

UNITED STATES DISTRICT COURT  
DISTRICT OF MARYLAND

CLAUDIO DE SIMONE,

Plaintiff/Counterclaim Defendant,

v.

VSL PHARMACEUTICALS, INC. and  
SIGMA-TAU PHARMACEUTICALS, INC.,

Defendants/Counterclaim Plaintiffs,

v.

EXEGI PHARMA, LLC,  
DANISCO USA, INC., and  
MENDES SA,

Third-Party Defendants.

Civil Action No. TDC-15-1356

MEMORANDUM OPINION

In the 1990s, Plaintiff and Crossclaim Defendant Claudio De Simone, in collaboration with two other scientists, invented a probiotic that De Simone would later bring to the United States market through a partnership with Defendants and Crossclaim Plaintiffs VSL Pharmaceuticals, Inc. (“VSL”) and Sigma-Tau Pharmaceuticals, Inc. (“Sigma-Tau”) (collectively, “the VSL Parties”). That probiotic was sold and prescribed under the VSL-owned trademark “VSL#3.” In 2015, De Simone parted ways with the VSL Parties and began a partnership with Third-Party Defendant ExeGi Pharma, LLC (“ExeGi”) to bring his probiotic formulation to market under the name “Visbiome.” De Simone and ExeGi (collectively, “the De Simone Parties”) have made efforts to compete with VSL#3 during the pendency of this lawsuit, in which the parties dispute who rightfully owns certain intellectual property connected with the

probiotic and whether De Simone breached any contractual or fiduciary duties to his former business partners by now allying with ExeGi. As relevant here, the VSL Parties allege that the De Simone Parties have infringed the VSL#3 trademark in their efforts to market Visbiome and have falsely advertised that VSL#3 is no longer on the market or that Visbiome is the rebranded version of that product. It is these trademark infringement and false advertising claims that are presently before the Court, as part of Motions for a Preliminary Injunction filed by the VSL Parties seeking to enjoin the De Simone Parties from continuing to engage in this allegedly unlawful activity. The Motions are fully briefed, the Court held an evidentiary hearing on May 19, 2016, and it heard oral argument on the Motions at a second hearing on June 3, 2016. For the reasons outlined below, the Motions for a Preliminary Injunction are GRANTED IN PART and DENIED IN PART.

## **BACKGROUND**

### **I. The Court's Orders**

#### **A. The September 2015 Order**

On September 23, 2015, this Court issued a Memorandum Opinion and Order granting in part and denying in part Motions for a Preliminary Injunction (the "First Preliminary Injunction Motions") filed by the VSL Parties. The full history among the parties that has led to this present litigation is set out in detail in that Opinion and will not be repeated here. As relevant to the present Motions for a Preliminary Injunction ("Second Preliminary Injunction Motions"), in the First Preliminary Injunction Motions, VSL sought to enjoin ExeGi from distributing various marketing and packaging materials for Visbiome because, it contended, those materials infringed the "VSL#3" trademark. The materials at issue included the website depiction of the Visbiome product box that referred to the product as the "Original Formula VSL#3 Probiotic Blend" and

“Visbiome/VSL#3 blend.” First Mot. Prelim. Inj. Exs. BB & CC, ECF Nos. 55-31 & 55-32. On September 23, 2015, the Court concluded that the original Visbiome materials likely infringed the VSL#3 mark and thus enjoined ExeGi from using those materials and the identifiers “Original Formula VSL#3 Probiotic Blend” and “Visbiome/VSL#3 blend” in any future marketing materials or packaging. First Prelim. Inj. Mem. Op. at 42, ECF No. 99.

**B. The November 2015 Order**

On November 12, 2015, after reviewing ExeGi’s revised marketing materials, the Court found that they continued to be likely to confuse consumers about the relationship between Visbiome and VSL#3. The Court accordingly issued an Order enjoining ExeGi from using the following on any of its marketing or packaging materials:

1. The phrase “Same as Original Formula VSL#3 Probiotic Blend.”
2. References to clinical studies as “Reported as VSL#3.”
3. The general statement that Visbiome is “the same” as VSL#3.

Nov. 12, 2015 Order at 2, ECF No. 113.

In that November 12, 2015 Order (the “November 2015 Order”), the Court also provided safe harbor language, which the Court indicated would likely constitute a fair use of the VSL#3 trademark if employed within the parameters set out by the Court. Specifically, the Court stated that ExeGi could use in the Visbiome marketing materials and packaging:

1. The phrase “Compare to Ingredients in VSL#3,” as long as it is accompanied in close proximity by the disclaimers that VSL#3 is a registered trademark of, and manufactured exclusively for, VSL Pharmaceuticals, Inc., and that Visbiome is manufactured exclusively for ExeGi Pharma, LLC and is not affiliated with, endorsed by, or distributed by VSL Pharmaceuticals, Inc.
2. The statement that “Visbiome contains the same strains, in the same concentrations and proportions, as the VSL#3 probiotic blend as produced before [Date],” provided that such a statement appears only once in the Visbiome materials and is accompanied in close proximity by the disclaimers

that VSL#3 is a registered trademark of, and manufactured exclusively for, VSL Pharmaceuticals, Inc., and that Visbiome is manufactured exclusively for ExeGi Pharma, LLC and is not affiliated with, endorsed by, or distributed by VSL Pharmaceuticals, Inc.

3. Accurate information about De Simone's role in developing VSL#3 that makes clear that there is no current affiliation between Visbiome and ExeGi Pharma, LLC on the one hand and VSL#3 and VSL on the other. For example, the following language would not be barred by the injunction: "In the mid-1990s, Professor Claudio De Simone, M.D. invented a proprietary blend of probiotic strains and collaborated with VSL Pharmaceuticals, Inc. to produce and market it as 'VSL#3,' a trademark owned by VSL Pharmaceuticals, Inc. In 2014, Professor De Simone decided to leave VSL Pharmaceuticals and is now collaborating with ExeGi Pharma, LLC to produce Visbiome, a probiotic using the same proprietary blend of probiotic strains that De Simone originally invented." Any discussion of De Simone's role in the creation of VSL#3 and his history with VSL must be accompanied in close proximity by the disclaimer that VSL#3 is a registered trademark of, and manufactured exclusively for, VSL Pharmaceuticals, Inc., and that Visbiome is manufactured exclusively for ExeGi Pharma, LLC and is not affiliated with, endorsed by, or distributed by VSL Pharmaceuticals, Inc.

*Id.* at 3.

### **C. The February 2016 Order**

ExeGi decided to launch Visbiome into the marketplace on February 1, 2016, the day after the 2010 Know-How License Agreement between VSL and Danisco, the original manufacturer of VSL#3 and current manufacturer of Visbiome, expired on January 31, 2016.<sup>1</sup> On January 28, 2016, Saara Khadir of JPA Health Communications, allegedly acting on behalf of ExeGi, sent an email to several U.S. media outlets stating that, "The probiotic formulation that's recommended in multiple clinical practice guidelines for those three conditions will be

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<sup>1</sup> The De Simone Parties contend that with the expiration of the 2010 Know-How Agreement, VSL's right to use any of the know-how involved in producing VSL#3 was extinguished and claim that the Court's Memorandum Opinion of September 23, 2015 "implicitly endorsed" the validity of that Agreement. *See* Resp. Opp'n Second Prelim. Inj. Mots. at 6-7, ECF No. 174. Contrary to this characterization, the Court has not made any final rulings on this issue, and it need not do so to resolve the pending Motions.

available under a new name,” which it identified as Visbiome. VSL Mem. Supp. Second Mot. Prelim. Inj. at 11, ECF No. 144.

On February 1, 2016, ExeGi issued a press release and a LinkedIn posting. Conforming to the safe harbor language of the November 2015 Order, the press release stated that Visbiome “has the same strains, in the same concentrations and proportions, and is therapeutically equivalent to the VSL#3 probiotic blend produced before January 31, 2016,” with a footnote to “VSL#3” containing the same language (the “Disclaimer”) suggested in the November 2015 Order:

VSL#3 is a registered trademark of, and manufactured exclusively for, VSL Pharmaceuticals, Inc. Visbiome is manufactured exclusively for ExeGi Pharma, LLC and is not affiliated with, endorsed by, or distributed by VSL Pharmaceuticals, Inc.

Hr’g Exhibit No. 111-1: Press Release. The press release also redefined those specific strains and concentrations as the “De Simone Formulation,” nomenclature designed to indicate a continuity with VSL#3 without the actual use of that trademark, and asserted that the De Simone Formulation had undergone numerous scientific trials and was the subject of “over 60 peer-reviewed studies.” *Id.*

Echoing the safe harbor language relating to Professor De Simone’s role with ExeGi, the press release stated:

Professor De Simone initially partnered with VSL Pharmaceuticals, Inc. to produce and market his proprietary blend of probiotic strains under the designation “VSL#3,” which is a trademark owned by VSL Pharmaceuticals, Inc. Professor De Simone is now collaborating exclusively with ExeGi Pharma, LLC to produce Visbiome.

However, the release then added:

The license agreement between Professor De Simone and VSL Pharmaceuticals, Inc., which provided VSL Pharmaceuticals, Inc. the rights to market the De Simone Formulation using the ‘VSL#3’ trademark, expired on January 31, 2016.

(the “License Expiration Language”). Press Release at 1-2.

That same day, ExeGi sent a message to its 85 LinkedIn followers stating:

Have you prescribed the medical food VSL#3 in the past to your patients with IBS, Pouchitis or Ulcerative Colitis? The De Simone formulation you’ve been prescribing to your patients will now be available as Visbiome. Learn more at <http://buff.ly/1nABFRY>.

Hr’g Ex. 111-2: LinkedIn Posting. The posting did not contain the Disclaimer.

VSL promptly took issue with these materials and notified the Court of its intent to seek a temporary restraining order (“TRO”) and preliminary injunction that would prevent ExeGi from circulating these and any similar marketing materials, bar ExeGi from making reference to clinical studies on VSL#3, and issue an order to show cause as to why those materials did not violate the November 2015 Order. The Court convened a conference call on February 2016 and brokered an agreement that would prove to be a precarious détente. In exchange for the VSL Parties agreeing not to proceed with their proposed motion, the De Simone Parties agreed to the entry of an order, issued on February 4, 2016 (“the February 2016 Order”), imposing various additional restrictions on its marketing activities, including:

1. In the press release . . . and in any future public materials using the same or similar language, ExeGi shall:
  - a. Remove the [License Expiration Language] and generally refrain from stating or suggesting that the license agreement has expired or that VSL#3 will no longer be on the market . . . .
2. In any promotional materials that reference VSL#3, such as in the LinkedIn posting of February 1, 2016, . . . ExeGi shall include in close proximity to the VSL#3 reference a disclaimer that VSL#3 is a registered trademark of VSL Pharmaceuticals, Inc., and that Visbiome and ExeGi Pharma, LLC are not affiliated with VSL Pharmaceuticals, Inc.
3. Prior to the release of any and all promotional materials, ExeGi shall have its legal counsel review the materials for compliance with the law and all existing court orders. ExeGi’s legal counsel shall maintain written documentation certifying that an authorized member of the legal team with knowledge of all

court orders has reviewed and approved each piece of promotional material before release.

