the De Simone Formulation, such that Visbiome and VSL#3, though differently branded, were the exact same product. As a result, the Court found that VSL was likely to succeed on its claim that Visbiome's exclusivity statements were false advertising and enjoined the De Simone Parties from making statements that suggested that they were the exclusive supplier of the De Simone Formulation. *De Simone v. VSL*, No. TDC-15-1356, 2016 WL 3466033 at *18–20, *27 (D. Md. June 20, 2016). VSL further asserted, as part of its trademark claim, that the inclusion on the Visbiome website of citations to scientific studies with the term "VSL#3" in the title created confusion about whether VSL#3 and Visbiome were the same product. In light of the extensive use of the VSL#3 mark on the Visbiome website and in other promotional materials, the Court found VSL likely to succeed on this claim and enjoined, among other activities, the inclusion on the Visbiome website of statements that studies with "VSL#3" in the title constituted studies relating to the "De Simone Formulation." *Id.* at *24–27.

DISCUSSION

The DeSimone Parties now assert that VSL is no longer selling product manufactured by Danisco pursuant to instructions originally provided by De Simone and that consequently the composition of VSL#3 sold in the U.S. market is clinically different from that of Visbiome. Based on this assertion, they argue that they should be permitted to advertise Visbiome as the "exclusive provider" of the De Simone Formulation and to cite prior studies with VSL#3 in the title. VSL, which now manufactures VSL#3 at a production facility in Italy, asserts that no

changes to the existing Orders are warranted because any changes to VSL#3 are not clinically significant. Alternatively, VSL asserts that no modifications should be made to the Orders because any changes to VSL#3 have been the result of De Simone's breach of his fiduciary duty to VSL. Both sides marshal various scientific experts and articles in support of their arguments.

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). 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.

Although the Court granted a preliminary injunction in the June 2016 Order, a court has the power "to modify an injunction in adaptation to changed conditions." *United States v. Swift & Co.*, 286 U.S. 106, 114 (1932) (noting that this power extends to injunctions entered into by consent); *see also* Fed. R. Civ. P. 54(b) (permitting "any order or other decision . . . that adjudicates fewer than all the claims" to be "revised at any time before the entry of judgment"). For example, a court may order such a modification if the injunction "has been turned through changing circumstances into an instrument of wrong." *Swift & Co.*, 286 U.S. at 115. Because a preliminary injunction is not a final judgment, the Court will not require the De Simone Parties to meet the requirements of Federal Rule of Civil Procedure 60(b). *K.C. ex rel. Africa H. v.*

Shipman, 716 F.3d 107, 117 n.3 (4th Cir. 2013) (stating that a "preliminary injunction is not a 'final judgment, order, or proceeding' that may be addressed by a motion under Rule 60(b)").

II. Leadiant

Turning first to the De Simone Parties' request that the Court rescind the injunctions as they relate to Leadiant because Leadiant no longer has an interest in VSL#3, no party objects to that request, so that portion of the De Simone Parties' Motion will be granted.

III. VSL#3 Studies

The De Simone Parties also seek to have the June 2016 Order altered to allow them to cite to studies that use the term VSL#3 in the title. The June 2016 Order enjoined those citations because the Court found that the manner in which the De Simone Parties used those citations created "confusion" and concluded that "[e]ven if ExeGi has a reason to refer to those studies because Visbiome is, as a scientific matter, the same formulation that was subjected to those trials, that scientific equivalence cannot be used as an opportunity or excuse to erode VSL's trademark." *De Simone*, 2016 WL 3466033 at *25. On the present Motion, the evidence submitted by the De Simone Parties is directed at establishing that VSL#3 and Visbiome are now clinically distinct products. Such evidence is relevant to the VSL Parties' argument that they may now claim they are the exclusive supplier of a probiotic using the De Simone Formulation, but that evidence does not speak to the significant trademark confusion that the De Simone Parties created through their references to studies with "VSL#3" in the title. The De Simone Parties have failed to establish changed conditions relevant to the trademark claim because they have not shown that the alleged alteration to the formulation of VSL#3 obviates VSL's need for trademark protection. Moreover, such information does nothing to dispel the Court's concern, which underlay the relevant part of the June 2016 Order, that the De Simone Parties' history of

"aggressive and in some instances unreasonable interpretations" of the Court's rulings on the use of the VSL#3 mark necessitates the broad prohibition imposed. *De Simone*, 2016 WL 3466033 at *26. The Motion is therefore denied as to the request to alter the June 2016 Order to permit the De Simone Parties to cite studies that contain the term VSL#3 in the title.