Feb. 2016 Order at 1-2, ECF No. 126. The Court also granted the VSL Parties leave to amend their counterclaims to include claims for false advertising, which both later did.

## **II. The Second Motions for Preliminary Injunction**

This uneasy peace was short-lived. On March 7, 2016, the VSL Parties filed their Second Preliminary Injunction Motions, asserting that ExeGi's infringement of VSL's trademark had continued despite, and, in their estimation, in active defiance of, the February 2016 Order. In those Motions, the VSL Parties claim that the Visbiome website, ExeGi's use of Google advertisements, and statements by Visbiome sales representatives that VSL#3 was being discontinued violate the Court's existing orders, contain new infringing content, and constitute false advertising. On March 23, 2016, the De Simone Parties submitted a consolidated Response in opposition to the Motions. On April 1, 2016, VSL and Sigma-Tau each submitted a Reply memorandum. On April 8, 2016, after their original Response was stricken for exceeding the page limits, De Simone and ExeGi submitted a revised Response that conformed to the Court's page limitations. The Court held an evidentiary hearing on May 19, 2016 and heard oral argument on June 3, 2016.

The evidence presented can be grouped into three categories, which the Court discusses in turn: (1) the content of the Visbiome website; (2) the content and format of ads appearing in response to Google searches; and (3) statements made by ExeGi sales representatives and the sales training materials they received and used.

### **A. The Visbiome Website**

As of February 29, 2016, the Visbiome website contained over 100 references to "VSL#3." The references are on various webpages under the broad headline categories of

“About Visbiome,” “Visbiome Extra Strength,” and “Healthcare Professionals.” These references include the following language.

### **1. Safe Harbor Language**

Many of the references to VSL#3 appear in text that is identical to, or substantially similar to, safe harbor language referenced in the November 2015 Order. The statement “Visbiome contains the same strains, in the same concentrations and proportions, as the VSL#3 probiotic blend as produced before January 31, 2016” (the “Same Strains Language”), or comparable language, appears at least eight different times, including (1) on the main home page, in response to the headline question “How does Visbiome™ compare to the VSL#3®\* brand probiotic?”; (2) under “About Visbiome,” in an open letter from Professor De Simone entitled, “A Message from the Inventor”; (3) under “About Visbiome,” in the Frequently Asked Question (“FAQ”) section entitled, “Visbiome FAQs,” in response to the question “What is the most important information I should know about Visbiome?”; (4) under “Visbiome Extra Strength,” in response to a similar FAQ; (5) under the “Overview” page of the “Healthcare Professionals” tab of the main web page; and (6) in each of three images of package inserts for the various Visbiome products.

The website also contains the following language from the November 2015 Order, or substantially similar language, at least 11 different times:

In the mid-1990s, Professor Claudio De Simone, M.D. invented a proprietary blend of probiotic strains and collaborated with VSL Pharmaceuticals, Inc. to produce and market it as “VSL#3,” a trademark owned by VSL Pharmaceuticals, Inc. In 2014, Professor De Simone decided to leave VSL Pharmaceuticals and is now collaborating with ExeGi Pharma, LLC to produce Visbiome, a probiotic using the same proprietary blend of probiotic strains that De Simone originally invented.



(the “De Simone History Language”). Among the places this language appears on the Visbiome website are: (1) on the main home page, in response to the headline question “How does Visbiome™ compare to the VSL#3®\* brand probiotic?”; (2) under “About Visbiome,” in an open letter from Professor De Simone entitled, “A Message from the Inventor,” (3) again under “The De Simone Formulation Probiotic,” and (4) yet again under “Important Safety Information”; (5) under “About Visbiome,” in the “Visbiome FAQs” section, in response to a question “How does Visbiome compare to the VSL#3 brand probiotic?”; (6) under “Visbiome Extra Strength,” in response to a similar FAQ; (7) under “Healthcare Professionals, on the main web page and (8) again under “Clinical Experience”; and (9) in each of three images of package inserts for the various Visbiome products.

The Disclaimer, or substantially similar language, appears approximately 25 times, at the bottom of every page of the website, even on pages where there is no other reference to VSL#3. It appears in a text box with a black outline, in the same font size and color as the rest of the text on the website.

## **2. Clinical Trial References**

The Visbiome website refers to the presence of “over 60 published human clinical studies” on Visbiome or the De Simone Formulation in at least eight different places, including on the main homepage in response to the question “What is Visbiome?” It also provides more specific discussion of clinical studies on two other webpages and in the three images of package inserts. Although these references do not use the term “VSL#3” or cite specific studies, the website contains a page entitled “References” which lists the titles of 45 clinical trials, including 14 that have “VSL#3” in the title. A similar list appears on the images of three different package inserts. Notably, none of the studies containing “VSL#3” in the title is accompanied by a

footnote directing the reader to the Disclaimer at the bottom of the page. Nor does the References page otherwise explain why the list of clinical trials ostensibly related to the De Simone Formulation contains clinical trials explicitly conducted on “VSL#3.”

### 3. Exclusivity Language

In February 2016, after the issuance of the February 4, 2016 Order, the Visbiome website contained several references to the exclusive nature of ExeGi’s product. As of February 10, 2016, the Visbiome website contained a page entitled “A Message From The Inventor,” a letter addressed to the general public in which De Simone asserted that he “invented the DeSimone Formulation.” Hr’g Ex. 112-A: Feb. 10, 2016 Screenshot of “Message From Inventor” at 1. De Simone further stated:

Recently, I made the decision to end my long-term partnership with VSL Pharmaceuticals, Inc., the company for which I collaborated for many years to produce and market the De Simone Formulation under the trademark, “VSL#3®,” a trademark owned by VSL Pharmaceuticals, Inc.

I am pleased to announce that my formulation is now exclusively available from ExeGi Pharma under the trademarks Visbiome™ and Visbiome™ Extra Strength.

*Id.*

As of February 11, 2016, on a page of the website entitled, “History of the De Simone Formulation & Visbiome,” a chronology of the events leading to the launch of Visbiome culminated with “February 1, 2016 – ExeGi Pharma, LLC becomes the exclusive manufacturer of the De Simone Formulation, in both the U.S. and Canada.” Hr’g Ex. 112-B: Feb. 11, 2016 Screenshot of “Visbiome History” at 1. Elsewhere, both in response to an FAQ and on the webpage “For Healthcare Professionals,” the website stated that De Simone “is now collaborating exclusively with ExeGi Pharma, LLC to produce Visbiome, a probiotic using the same proprietary blend of probiotic strains that the Professor originally invented.” Hr’g Ex. 112-

D: Feb. 11, 2016 Screenshot of “Visbiome FAQs” at 1; Ex. 112-E: Feb. 11, 2016 Screenshot of “For Healthcare Professionals” at 1. Although this language is largely drawn from the De Simone History Language set forth in the November 2015 Order, the term “exclusively” was not included in that Order’s safe harbor language.

By February 29, 2016, the “exclusivity” language on the “History of the De Simone Formulation & Visbiome” page was removed, leaving the February 1, 2016 entry in the chronology to read “Visbiome Introduced: ExeGi Pharma, LLC manufactures the De Simone Formulation, in both the U.S. and Canada.” Hr’g Ex. 107: Feb. 29, 2016 Website Screenshots at 60. By at least May 2016, all references to the De Simone formulation being “exclusively” available through ExeGi or to an “exclusive” collaboration between De Simone and ExeGi had been scrubbed. Otherwise, the site was largely the same as it was on February 29, 2016.<sup>2</sup>

## **B. Google Searches**

### **1. Google AdWords**

At some point in February 2016, ExeGi contacted Google to set up an “AdWords” account, the name of a Google advertising system through which a company can arrange to have short advertisements appear in response to the use of designated “keywords” in a Google search. A Google AdWords advertisement is limited to four lines: (1) a headline, which must be fewer than 25 characters; (2) a body line for ad text, which must be fewer than 35 characters; (3) a

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<sup>2</sup> The May 2016 observations are based on the Court’s own examination of the Visbiome website, of which it takes judicial notice. Fed. R. Evid. 201(b)(2).

second body line for ad text, which must also be fewer than 35 characters; and (4) a URL display line (a link to a webpage), which again must be fewer than 35 characters.<sup>3</sup>

Google's AdWords system allows its users to create two different types of advertisements: static ads and dynamic ads, both of which ExeGi used. For a static ad, when a specified search term, or "keyword," is used in a Google search, a pre-drafted advertisement appears in the search results. For a dynamic ad, when a specified keyword is used in a Google search, that keyword is automatically incorporated into the text of the otherwise pre-drafted advertisement so that the user sees an advertisement that more closely mirrors the query, making the advertisement theoretically more attractive. A line of code for a dynamic ad might read "Best treatment for {keyword}," with the user's search term to be inserted in place of "{keyword}" when the ad appears. Here, ExeGi designated "VSL#3," and certain variations on it, as keywords for its ads.<sup>4</sup>

ExeGi drafted three static ads and three dynamic ads. As relevant here, four of these ads contain "VSL#3" in the scripted body of the text. Specifically, ExeGi used the following two static ads, as they were drafted in AdWords, referencing VSL#3:

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<sup>3</sup> Dr. Jason McDonald, who testified for the VSL Parties as an expert on Google AdWords, explained that when entering an ad in Google AdWords, an advertiser has only four lines of text to use. His testimony on this score comports with the format of ExeGi's AdWords account page. However, the Court notes that in the screenshots provided by VSL, some of the Visbiome advertisements actually contain five lines, and the lines appear in a different order than they are entered in AdWords. Specifically, they appear in the search results as a headline, a link to a website, two lines of body text, and additional line of text in a different color that appears to contain links to particular pages of the website.

<sup>4</sup> Whether and where in the search results such ads will display is determined by an auction process between advertisers who have entered the same keyword. An advertisement will display only if the advertiser wins the auction, the rules of which were not explained as part of the testimony on the Motions.

Have You Ever Used VSL#3?  
If So, Check Out Visbiome  
High-Potency Probiotic. Buy Now!  
www.visbiome.com

Using VSL#3 for UC/IBS?  
If So, Check Out Visbiome  
High-Potency Probiotic. Shop Now!  
www.visbiome.com

It used the following two dynamic ads, as they were drafted in AdWords, referencing VSL:

{Keyword: Have You Ever Used VSL#3}  
If So, Check Out Visbiome  
High-Potency Probiotic. Buy Now!  
www.visbiome.com

{Keyword: Using VSL#3 for UC/IBS?}  
If So, Check Out Visbiome  
High-Potency Probiotic. Shop Now!  
www.visbiome.com

Hr'g Ex. 9: Google AdWords Emails at 6. None of these ads contained the Disclaimer required by the February 2016 Order.

In February 2016, some of the dynamic ads, when displayed in response to a search using the term "VSL#3," appeared as follows:

VSL#3  
www.visbiome.com  
If So, Check Out Visbiome High-Potency Probiotic. Buy Now!  
Manage Pouchitis/IBS/IBD Proven by Research.  
Message from the Inventor – Reimbursement Support – Order Now

Hr'g Ex. 109: Singh Decl.: Website Screenshots at 2.

The proposed questions to be included in the AdWords text, "Have You Ever Used VSL#3?" or "Using VSL#3 for UC/IBS?," did not appear in the first line of the dynamic ads. Additional searches using VSL#3 and variations on it returned the same results: a headline with the user's search term but without either version of ExeGi's drafted questions. ExeGi learned of

this ad text when, on March 7, 2016, VSL filed its Second Motion for a Preliminary Injunction, which included a screen shot of one such ad. According to Dr. Jason McDonald, an expert witness offered by VSL on the functioning of Google AdWords and search engine optimization, the keyword generally appears on its own in this manner when the proposed dynamic headline, including the keyword, would exceed 25 characters.

According to ExeGi, although it had the assistance of Google personnel in crafting the ad, it never intended for the keyword “VSL#3” to appear by itself without the proposed question. Yamil Hernandez, ExeGi’s Chief Business Officer, testified that on March 20, 2016, he contacted ExeGi’s Google representative to ask why the headline text was being truncated to only the user’s search term. The Google representative was unable to provide an answer over the course of email exchanges over the next two weeks. On April 4, 2016, the Court scheduled a telephone conference for the afternoon of April 6, 2016. On the morning of April 6, 2016, Hernandez emailed ExeGi’s Google representative, asked for and received instructions on how to discontinue the use of the ad, then “paused” the dynamic ads so they would no longer appear.

## **2. Search Engine Optimization**

According to Dr. McDonald, Visbiome’s website bears certain hallmarks of “keyword stuffing”: the practice of repeatedly using a specific term on a website to increase the likelihood that Google’s search algorithm will associate the website with that term and thereby increase the prominence of that site in search results relating to that term. For example, the term “VSL” was the second most frequently used term on the Visbiome website, used even more frequently than “ExeGi.” McDonald Test. at 53, ECF No. 205. In addition, the term “VSL#3” frequently appears “below the fold,” meaning toward the bottom of individual webpages, where it is visible only if the user scrolls down, a placement that may indicate that the term is used more to

influence the search algorithm than as text intended for website users. *Id.* at 54-55. ExeGi, for its part, denies that it was engaged in any kind of keyword stuffing and asserts that Google, in fact, “ding[s]” a website if it detects evidence of keyword stuffing. *Tewey Test.* at 133. According to ExeGi Chief Executive Officer Mark Tewey, the term VSL#3 appears on the Visbiome website so frequently because it appears in the Disclaimer, and ExeGi decided to put the Disclaimer on every page of the website to be responsive to VSL’s concerns about potential confusion between Visbiome and VSL#3. ExeGi chose to place the Disclaimer at the bottom of the page in the “black box,” because that location is understood by medical professionals to contain important information, such as safety warnings about the product.

**C. Sales Representatives**

**1. Training Materials**

By the end of January 2016, ExeGi had assembled a team of four sales representatives, including Debora Hudak, based out of Los Angeles, California, and Conrad Shepard, based out of Dallas, Texas. On February 2, 2016, the day after the Court’s February 1 telephone conference with the parties regarding ExeGi’s allegedly infringing promotional materials, the sales team convened at ExeGi headquarters in Gaithersburg, Maryland for a two-day training session. Prior to that training, the ExeGi executive team had created training materials, including a PowerPoint presentation summarizing the key points for sales representatives to make and language for them to avoid during sales calls.

The PowerPoint presentation provides, under the header “How Does Visbiome Compare to VSL#3?”, the Same Strains Language and the De Simone History Language, but includes in the latter the statement that De Simone “is now collaborating exclusively” with ExeGi to produce

Visbiome. Hr'g Ex. 2: PowerPoint Slides at 6. The PowerPoint advises the sales team that it may not use:

- The phrase “Same as Original Formula VSL#3 Probiotic Blend.”
- The general statement that Visbiome is “the same” as VSL#3.
- “The name is changing from VSL to Visbiome.”
- “VSL#3 is being discontinued.”
- “VSL#3 is no longer available.”

*Id.* at 19. Sales representatives are instructed that they may use the Same Strains Language, the De Simone History Language, and the following statements:

- “Visbiome contains the same formulation and is therapeutically equivalent to the VSL#3®\* probiotic blend produced before January 31, 2016.”
- “Visbiome contains the same formulation as the pre-Jan. 31, 2016 VSL#3.”
- “Visbiome is produced using the same manufacturing facility, production methods, and quality standards used for the VSL#3® probiotic blend as produced before January 31, 2016.”
- “Visbiome contains the De Simone Formulation, which was originally sold by VSL Pharmaceuticals, Inc. under a different trade name, and will now be sold as Visbiome.”
- “ExeGi Pharma now holds the exclusive license to the DeSimone Formulation in both the U.S. and Canada.”

*Id.* at 21.

The PowerPoint also advises sales representatives to “take the high road” and avoid disparaging VSL#3, VSL, or Sigma-Tau. *Id.* at 23. They must also “[a]lways distinguish the De Simone Formulation from the trademark VSL#3” and limit the use of “VSL#3” in conversation “to only what is absolutely necessary.” *Id.* If customers have questions about the status of VSL#3, sales representatives are directed to refer them to Sigma-Tau. The PowerPoint also notes, in an FAQ section, that:

On January 31, 2016, the license[] agreement between VSL Pharmaceuticals and the inventor of the product expired. After this point, VSL Pharmaceuticals no longer has access to the proprietary technology and strain supply required to manufacture the inventor’s formulation. Therefore, any comparisons of the two products are only relevant to the product sold under the “VSL#3” trademark produced prior to January 31, 2016.



*Id.* at 30.

According to Tewey, during a conference call with the sales team on February 5, 2016, the sales representatives were instructed that, based on the February 2016 Order, issued the day before, they should make no reference to the expiration of the license agreement in their sales calls.

At some point, the sales representatives were also give a one-page “cheat sheet,” which many of them have since laminated and bring with them on sales calls. The cheat sheet is divided into two sections: “Statements to Discuss Visbiome” and “Off Limits Statements.” Each of the “Statements to Discuss Visbiome” repeats a statement contained in the PowerPoint, including the statement that “Visbiome contains the De Simone Formulation, which was originally sold by VSL Pharmaceuticals, Inc. under a different trade name, and will now be sold as Visbiome.” Hr’g Ex. 3: Cheat Sheet. This section also contains the Disclaimer and instructs sales representatives to “Note in discussions that the VSL#3 is a registered trademark of VSL Pharma and Visbiome is not associated with/endorsed by VSL Pharma.” *Id.* Under “Off Limits Statements,” each of the statements tracks an off-limits statement from the PowerPoint, except for the additional instructions to “Refrain from stating/suggesting that the license agreement has expired” and that “Generally, we wish to stay away from reference to the term ‘VSL#3’ outside of the context of the approved statements.” *Id.*

On March 1, 2016, in response to complaints by VSL, ExeGi modified the PowerPoint and recirculated it to the sales staff. The revised version added to the list of “What We Must Not Say About Visbiome and VSL#3” that VSL#3 is “Going off the market” and the general statement that “we wish to stay away from the reference to the term ‘VSL#3’ outside of the context of the ... approved statements.” Hr’g Ex. 4: Revised PowerPoint Slides at 3.

In addition, ExeGi removed from the “Safe Statements Re DeSimone Formulation” slide the statements:

- “Visbiome contains the De Simone Formulation, which was originally sold by VSL Pharmaceuticals, Inc. under a different trade name, and will now be sold as Visbiome.”
- “ExeGi Pharma now holds the exclusive license to the DeSimone Formulation in both the U.S. and Canada.”

*Id.* at 4. In the same time frame, ExeGi removed from the Visbiome website all references to the “exclusive” nature of De Simone’s relationship with ExeGi.

## **2. Sales Visits**

According to the VSL Parties, since February 2016, ExeGi sales representatives have on at least three occasions suggested in communications with doctors’ offices that VSL#3 is no longer being sold. Since the launch of Visbiome in February 2016, ExeGi sales representatives have called on approximately 1,000 doctors’ offices to promote Visbiome. While Visbiome is available on the shelf in a “handful” of pharmacies, its two primary distribution streams are through gastroenterologists’ offices and through the internet. *Tewey Test.* at 141. At the evidentiary hearing on May 19, 2016, the parties presented the following evidence on this issue.

### **a. Dr. Varon’s Office**

Dr. David Varon, a gastroenterologist in Concord, California, is the number one prescriber of VSL#3 in the world. On or about February 2, 2016, Erika Garcia, Dr. Varon’s office manager, received a call from Hudak in which Hudak offered to send samples of Visbiome and asked to schedule a time to meet with Dr. Varon to discuss the product. According to Garcia, as part of that conversation, Hudak asserted that she was selling a new product because “VSL#3 is being discontinued.” Hr’g Ex. 104: Garcia Decl. ¶ 6; Hr’g Ex. 119: Garcia Dep. at 13-17. By Garcia’s recollection, the phone conversation lasted less than two minutes. Garcia

declined Hudak's offer to send Dr. Varon samples but did schedule a meeting between Hudak and Dr. Varon for March 2, 2016. Several days after that phone call, the VSL#3 representative assigned to Dr. Varon's office came by to drop off samples. While the VSL#3 sales representative was there, Garcia asked her if VSL#3 was being discontinued, and the VSL#3 sales representative clarified that VSL#3 was not going off the market but that there was now "another company with a similar product." Garcia Dep. at 37-38.

According to Hudak, her call to Garcia occurred on February 11, 2016, and she never stated that "VSL#3 is being discontinued." Instead, she asserts, she followed a script provided to her as part of the February 2-3, 2016 training, but which differs from the PowerPoint or the cheat sheet. The script includes the following statements:

We have a product that is a probiotic that contains the same formulation found in VSL#3, produced before January 31st of this year.

\* \* \*

As of February 1st of this year, Dr. De Simone, the inventor of the probiotic formulation, has partnered with ExeGi Pharma, who is now producing the formulation under the name "Visbiome Extra Strength," and he no longer has a relationship with VSL Pharma.

As far as I know, VSL Pharma still has inventory of the formulation, but after February 1st of this year, the formulation is being produced by ExeGi Pharma under the name Visbiome.

Hr'g Ex. 106: Hudak Decl. ¶ 6. Hudak also specifically recalled stating, as she followed the script, "Visbiome has the same bacterial strains in the same concentrations as the VSL that was manufactured before . . . January 31st of 2016." Hudak Test. at 181.