IV. Exclusive Provider

The De Simone Parties' remaining requests for modifications stem from VSL's false advertising claims and seek in various ways to allow the De Simone Parties to assert that the De Simone Formulation is available exclusively through Visbiome. The Court agrees that some conditions have changed. As noted above, the Court's issuance of the February 2016 Order and the June 2016 Order were premised on the Court's findings, which were beyond dispute at the time, that while the license agreement between De Simone and VSL had recently expired, VSL continued to have inventory of product produced under that agreement, and that the versions of VSL#3 and Visbiome sold in the U.S. market at that time were therefore exactly the same product, with each manufactured by Danisco using the same process. Based on these undeniable facts, the Court found that VSL and Sigma Tau were likely to succeed on the merits of their claim that the De Simone Parties' statements at that time that they were the "exclusive" provider of the De Simone Formulation constituted false advertising. It is now undisputed that as of at least May 17, 2016, VSL#3 is no longer manufactured by Danisco and is instead made in Italy. Promotional materials from VSL and Sigma-Tau, including those touting VSL#3 as dairy-free, make clear that VSL#3 and Visbiome are no longer exactly the same. Thus, the factual predicate for the Court's June 2016 Order barring the claim that ExeGi is the "exclusive provider" of the De Simone Formulation no longer exists. In the proceedings leading to the February 2016 Order and the June 2016 Order, the parties did not litigate, and thus the Court did not adjudicate, the

propriety of Visbiome promotional statements when Visbiome and VSL#3 are manufactured in different plants using different methods.

In order for that part of the injunction to continue, the Court must find that the present factual landscape justifies the same restriction. First, it is clear that the license agreement between De Simone and VSL relating to production at Danisco has long since ended. Thus, there is no longer a basis to prevent the De Simone Parties from stating that fact. Second, upon review of the submitted materials, the Court concludes that the likelihood of success of a false advertising claim arising from present exclusivity claims has been significantly altered. The De Simone Parties have submitted evidence supporting a conclusion that VSL#3 has a different number of bacterial strains than the De Simone Formulation, and they have provided peer-reviewed scientific studies asserting that the current scientific makeup of VSL#3 is different from the De Simone Formulation. Although VSL has provided explanations for the alleged discrepancy in the number of strains, and it has criticized the submitted studies by asserting that De Simone engineered the conducting and publishing of these studies and that he is affiliated with some of the authors, they have not provided a comparable published study opining that the current version of VSL#3 and Visbiome, which uses the De Simone Formulation, are identical or even functionally equivalent. Based on this record, the Court finds that VSL's likelihood of success on its false advertising claim has been sufficiently altered as to warrant a modification of the injunction. Moreover, the balance of equities has shifted because VSL#3 has been marketed as "the same quality product, containing the same genus and species of bacteria, in the same proportions that you have come to expect," Mot. Modify Inj. Ex. 5, ECF No. 451-6, while ExeGi is not permitted to assert a contrary position. This imbalance warrants some adjustment of the terms of the injunction.

Although the Court will modify the injunction to remove the bar on the assertions that the licensing agreement between De Simone and VSL has expired and that ExeGi is the exclusive provider of the De Simone Formulation, it will not grant the De Simone Parties' overly broad request for an order declaring that ExeGi is free to "engage in commercial speech critical of its competitor's products." Proposed Order at 2, ECF No. 476-29. First, in finding that modification is warranted, the Court has not made final determinations on whether the current version of VSL#3 actually uses the De Simone Formulation, or whether VSL#3 and Visbiome are functionally equivalent. Such determinations are best left for the forthcoming trial. Second, the Court is particularly mindful of the De Simone Parties' history of stretching this Court's orders up to and past the breaking point. With trial scheduled to commence in the near future, the Court concludes that the balance of equities and public interest warrant a limited modification to permit only narrow public statements during the pre-trial period on an issue that will likely be resolved in the near future, with a disclaimer that the issue of exclusivity is the subject of pending litigation. Accordingly, the Court will modify its prior Orders as follows:

It is hereby ORDERED that the De Simone Parties' Motion to Modify Injunction, ECF No. 451, is GRANTED IN PART and DENIED IN PART. The Motion is GRANTED to the extent that:

1. Leadiant, formerly known as Sigma-Tau, shall no longer be entitled to enforce any provision of any Order in this case granting prospective injunctive relief.
2. Section 1(a) of the February 4, 2016 Order, ECF No. 126, stating, in relevant part, that the De Simone Parties must "generally refrain from stating or suggesting that the license agreement has expired or that VSL#3 will no longer be on the market," is

modified to state that the De Simone Parties must "generally refrain from stating or suggesting that VSL#3 will no longer be on the market."

3. Section 6, subpart (2) of the June 20, 2016 Order, ECF No. 213, which enjoins the De Simone Parties from making advertising statements claiming or suggesting "that the De Simone Parties are the exclusive provider of the De Simone Formulation or the probiotic formulation in VSL#3" is modified to remove the language enjoining statements that the De Simone Parties "are the exclusive provider of the De Simone Formulation." During the limited period from the date of this Order until the resolution of this case after the November 2018 trial, any statements asserting that the De Simone Parties are the exclusive provider of the De Simone Formulation must take the following specific form:

> *We believe that ExeGi is the exclusive provider of the De Simone Formulation because it is our position that the current version of VSL#3 uses a different formulation. Whether VSL#3 presently uses the De Simone Formulation is the subject of pending litigation in federal court.*

Any such statements are subject to the existing pre-approval process. *See* June 2016 Order ¶ 7.

4. Section 6, subpart (3) of the June 20, 2016 Order, enjoining statements "that VSL#3's license to sell this formulation has or will expire," is removed entirely.

The Motion is otherwise DENIED.

Date: September 24, 2018

THEODORE D. CHUANG
United States District Judge