As a result of Garcia's allegations, Tewey decided to join Hudak at her March 2, 2016 meeting with Dr. Varon. During that meeting, Tewey and Hudak informed Dr. Varon that VSL#3 was not being discontinued. Dr. Varon observed that it appeared that the two products were "identical" and that he would consider Visbiome only if he could "see some sort of

advantage over VSL.” Req. for Conf. Ex. 1: Varon Dep. at 40, ECF No. 198-1.<sup>5</sup> Following the meeting, Hudak hand-delivered to Dr. Varon a letter from Tewey in which Tewey clarified that “[t]o the best of our knowledge, *VSL#3 and VSL#3 DS trademarked probiotic products are not being discontinued.*” Hr’g Ex. 7: Varon Letter (emphasis in original). The letter also contained, as a footnote, the Disclaimer.

At some point in April 2016, during another visit with Dr. Varon, when the conversation turned to Garcia’s allegation, Hudak showed Dr. Varon the cheat sheet she had been provided by ExeGi and emphasized that she understood the importance of following that guidance. Dr. Varon replied that, based on the first three statements on the sheet, “I can understand how somebody can infer from this that [VSL#3] is being discontinued.” Hudak Test. at 185, 205. The third statement is: “Visbiome contains the De Simone Formulation, which was originally sold by VSL Pharmaceuticals, Inc. under a different trade name, and will now be sold as Visbiome.” Cheat Sheet. Hudak has also acknowledged that “on occasion” during sales calls, personnel at doctors’ offices have been confused and asked whether VSL#3 is going off the market. Hudak Test. at 207. Since receiving Dr. Varon’s feedback, she has altered her script and changed her approach to more carefully explain that the two products are different.

**b. Dr. Siegel’s Office**

On or about February 23, 2016, while at Sigma-Tau’s annual national sales meeting in Hawaii, Patti Godfrey, a territory manager for Sigma-Tau, received a call from Michelle Moisse, who works for Dr. Daniel Siegel in his Denver, Colorado office. Moisse stated that on February 22, 2016, Conrad Shepard, an ExeGi sales representative, had visited Dr. Siegel’s office and

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<sup>5</sup> The parties jointly agreed to admit Dr. Varon’s deposition testimony into evidence, *see* Hr’g Tr. at 242, but the deposition was not assigned an exhibit number.

informed her that “VSL#3 is being discontinued” and that “Visbiome is a generic version of VSL#3.” Hr’g Ex. 105: Moisse Decl. ¶ 5; Hr’g Ex. 120: Moisse Dep. at 17. Moisse was certain that Shepard had said that VSL#3 was being discontinued because “[w]hen it comes to medications being discontinued,” that is something that “we ingrain into our brains so we can assist the patients.” Moisse Dep. at 17. Godfrey and her manager, Gena Groy, assured Moisse that VSL#3 was not going off the market, and Godfrey promised to stop in at Dr. Siegel’s office soon after her return from Hawaii.

Shepard, who used to work for Sigma-Tau selling VSL#3, acknowledges visiting Dr. Siegel’s office on February 22, 2016 to set up a lunch meeting, but he denies telling Moisse that VSL#3 had been discontinued. According to Shepard, he told Moisse that “Visbiome contains the same strains, same concentration, the same formulation, and it’s therapeutically equivalent to VSL#3 produced prior to January 31, 2016.” Shepard Test. at 224. During that conversation, Moisse asked a few follow-up questions, which prompted Shepard to explain that Visbiome was “the generic of VSL#3.” *Id.* When Moisse asked what was happening with VSL#3, he gave his “standard” answer that she should contact her VSL#3 sales representative. *Id.*

On April 12, 2016, Tewey sent Dr. Siegel a letter identical to the one sent to Dr. Varon clarifying the relationships between Visbiome and VSL#3, and between ExeGi and VSL. The parties have stipulated that nothing in Shepard’s conversations with Moisse had any impact on Dr. Siegel’s decisions regarding whether to prescribe VSL#3.

Although Shepard denies ever telling any doctor’s office that VSL#3 had been discontinued, at one point, Shepard gave to doctors and office staff a January 28, 2016 letter from DuPont, which owns Danisco, stating that:

[A]s of February 1, 2016, ExeGi will be the exclusive distributor in the United States of the probiotic products containing the [De Simone] Formulation.

\* \* \*

Danisco hereby informs ExeGi that the formulation of the Visbiome™ Products to be manufactured by Danisco and supplied to ExeGi as of February 1, 2016 will be the same as the formulation of the VSL#3 Products Danisco previously manufactured for various sellers of the VSL#3® brand probiotics.

Hr'g Ex. 125: DuPont Letter. DuPont has since withdrawn that letter.

**c. Southland Gastroenterology**

At the May 19, 2016 Hearing, Kelly Hamilton, a VSL#3 sales representative, recounted her conversations with “Emily,” a staff member at Southland Gastroenterology in Murietta, California.<sup>6</sup> Hamilton testified that on April 18, 2016, she stopped by Southland Gastroenterology to leave behind some VSL#3 promotional materials and samples. When Hamilton introduced herself to Emily as a representative of VSL#3, Emily gave her a “puzzled look.” Hamilton Test. at 90. Emily then stated, “I heard you were changing your name.” *Id.* When Hamilton responded that VSL#3 “has not changed its name at all,” Emily went to a back room and returned with a box of Visbiome. *Id.* Hamilton told Emily that “there must be some confusion” and stated that VSL#3 was “still around.” *Id.* When Hamilton asked whether she could leave behind samples of VSL#3, Emily declined, noting that the office already had enough of the other product, referring to Visbiome.

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<sup>6</sup> Although such evidence would normally be inadmissible as hearsay, the Court accepted the evidence for purposes of these Motions because the nature of preliminary injunctions justifies relaxation of normal evidentiary standards. *G. G. ex rel Grimm v. Gloucester Cty. Sch. Bd.*, \_\_\_ F.3d \_\_\_, 2016 WL 1567467 at \*9-10 (4th Cir. Apr. 19, 2016) (holding that a district court erred in excluding hearsay evidence on a preliminary injunction motion because “the nature of evidence as hearsay goes to weight, not preclusion” on a preliminary injunction motion, which is customarily resolved on the basis of “procedures that are less formal and evidence that is less complete than in a trial on the merits”) (internal quotation marks and citation omitted).

Before leaving, Hamilton asked Emily to follow up on the source of her confusion and indicated that she would be in touch with Emily again. On May 18, 2016, the day before the evidentiary hearing, Hamilton contacted Emily, who then stated that she had spoken with the Visbiome representative, named "Debora," and that Emily's notes of that conversation reflected that "as of January 31st, VSL had changed its name." Hamilton Test. at 91-92, 97, 99. Emily again declined to accept Hamilton's offer of samples of VSL#3 because the office had enough samples of Visbiome.

In her hearing testimony, Hudak confirmed that she had visited Southland Gastroenterology sometime in late February and had spoken with Emily. During that visit, she told Emily that she wanted to provide information to the doctors about a "high-potency probiotic" that contained "the same bacterial strains and the same proportions as VSL that was manufactured prior to January 31st of 2016." Hudak Test. at 189. She denied ever stating that VSL#3 was changing its name. According to Hudak, Emily set up a meeting for Hudak with one of the doctors in the practice. Hudak made several more visits to Southland Gastroenterology, during which she met with a doctor, provided samples of Visbiome and literature on the product, and followed up to see if more samples were needed. During those interactions, Hudak did not perceive that the doctor was confused about the relationship between Visbiome and VSL#3. On May 11, 2106, Hudak received a call from Emily asking Hudak to clarify the relationship between Visbiome and VSL#3. Hudak explained to her that "VSL has not changed its name," and VSL and Visbiome were made by "two separate companies." Hudak Test. at 191. She added that Visbiome "is therapeutically equivalent to the VSL that was manufactured before January 31st of this year," and that as of February 1, 2016, "De Simone is now with ExeGi

Pharma, and he has collaborated with ExeGi Pharma, so Visbiome is made under a new company and a different name.” *Id.*

## DISCUSSION

Based on the De Simone Parties’ marketing activities for Visbiome, the VSL Parties ask this Court (1) to find the De Simone Parties in contempt of this Court’s prior orders; (2) to issue a preliminary injunction related to the VSL Parties’ false advertising claims; and (3) to expand this Court’s prior preliminary injunction related to VSL’s trademark claims. In terms of the scope of the proposed preliminary injunction, the VSL Parties seek (1) a bright-line rule barring the De Simone Parties from any use of the VSL#3 trademark in Visbiome promotional materials; (2) an order barring the De Simone Parties from engaging in false advertising or otherwise misleading customers and medical professionals into believing that VSL#3 will no longer be on the market, that the De Simone Parties are the exclusive provider of the probiotic, or that VSL#3 has a new name or has been rebranded as Visbiome; and (3) an order requiring ExeGi to issue a message, preapproved by the VSL Parties, to abate the harm caused by the prior alleged infringing activity.

### I. Civil Contempt

The Court first addresses whether the De Simone Parties have violated any existing court orders and whether they should be held in contempt for any such violations. The VSL Parties allege the following violations: (1) the Visbiome website violates the November 2015 Order because it makes excessive use of the VSL#3 mark and the Same Strains Language and fails to include the Disclaimer in close proximity to the VSL#3 mark; (2) the Google AdWords ads violate the February 2016 Order by failing to include the Disclaimer in close proximity to the VSL#3 mark; (3) the promotional materials stating that ExeGi is the “exclusive” supplier of the



“De Simone Formulation” violate the February 2016 Order by suggesting that VSL#3 is no longer on the market; and (4) statements by ExeGi sales representatives violate the February 2016 Order because they suggest that VSL#3 has been discontinued or changed its name to “Visbiome.”

**A. 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.

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 quotation marks and citation omitted).

**B. The Visbiome Website**

The VSL Parties assert that the Visbiome website violates the provisions of the Court’s November 2015 Order and February 2016 Order by using the VSL#3 mark and the Same Strains Language excessively and by failing to place the Disclaimer in close proximity to the use of the

mark. In the November 2015 Order, the Court stated that the Same Strains Language “would likely constitute a fair use of the VSL#3 trademark” and would not be barred by the injunction if it appeared “only once in the Visbiome materials and is accompanied in close proximity” by the Disclaimer. Nov. 2015 Order at 3. Rather than use it once on the website, ExeGi uses it approximately eight times. The De Simone Parties have claimed that it was reasonable to interpret the term “only once in the Visbiome materials” as permitting multiple uses on the Visbiome website, up to once on each individual page of the website.

The Court finds this interpretation to be wholly unreasonable, particularly to the extent that the De Simone Parties argue that the Court sanctioned eight separate uses of that language on the website. The Court considers the eight uses of the Same Strains Language and the 11 uses of the De Simone History Language on the Visbiome website to be excessive and in violation of the spirit in which the safe harbor language was offered in the November 2015 Order.

Nevertheless, the Court finds no actual violation of the November 2015 Order arising from these uses, or from the high number of references to VSL#3 throughout the website, because the Order never expressly barred any particular number of uses of VSL#3, the Same Strains Language, or the De Simone History Language. The reference to the Same Strains Language merely conditioned a finding that it constituted a fair use of the VSL#3 trademark on its single use and the close proximity of the Disclaimer. Having used the Same Strains Language multiple times on the Visbiome website, the De Simone Parties cannot take advantage of this safe harbor, but such use did not violate the November 2015 Order. As discussed below, the De Simone Parties will no longer be able to continue with such repetitive use of this language. *See infra* parts III.A. and IV.A.

The VSL Parties also claim that the placement of the Disclaimer in a footnote at the bottom of a webpage “below the fold,” rather than in the text, violated the Court’s order. The November 2015 Order did not mandate the use of the Disclaimer “in close proximity,” but instead required it as a condition of the safe harbor relating to the Same Strains Language. The February 2016 Order, however, specifically ordered that “[i]n any promotional materials that reference VSL#3,” the Disclaimer had to be included “in close proximity.” Feb. 2016 Order at 2.

The Court finds no violation of the February 2016 Order. In some instances, such as on the main home page, the Disclaimer appears in the text shortly after the reference to VSL#3. When the Disclaimer appears only in a footnote, it appears in the same font, same size, and same color as the main text. The use of a footnote and placement of the Disclaimer “below the fold” may reduce the likelihood that a user will read it, but with Visbiome’s own content at times requiring the reader to scroll down, the Court cannot say that there is clear and convincing evidence that ExeGi has placed its required disclaimers at a distance too far from the VSL#3 mark to satisfy the requirement of “close proximity.”

However, the Court is troubled by the lack of footnote reference markers next to the term VSL#3 on the “References” page of the website, which lists clinical studies asserted to relate to the same formulation used in Visbiome. The De Simone Parties’ explanation for this omission, that they believed that the February 2016 Order did not require a footnote reference marker when the use of “VSL#3” appeared in the title of a clinical study, is unconvincing. The failure to direct the reader to the Disclaimer substantially decreased the likelihood that it would be noticed, so this omission could be viewed as indicating an intent to obfuscate the fact that the clinical trials were performed on a product offered by a different company. Nevertheless, the February

2016 Order mandated only “close proximity,” and the Disclaimer did appear at the bottom of the Reference page. Under these circumstances, the Court does not find a violation of the Order.

### **C. Google AdWords**

In the briefs and during the hearing, the parties expended significant energy autopsying ExeGi’s faulty or deliberately misleading, depending on one’s perspective, dynamic keyword insertion Google AdWords advertisements. While the Court agrees that the headline “VSL#3,” accompanied by no other text, would appear to be an aggressive attempt to co-opt the VSL#3 mark, the Court has issued no orders barring advertising through Google AdWords, employing dynamic ads, or using VSL#3 as a keyword for such ads, so the fact that a dynamic ad resulted in such a headline, intentionally or unintentionally, does not specifically implicate any of the Court’s prior orders.

What the Court has ordered, in clear and unequivocal terms in its February 2016 Order, is the following:

In any promotional materials that reference VSL#3, such as in the LinkedIn posting of February 1, 2016, ExeGi shall include in close proximity to the VSL#3 reference a disclaimer that VSL#3 is a registered trademark of VSL Pharmaceuticals, Inc. and that Visbiome and ExeGi Pharma, LLC are not affiliated with VSL Pharmaceuticals, Inc.

Feb. 2016 Order, at 2.

The De Simone Parties do not dispute that several of ExeGi’s Google AdWords ads, whether static or dynamic, contained the mark “VSL#3” in the headline, yet the Disclaimer did not appear in any of those ads. At varying times, the De Simone Parties have offered no less than five different explanations for this non-compliance with the Order. In their brief, the De Simone Parties assert the equivalent of an impossibility defense: that the required Disclaimer would not meet the character limits of Google AdWords ads. They also claim that the Court’s Order required a Disclaimer only when the Same Strains Language was used. Then, during the

evidentiary hearing, ExeGi Chief Business Officer Hernandez echoed another explanation offered in the De Simone Parties' brief, claiming that ExeGi believed that because a link to the Visbiome website appeared in each Google AdWords ad, the February 2016 Order's requirement of a Disclaimer in "close proximity" was satisfied by the presence of the Disclaimer on the Visbiome website. During his testimony at the evidentiary hearing, ExeGi CEO Tewey offered a different explanation, asserting that a Google AdWords ad does not qualify as a "promotional material" because it is merely a "teaser" that directs a user to the Visbiome website. Tewey Test. at 146. Finally, at oral argument, the De Simone Parties argued that they interpreted the February 2016 Order to require a Disclaimer only when VSL#3 was used in conjunction with the language in the referenced LinkedIn posting, which stated "Have you prescribed the medical food VSL#3 in the past to your patients with IBS, Pouchitis or Ulcerative Colitis?"

None of these explanations excuse the clear violation of the February 2016 Order. The Order contains no exceptions for space limitations in particular advertising media. Although the November 2015 Order related to the Same Strains Language, the February 2016 Order never referenced that language. Instead, the February 2016 Order set out the clear and unambiguous instruction that whenever VSL#3 was used, the Disclaimer was required in close proximity. While the February 2016 Order referenced the LinkedIn posting, its use of the phrase "such as" clearly identified the LinkedIn posting as a non-exclusive example of when a Disclaimer was required. In any event, the Google AdWords ad containing the question "Using VSL#3 for UC/IBS?" plainly addresses the same subject matter as the LinkedIn posting.

The "close proximity" instruction, while subject to some reasonable interpretation relating to distance that allowed the Court to determine that a Disclaimer in a footnote at the bottom of the same webpage satisfied that requirement, cannot be stretched to encompass a

Disclaimer that appears on a separate website. “Proximity” is a measure of distance, and there is no way to measure the distance between the Google AdWords ad and another website. The De Simone Parties’ interpretation of proximity as “one click away” defines that term as a physical act, not a measure of distance, and thus cannot be deemed a reasonable interpretation of the language of the February 2016 Order. This is particularly true considering that through that definition, the De Simone Parties shift the burden of compliance with this Court’s Orders to Google users, who must click on the Visbiome advertisement in order to see the required Disclaimer. As for the claim that a Google AdWords ad does not qualify as promotional material, the absurdity of that claim is apparent from the fact that Google places the word “Ad” as a marker next to each Google AdWords ad that appears among search results.

That the De Simone Parties’ explanations for violating the February 2016 Order kept shifting over time smacks of after-the-fact damage control. The Court’s February 2016 Order was clear and unequivocal that a Disclaimer must be in “close proximity” to any use of the VSL#3 mark. Because no such disclaimer appeared anywhere on the same webpage as the Google AdWords ads at issue, the Court finds that there is clear and convincing evidence that the Google AdWords advertisements violated that Order.

**D. “Exclusivity” Language**

The VSL Parties further argue that various promotional materials violated the provision of the February 2016 Order that “In the press release dated February 1, 2016, and in any future public materials using the same or similar language, ExeGi shall . . . generally refrain from stating or suggesting that the license agreement has expired or that VSL#3 will no longer be on the market.” Feb. 2016 Order at 1. The version of the Visbiome website active on February 10, 2016 contained the statement by De Simone on the page entitled “A Message From The

Inventor” that “I am pleased to announce that my formulation is now exclusively available from ExeGi Pharma under the trademarks Visbiome™ and Visbiome™ Extra Strength.” Feb. 10, 2016 Screenshot of “Message From Inventor” at 1. In a version of the website active on February 11, 2016, in the chronology entitled the “History of the De Simone Formulation & Visbiome,” an entry stated: “February 1, 2016 – ExeGi Pharma, LLC becomes the exclusive manufacturer of the De Simone Formulation, in both the U.S. and Canada.” Feb. 11, 2016 Screenshot of “Visbiome History” at 1.

These statements were made on a public website, in the context of descriptions of the history of the De Simone Formulation, using language similar to that of the February 1, 2016 press release, which prompted the February 2016 Order. Although these statements do not explicitly state that VSL#3 is no longer on the market, the claim that the De Simone Formulation is “exclusively available” from ExeGi, coupled with the website’s assertion that the De Simone Formulation is the same as that used in VSL#3, leads to the unmistakable conclusion that VSL#3 is no longer available for sale. Likewise, the statement that ExeGi became “the exclusive manufacturer of the De Simone Formulation” supports the inference that any license VSL had to manufacture the product had expired. Thus, these statements are “suggesting that the license agreement has expired or that VSL#3 will no longer be on the market.” Feb. 2016 Order at 1.

Although the De Simone Parties may not have intended to thwart the Court’s February 2016 Order, and the use of language different from that contained in the Order may well have been an effort to get up to the line without crossing it, intent is not an element of civil contempt. Moreover, a party subject to a preliminary injunction has a “duty to keep a safe distance from the line drawn by the district court’s injunction.” *Oral-B Labs. v. Mi-Lor Corp.*, 810 F.2d 20, 24 (2d Cir. 1987); see *Howard Johnson Co., Inc. v. Khimani*, 892 F.2d 1512, 1517 (11th Cir. 1990)

("[T]he legal posture of this case places a heavier burden upon the [alleged infringer] of avoiding a colorable imitation of or diluting [its competitor's] trade and service marks than upon a party not already preliminarily enjoined from engaging in such activity."). Here, the Court finds by clear and convincing evidence that these statements on Visbiome's public website, that were present a week after the Court's Order and remained there for several more weeks, violated the February 2016 Order.

On the other hand, the assertion on several of the pages of the website that De Simone was "collaborating exclusively" with ExeGi merely states that De Simone has changed companies and does not suggest that VSL#3 is no longer on the market. Those statements in no way violate the February 2016 Order.

#### **E. Sales Representatives**

The VSL Parties argue that the De Simone Parties violated the same provision of the February 2016 Order when ExeGi sales representatives Debora Hudak and Conrad Shepard told personnel at a total of three medical offices that VSL#3 had been discontinued or had changed its name. In her deposition testimony, Erika Garcia of the office of Dr. Varon testified that Hudak had told her that VSL#3 had been discontinued. Michelle Moisse of the office of Dr. Siegel similarly testified that Shepard told her that VSL#3 was discontinued. Even as deposition testimony, Moisse's account had indicia of reliability because she specifically recalled the word "discontinued" and noted that the use of the term "discontinued" would "ingrain into our brains" and have special significance to a medical office because it could impact what treatments are available to its patients. Moisse Dep. at 17. These accounts are further bolstered by the undisputed fact that both Garcia and Moisse affirmatively asked VSL or Sigma Tau personnel whether it was true that the product was being discontinued. Likewise, Kelly Hamilton, a



Sigma-Tau sales representative, testified in significant detail about an encounter with Emily, a staff member at Southland Gastroenterology, who gave a puzzled look when Hamilton said she was a sales representative for VSL#3, told her that she thought that VSL had changed its name, showed her packages of Visbiome, and declined to accept VSL#3 samples because she had enough Visbiome samples. Emily later reported back to Hamilton that the Visbiome representative she met was Debora Hudak and stated her understanding from Hudak that VSL#3 had changed its name as of January 31, 2016. This evidence strongly suggests that ExeGi sales representatives told medical offices that VSL#3 was discontinued or had changed its name.

On the other hand, both Hudak and Shepard vigorously denied stating to any doctors or medical office staff that VSL#3 was discontinued or had changed its name. While Hudak and Shepard took the witness stand, the Court did not have the opportunity to observe Garcia and Moisse, whose testimony was submitted through declarations and deposition transcripts. The VSL Parties' live witnesses, Patti Godfrey and Kelly Hamilton, were Sigma-Tau sales representatives who provided hearsay accounts of what Moisse and Emily told them. Such testimony, though admissible at a preliminary injunction hearing, carries less weight. *See G. G. ex rel Grimm*, \_\_\_ F.3d \_\_\_, 2016 WL 1567467 at \*9-10. Thus, the evidence that Hudak and Shepard specifically told medical offices that VSL#3 was "discontinued" or "changed its name" cannot be said to be clear and convincing, as required to support a contempt finding.

There was, however, clear and convincing evidence that even if Hudak did not use the word "discontinued," she suggested that VSL#3 was no longer on the market or had changed its name. In addition to the above-referenced testimony, which strongly indicated that Garcia, Moisse, and Emily, at a minimum, received the clear impression that VSL#3 was no longer on

the market or had changed its name, Hudak acknowledged that she made statements based on one or more scripts. These statements included:

Visbiome contains the De Simone Formulation, which was *originally* sold by VSL Pharmaceuticals, Inc. under a different trade name, and *will now be sold as Visbiome*. Cheat Sheet (emphasis added).

We have a product that is a probiotic that contains the same formulation found in VSL#3, produced before January 31st of this year. . . . *As far as I know, VSL Pharma still has inventory of the formulation, but after February 1st of this year, the formulation is being produced by ExeGi Pharma under the name Visbiome.* Hudak Decl. ¶ 6 (emphasis added).

In addition, in recounting what she told medical office personnel in following the script, Hudak twice recited a slightly but significantly different version of the Same Strains Language, referring to VSL in the past tense: “Visbiome has the same bacterial strains in the same concentrations as the VSL *that was* manufactured before . . . January 31st of 2016.” Hudak Test. at 181 (emphasis added) The italicized portions of these statements, which were not endorsed by the Court in any prior Order, are fairly construed as suggesting that VSL#3 is no longer on the market or has been renamed Visbiome. In fact, Hudak acknowledged that “on occasion” during sales calls, personnel at doctors’ offices have been confused and asked whether VSL#3 is going off the market, Hudak Test. at 207, and that when she showed Dr. Varon her script, he told her, “I can understand how somebody can infer from this that [VSL#3] is being discontinued.” *Id.* at 185, 205. When coupled with the credible accounts that Garcia, Moisse, and Emily believed that they had been informed that VSL#3 had been discontinued or changed its name, there is significant

evidence that ExeGi sales representatives in fact “suggest[ed] that . . . VSL#3 will no longer be on the market.”<sup>7</sup> Feb. 2016 Order at 1.

Nevertheless, the Court does not find a violation of the February 2016 Order to support a finding of contempt. What saves ExeGi from contempt—but only by the slimmest of margins—is that the February 2016 Order applies only to the “the press release dated February 1, 2016 . . . and any future public materials using the same or similar language.” Feb. 2016 Order at 1. There was no evidence presented that the cheat sheet or Hudak’s personal script were publicly circulated documents, and the oral statements of ExeGi sales representatives cannot fairly be construed as a “press release” or “public materials,” terms which connote written documents released to the public. Feb. 2016 Order at 1, 2. Thus, the ExeGi sales representatives’ statements did not technically violate the February 2016 Order.

**F. Harm**

Finally, the Court finds that these violations, which were designed to further ExeGi’s efforts to take away market share from VSL#3 by eroding any distinction between VSL#3 and Visbiome, created a likelihood of confusion and thus caused harm to the VSL Parties. *See Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 273 (4th Cir. 2002) (noting that “a presumption of irreparable injury is generally applied once the [movant] has demonstrated a likelihood of confusion”). Although the De Simone Parties claim that the VSL Parties are not harmed because they have no right to sell the De Simone Formulation as VSL#3 after January 31, 2016, the Court

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<sup>7</sup> The November Order expressly enjoined ExeGi from asserting in its promotional materials “the general statement that Visbiome is ‘the same’ as VSL#3.” Nov. 2015 Order at 2. Although the above-referenced statements could be reasonably construed as suggesting that Visbiome is “the same” as VSL#3, the November 2015 Order, which refers to “the following language,” is fairly read to enjoin only the use of the specific term “the same,” so the statements do not violate that particular Order.

has made no finding to that effect, nor has the Court found that there is a provision in any of the parties' agreements that bars the VSL Parties from selling any remaining Danisco-produced inventory they have. Likewise, the claim that VSL has abandoned its trademark because the VSL#3 product sold in the United States now uses a different formulation, based on the allegation that a similar product sold in Europe has a different formulation, is not supported by any evidence in the record before this Court. Instead, the record in this case establishes that the VSL Parties stockpiled the Danisco-produced VSL#3, and that they therefore were continuing to sell the same formulation into March 2016. There is no evidence that the product sold in Europe has been introduced to the United States market. The De Simone Parties' arguments that the VSL Parties have not been harmed are thus unavailing.

The Court therefore finds ExeGi to be in contempt of this Court's prior Orders with respect to the failure to use the Disclaimer in the Google AdWords ads and the references to exclusivity in the "Message from the Inventor" and the "History of the De Simone Formulation & Visbiome" pages of the Visbiome website as those pages appeared in February 2016.

## **II. False Advertising**

The First Preliminary Injunction Motions, granted by the Court, were based on alleged trademark violations under the Lanham Act, 15 U.S.C. § 1114(1)(a) (2012). Having amended their counterclaims to assert claims of false advertising under the Lanham Act, 15 U.S.C. § 1125(a)(1)(B),<sup>8</sup> the VSL Parties now seek a preliminary injunction barring the De Simone Parties

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<sup>8</sup> In their Motions and the Second Amended Counterclaim, the VSL Parties do not identify whether they are asserting a claim under 15 U.S.C. § 1125(a)(1)(A) or § 1125(a)(1)(B). Because they identify the elements of false advertising with reference to case law relating to a claim under § 1125(a)(1)(B), *see Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 272 (4th Cir. 2002), the Court analyzes the false advertising claim as one arising under that provision.

from engaging in false advertising. As examples of such false advertising already perpetrated, the VSL Parties point to ExeGi's use of promotional material stating that ExeGi is the "exclusive" supplier of the "DeSimone Formulation" and statements by ExeGi sales representatives that VSL#3 has been discontinued.

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) (citing *Blackwelder Furniture Co. of Statesville v. Seilig Manufacturing Co.*, 550 F.2d 189, 196 (4th Cir. 1977)). 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. In the context of a preliminary injunction, the moving parties need not actually establish all of these elements, but they must "clearly demonstrate" that they "will *likely succeed* on the merits," rather than present a mere "grave or serious question for litigation." *Real Truth*, 575 F.3d at 346-347 (emphasis in original).

**A. 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 their claims of false advertising, 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 Visbiome or 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. *Id.* at 273 (internal quotation marks and 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.*

### **1. Visbiome Website Statements**

Although ExeGi has voluntarily altered portions of the Visbiome website, the Court must still analyze whether any of the prior content on the Visbiome website entered into evidence likely constituted false advertising. *See Knox v. Service Employees Intern. Union, Local 1000*, 132 S. Ct. 2277, 2287 (2012) (“The voluntary cessation of challenged conduct does not ordinarily render a case moot because a dismissal for mootness would permit a resumption of the challenged conduct as soon as the case is dismissed.”). As an initial matter, there is no dispute

that the statements on the website were made in interstate commerce. The fourth element of false advertising is therefore satisfied.

The VSL Parties have identified a statement on the February 2016 version of the Visbiome website that appears to be false or misleading, was likely to influence purchasing decisions, and had a tendency to deceive a substantial segment of the site's audience. In the "Message From the Inventor," appearing on the Visbiome website as of February 10, 2016, De Simone stated:

Recently, I made the decision to end my long-term partnership with VSL Pharmaceuticals, Inc., the company for which I collaborated for many years to produce and market the De Simone Formulation under the trademark, "VSL#3®," a trademark owned by VSL Pharmaceuticals, Inc.

I am pleased to announce that my formulation is now exclusively available from ExeGi Pharma under the trademarks Visbiome™ and Visbiome™ Extra Strength.

Feb. 10, 2016 Screenshot of "Message From Inventor" at 1.

As to actual falsity, the statement "my formulation is now exclusively available from ExeGi Pharma" as Visbiome is likely to be literally false. It is uncontested that VSL continued to purchase supply of VSL#3 from Danisco until January 31, 2016, when VSL's Know-How Agreement with De Simone expired, and that the Danisco supply is, adopting ExeGi's nomenclature, the "De Simone Formulation." The record also strongly indicates that VSL purchased as much of the Danisco product as it could, and that the De Simone Parties were well aware that VSL was stockpiling Danisco supply. *See* Nov. 30, 2015 Order, ECF No. 118 (determining, in response to the De Simone Parties assertions to the contrary, that the September Preliminary Injunction did not limit the VSL Parties to obtaining only enough supply of VSL#3 from Danisco to continue to sell it until January 31, 2016 and "d[id] not otherwise place any limits on the volume to be obtained"). The VSL Parties have submitted an affidavit from VSL

Vice President James Brady stating that as of March 4, 2016, “The product sold on the market today as VSL#3® was manufactured by Danisco USA, Inc.” Hr’g Ex. 107: Brady Decl. ¶ 7. Thus, for the Visbiome website to assert on February 10, 2016 that the “De Simone Formulation” was “exclusively available” through ExeGi as Visbiome was simply untrue.

As to the second element, a material misrepresentation, defined as a statement likely to affect a purchasing decision, the website’s claim that the De Simone Formulation was “exclusively available” from ExeGi is a material misrepresentation because it suggests, as discussed above, that VSL#3 is no longer on the market. *See supra* part I.D. Coupled with the website’s claim that Visbiome has the same formulation as VSL#3, this claim would likely influence a consumer, even one who had previously used VSL#3, to choose Visbiome over the apparently discontinued VSL#3 and thus was likely “to influence a consumer’s purchasing decision.” *Scotts Co.*, 315 F.3d at 272. On the third element, that the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience, “when the statements of fact at issue are shown to be literally false, ... the court will assume that the statements actually misled consumers.” *Pizza Hut, Inc. v. Papa John’s Intern., Inc.*, 227 F.3d 489, 497 (5th Cir. 2000). This assumption is wholly warranted on these facts considering that the “exclusively available” language was accompanied by an explanation for VSL#3’s implicit demise: that De Simone, the inventor of the formulation, had left VSL and is now working only with ExeGi to produce the same product.

The exclusivity statement, which effectively conveyed the message that VSL#3 is no longer available, but that Visbiome has the exact same formula and is available, undoubtedly sought to convince prior VSL#3 customers to switch to Visbiome, such that VSL#3 was likely to lose at least some sales as a result. *Cf. F.T.C. v. Colgate-Palmolive, Co.*, 380 U.S. 374, 389



(1965) (noting, in the context of reviewing a Federal Trade Commission order regarding alleged false and deceptive advertising, that when a “misrepresentation has been used to break the habit” of consumers, “a misrepresentation for such an end is not permitted”). Indeed, as described above, when similar statements were made by Debora Hudak, an ExeGi sales representative, to staff at Southland Gastroenterology, that office accepted Visbiome samples and declined to accept any more VSL#3 samples. *See supra* part I.E. Considering that internet sales are one of ExeGi’s two primary distribution streams for Visbiome, the potential for lost VSL#3 sales should not be underestimated. The last element of false advertising—likely injury through diversion of sales or lessening of goodwill—is thus also likely satisfied.

The VSL Parties are therefore likely to succeed on their claim that the statement on the February 10, 2016 “Message From the Inventor” page, that the De Simone Formulation was now “exclusively available” from ExeGi as Visbiome, constitutes false advertising.

The VSL Parties have also alleged false advertising arising from an email sent from JPA Health Communications to media outlets on January 28, 2016 stating that “[t]he probiotic formulation that’s recommended in multiple clinical practice guidelines . . . will be available under a new name,” which was then identified as Visbiome. VSL Mem. Supp. Second Mot. Prelim. Inj. at 11. Although this statement likely was not literally false, the VSL Parties argue that it was a “misleading description of fact,” *Scotts Co.*, 315 F.3d at 264, that may have had the tendency to deceive consumers into believing that VSL#3 had changed its name to Visbiome and was no longer separately available. Because the VSL Parties have not submitted the actual email communication and did not offer evidence to establish that ExeGi was responsible for such a communication, the Court does not address whether this statement would provide further support for a preliminary injunction against false advertising.

## 2. Sales Representative Statements

The VSL Parties also seek a preliminary injunction based on statements allegedly made by two ExeGi sales representatives to staff at three doctors' offices. As discussed above, the Court finds that, at a minimum, ExeGi representatives made statements that falsely suggested that VSL#3 was no longer on the market or had changed its name, including:

“Visbiome contains the De Simone Formulation, which was originally sold by VSL Pharmaceuticals, Inc. under a different trade name, and will now be sold as Visbiome.” Cheat Sheet.

“As far as I know, VSL Pharma still has inventory of the formulation, but after February 1st of this year, the formulation is being produced by ExeGi Pharma under the name Visbiome.” Hudak Decl. ¶ 6.

These statements are both likely to be misleading and likely to influence a purchasing decision. The evidence that personnel at doctors' offices initially concluded that VSL#3 had been discontinued or had changed its name, and that one doctor—the number one prescriber of VSL#3 in the world—considered the script to be susceptible to that conclusion, indicates that such statements had the tendency to deceive. *See supra* part I.E; *Scotts Co.*, 315 F.3d at 273 (stating that misleading statements can establish false advertising if there is extrinsic evidence that the statements “tend to mislead or confuse consumers”). Southland Gastroenterology's decision, after speaking with Hudak, to accept Visbiome samples and reject VSL#3 samples on its initial understanding that those two products were the same, illustrates how the VSL Parties were likely to be injured as a result of these alleged misrepresentations. *See Scotts Co.*, 315 F.3d at 273.

The evidence to date, however, is not sufficient to establish a likelihood that the VSL Parties can successfully claim that the sales representatives' statements met the requirement that the false or misleading representations occurred “in commercial advertising or promotion.” 15 U.S.C. § 1125(a)(1)(B). What constitutes “commercial advertising or promotion,” as well as the

differences between those two terms, is nowhere elucidated in the statute or in the legislative history. See *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48, 56 n.1 (2d Cir. (stating that the “legislative history is equally unavailing” in providing a definition of “commercial advertising or promotion”). The United States Court of Appeals for the Fourth Circuit has yet to offer any interpretation of these statutory terms. The United States Court of Appeals for the Seventh Circuit has offered a narrow reading, holding that for purposes of a false advertising claim, “[a]dvertising is a form of promotion to anonymous recipients, as distinguished from face-to-face communication.” *First Health Group Corp. v. BCE Emergis Corp.*, 269 F.3d 800, 803 (7th Cir. 2001). Under this standard, the ExeGi sales representatives’ statements would not amount to commercial advertising or promotion.

The United States Court of Appeals for the Second Circuit, however, has expressly rejected the Seventh Circuit’s interpretation, noting that it collapsed the disjunctive statutory language “commercial advertising or promotion” into only commercial advertising. *Fashion Boutique*, 314 F.3d at 57. The Second Circuit concluded that the rules of statutory construction require that “promotion” be accorded its own meaning. *Id.* As for what that meaning is, the Court stated that “‘promotion’ may take other forms of publicity used in the relevant industry, such as displays at trade shows and sales presentations to buyers.” *Id.* Promotion includes statements for which there is “widespread dissemination within the relevant market,” rather than just “isolated disparaging statements.” *Id.* The “touchstone” of whether actions constitute “commercial advertising or promotion” is that “the contested representations are part of an organized campaign to penetrate the relevant market.” *Id.* at 58.

Thus, the Second Circuit, adopting parts of a test established in *Gordon & Breach Science Publishers, S.A. v. American Institute of Physics*, 859 F. Supp. 1521, 1535-36 (S.D.N.Y.

1994), held that statements qualify as “commercial advertising or promotion” for purposes of a claim for false advertising if they (1) constitute commercial speech; (2) for the purpose of influencing consumers to buy defendant’s goods or services; and (3) are disseminated sufficiently to the relevant purchasing public to constitute “advertising” or “promotion” within that industry. *Fashion Boutique*, 314 F.3d at 56, 58 (adopting three of the four elements of the *Gordon* test). This Court finds the thorough analysis and reasoning in *Fashion Boutique* to be persuasive and applies the Second Circuit’s approach.

Although the first two elements are plainly satisfied, the evidence presented to date, consisting of three incidents where statements by ExeGi sales representatives led medical office personnel to conclude that VSL#3 had been discontinued or changed its name to Visbiome, is likely insufficient to meet the third element. “The level of circulation [of a statement] required to constitute advertising and promotion will undeniably vary from industry to industry and from case to case.” *American Needle & Novelty, Inc. v. Drew Pearson Mktg., Inc.* 820 F. Supp. 1072, 1078 (N.D. Ill. 1993). If there is a nationwide marketplace, an “isolated” misrepresentation directed at one potential customer will not constitute “commercial advertising or promotion.” *Garland Co., Inc. v. Ecology Roof Systems, Corp.*, 895 F. Supp. 274, 279 (D. Kan. 1995).

Here, the evidence establishes that since the February 2016 launch of Visbiome, ExeGi sales representatives have made sales calls at about 1,000 doctors’ offices. In that context, the three alleged instances of false statements presented to date likely do not constitute the “widespread dissemination” in the marketplace necessary to satisfy the “commercial advertisement or promotion” requirement of the statute. *Fashion Boutique*, 314 F.3d at 57 (holding that oral statements by personnel at a Fendi store allegedly disparaging a competitor store did not constitute “commercial advertising or promotion”). Although the ExeGi

PowerPoint and cheat sheet for sales representatives indicate that there was an “organized campaign” to market Visbiome using the contents of those materials, and at least one statement in the cheat sheet could reasonably be construed as misleading, the VSL Parties have not presented sufficient evidence to date to establish that the actual statements delivered orally to doctors’ offices constituted “widespread dissemination” of false or misleading statements to qualify as “commercial advertising or promotion” within the meaning of the statute.<sup>9</sup>

Because VSL and Sigma-Tau have not demonstrated to date that they are likely to succeed on the merits of their claim that statements by ExeGi sales representatives constitute false advertising, the Court addresses the remaining *Winter* factors only as they relate to the false advertising claim stemming from the statements on the Visbiome website.

#### **B. Likelihood of Irreparable Harm**

To establish irreparable harm, plaintiffs must show that they are “likely to be irreparably harmed,” not just that they face a mere possibility of harm. *United States v. South Carolina*, 720 F.3d 518, 533 (4th Cir. 2013). The “irreparable harm” to be suffered must be “neither remote nor speculative, but actual and imminent.” *Direx Israel, Ltd. v. Breakthrough Med. Corp.*, 952 F.2d 802, 812 (4th Cir. 1991) (quoting *Tucker Anthony Realty Corp. v. Schlesinger*, 888 F.2d

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<sup>9</sup> The VSL Parties also assert that based on the reference to an “organized campaign” in *Fashion Boutique*, the Court should consider the statements by ExeGi sales representatives in conjunction with allegedly false statements made on the Visbiome website and in other promotional materials to conclude that they collectively meet the requirement of “widespread dissemination.” 314 F.3d at 57. In *Fashion Boutique*, the Court found that different disparaging face-to-face statements could be construed together for purposes of this analysis, but it did not hold that face-to-face statements could be combined with distinct forms of commercial advertising, such as websites or press releases, to satisfy this requirement. *Id.* at 57-58. The VSL Parties cite no other authority in support of this approach, and the Court declines to adopt such a rule here.

969, 975 (2d Cir. 1989)). Here, because the literally false statement on the website is comparative advertising, stating that De Simone had left VSL and that ExeGi was now the exclusive supplier of the formulation, irreparable harm is presumed. 4 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* § 27:37 (4th ed. 2015) (“Where the challenged advertising makes a misleading comparison to a competitor’s product, irreparable harm is presumed.”); *see also Scotts*, 315 F.3d at 273 (noting that the case law indicates that irreparable harm is either presumed in false advertising cases generally, or at least in cases involving false comparative advertising). As discussed above, the De Simone Parties’ arguments that such statements have not caused harm are unpersuasive. *See supra* part I.F. Thus, the VSL Parties have satisfied the requirement of likely irreparable harm.

### **C. The Balancing of Equities and the Public Interest**

Finally, the equities and the public interest weigh in the VSL Parties’ favor on their false advertising claim related to the Visbiome website. The “exclusively available” language on the website was likely to mislead consumers into concluding that VSL#3 is no longer on the market, or that Visbiome is VSL#3 under a new name. To allow ExeGi to lure away its main rival’s customers through that misrepresentation would be unfair, particularly considering that ExeGi was making this misrepresentation at a time—a mere 10 days after the expiration of the Know-How Agreement—when VSL#3 was still selling the same Danisco-manufactured product that it had been marketing since its inception. Moreover, it has been abundantly clear since the onset of this litigation that the De Simone Parties’ goal is to supplant VSL#3 in the marketplace, and the identified misrepresentation must be viewed in the context of the numerous other means by which the De Simone Parties’ have aggressively pursued that goal, including the Google AdWords ads and the suggestions by the sales representatives that VSL#3 is off the market,

efforts that have violated either the substance or the spirit of this Court's Orders. Under these circumstances, the equities weigh in favor of an injunction to reign in such activities that violate the law. Lastly, the public interest also weighs in favor of the VSL Parties because "there is a strong public interest in the prevention of misleading advertisements," *Scotts*, 315 F.3d at 286, and there is no countervailing interest in favor of allowing the De Simone Parties to continue prematurely to insinuate the demise of VSL#3.

Because all four requirements for a preliminary injunction have been established, the Court will grant the Motion as to a preliminary injunction against false advertising.

### **III. Expansion of the Injunction on Trademark Infringement**

In its September 23, 2015 Memorandum Opinion, this Court granted the First Preliminary Injunction Motions as to the trademark infringement claim based on its initial finding that the VSL Parties were likely to succeed on a claim that terminology used by the De Simone Parties in their Visbiome marketing materials, including "Original Formula VSL#3 Probiotic Blend" and "Visbiome/VSL#3 blend," infringed the VSL#3 trademark. The VSL Parties now seek an expansion of the injunction based on the De Simone Parties' use of the mark VSL#3 on the Visbiome website, in Google AdWords ads, and in sales calls, some of which the Court has concluded violated its prior orders. *See supra* part I.C. The Court agrees that some expansion of the injunction is warranted in order to maintain the status quo during the pendency of this litigation.

The touchstone of any analysis of trademark infringement is whether the unauthorized use of another's trademark is "likely to cause confusion." 15 U.S.C. § 1114(1)(a). The evidence presented has amply established that the De Simone Parties' activities in all three areas continue to be likely to cause confusion over whether Visbiome and VSL#3 are the same product.

### A. The Visbiome Website

Although the use of VSL#3 on the Visbiome website does not technically violate the Court's prior orders, *see supra* part I.B, it goes well beyond what the Court deemed in the November 2015 to constitute "fair use." Rather than use the approved Same Strains Language and De Simone History Language once, as contemplated by the Court's safe harbor provision, the De Simone Parties interpreted that provision in an unreasonable and self-serving manner, using that language on the website at least eight and 11 times, respectively. They use the term VSL#3 over 100 times, the vast majority of which appear outside of the required Disclaimers, both in the main body of the website text and in the clinical study names, making VSL#3 the second most frequently used term on the website, ahead of ExeGi. This interweaving of the VSL#3 mark into the website so extensively, and the repetitive use of it throughout, likely goes beyond appropriate fair use, *see* 15 U.S.C. § 1115(b)(4), and appears more like an effort to blur the distinctions between these two products. *Dayton Progress Corp. v. Lane Punch Corp.*, 917 F.2d 836, 840 (4th Cir. 1990) (describing the "fair use" defense as applying if the mark is used "fairly and in good faith" only to describe the product and not as a trademark); *Selchow & Righter Co v. Decipher, Inc.*, 598 F. Supp. 1489, 1501 (E.D. Va. 1984) (finding that the defendant infringed the plaintiff's "Trivial Pursuit" trademark in part because of the defendant's "prominent" and "constant usage" of the mark and terms associated with it on its product packaging); *see* 2 J. Thomas McCarthy, *Trademarks and Unfair Competition* § 11:48.50 (4th ed. 2015) ("Overuse of another's trademark, even in a descriptive sense, may not be a fair use because such repetition builds up a likelihood of confusion of connection or sponsorship.").

This conclusion is bolstered by the fact that the Disclaimer frequently appears only in a footnote at the very bottom of the page, referenced in the text by an extremely small footnote



marker, barely within “close proximity” to the VSL#3 mark. Although the Court does not find evidence to establish that the De Simone Parties used the Disclaimer to engage in “keyword stuffing,” it is clear that the De Simone Parties sought to distance the Disclaimer as much as possible from the VSL#3 mark without running afoul of the Court’s prior orders. Notably, on the References page, 14 clinical studies with “VSL#3” in the title are listed, without any footnote reference marker directing the reader to the Disclaimer. Although the Court had previously declined to bar entirely references to the clinical trials, it did so, as the De Simone Parties acknowledge in their brief, “so long as the VSL#3 trademark was not used in such references,” Resp. Opp’n at 12, and the Court explicitly prohibited the use of the added parenthetical “Reported as VSL#3” in connection with clinical studies. *See* Nov. 2015 Order at 2. But the combination of the repeated claim throughout the website that the De Simone Formulation has been the subject of over 60 clinical trials and this listing of numerous clinical studies with VSL#3 in the title without a cross-reference to the Disclaimer creates significant confusion whether VSL#3 and Visbiome are the same product. Even 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.

Finally, the false or misleading statements on prior versions of the Visbiome website, asserting that the formulation used in VSL#3 was now “exclusively available” as Visbiome, *see supra* part I.D, created additional confusion whether VSL#3 had simply been renamed as Visbiome. Although ExeGi has since removed this language, its appearance on the Visbiome site even after the November 2015 and February 2016 Orders is a telling indicator of ExeGi’s market posture. ExeGi’s invocation of VSL#3 on the Visbiome website is not incidental; it is a

key way that it has come to define what Visbiome itself is. The Court therefore can draw no other conclusion than that ExeGi has and continues to use the VSL#3 mark on the Visbiome website in a way that creates confusion and thereby enables Visbiome to impermissibly “profit from another’s reputation.” *Pizzeria Uno Corp. v. Temple*, 747 F.2d 1522, 1535 (4th Cir. 1984).

## **B. Google AdWords**

As discussed above, ExeGi’s Google AdWords advertisements containing “VSL#3” violated this Court’s February 2016 Order, which arose from the Court’s original grant of a preliminary injunction relating to trademark infringement. *See supra* part I.C. The VSL Parties do not argue, and the Court does not conclude, that the mere use of VSL#3 as a keyword would constitute trademark infringement. *See Network Automation, Inc. v. Advanced Sys. Concepts, Inc.*, 638 F.3d 1137, 1153 (9th Cir. 2011) (stating that “[i]n the keyword advertising context, the likelihood of confusion will ultimately turn on what the consumer saw on the screen and reasonably believed, given the context”); *1-800 Contacts, Inc. v. Lens.com, Inc.*, 722 F.3d 1229, 1242-43 (10th Cir. 2013) (endorsing the district court’s determination that “because Google users view only the results of their searches and cannot tell exactly which keywords an advertiser has purchased,” the use of a competitor’s trademark as a keyword does not, by itself, amount to trademark infringement). Nor is there sufficient evidence to find that the De Simone Parties engaged in “keyword stuffing,” as the VSL Parties have offered only search results showing Visbiome appearing as part of one of ExeGi’s Google AdWords ads, not as a result of organic search results.<sup>10</sup> But the use of VSL#3 in those advertisements blatantly violated the Court’s

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<sup>10</sup> The efficacy of techniques like keyword stuffing to improve search results is unclear. In *Network Automation, Inc. v. Advanced Systems Concepts, Inc.*, 638 F.3d 1137 (9th Cir. 2011), for example, the United States Court of Appeals for the Ninth Circuit noted that “[m]odern

order and added to the confusion between VSL#3 and Visbiome. This is particularly true considering that a number of Visbiome ads appeared with only the word “VSL#3” as the headline, even if such advertisement text was not intended, and the stark use of that mark was accompanied by a link to the Visbiome website, a juxtaposition that in and of itself creates confusion. *See supra* part I.C. The Court thus finds that the Google Ads have exacerbated the confusion in the marketplace between Visbiome and VSL#3.

### **C. Sales Representative Statements**

As discussed above, based on statements by ExeGi sales representatives, three personnel from medical offices were led to believe that VSL#3 had been discontinued or had changed its name. *See supra* part I.E. Particularly where, in the case of Southland Gastroenterology, Hudak’s statements led a staff member to believe that VSL#3 had changed its name to Visbiome, the confusion implicates not just false advertising concerns, but also trademark infringement concerns, because the staff member appears to have believed that Visbiome was the same product, made by the same company, as VSL#3.

Based on all of these activities by the De Simone Parties that have sowed additional confusion relating to the VSL#3 mark, the Court agrees with the VSL Parties that some modification of the preliminary injunction relating to trademark infringement is necessary to maintain the status quo pending trial.

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search engines such as Google no longer use metatags. Instead they rely on their own algorithms to find websites.” *Id.* at 1146 n.3.

#### **IV. Remedies**

##### **A. Preliminary Injunction on Trademark Infringement**

The VSL Parties ask this Court to invoke the “safe distance rule” to bar the De Simone Parties from any use of the VSL#3 trademark. The safe distance rule is an equitable doctrine imported into the intellectual property context that allows courts, when “faced with recalcitrant parties who repeatedly violate the law, to craft permanent injunctions which proscribe activities that, standing alone, would have been unassailable.” *Innovation Ventures, LLC v. N2G Distributing, Inc.*, 763 F.3d 524, 544 (6th Cir. 2014). Under this rule, courts may require a business to “keep a safe distance away from the margin line—even if that requirement involves a handicap as compared with those who have not disqualified themselves.” *John Allan Co. v. Craig Allen Co., LLC*, 540 F.3d 1133, 1142 (10th Cir. 2008) (quoting *Taubman Co. v. Webfeats*, 319 F.3d 770, 779 (6th Cir. 2003)). The safe distance rule thus “prevent[s] known infringers from using trademarks whose use by non-infringers would not necessarily be actionable.” *Innovation Ventures*, 763 F.3d at 544. The Fourth Circuit has yet to expressly adopt the safe distance rule, but has suggested that the reasoning behind it is “persuasive[.]” *Osem Food Indust. Ltd. v. Sherwood Foods, Inc.*, 917 F.2d 161, 164 n.4 (4th Cir. 1990).

The safe distance rule is generally invoked in situations where a party has already been found to have violated a trademark or otherwise engaged in unfair competition. See *Innovation Ventures*, 763 F.3d at 544; *John Allan Co.*, 540 F.3d at 1142 (10th Cir. 2008) (describing the safe distance rule as applying to “a competitive business, once convicted of unfair competition in a given particular”); *Eskay Drugs, Inc. v. Smith, Kline & French Labs.*, 188 F.2d 430, 432 (5th Cir. 1951) (“In such a case as this, where the appellants have been found guilty of infringing the trade-mark rights of others, they should thereafter be required to keep a safe distance away from

the dividing line between violation of, and compliance with, the [permanent] injunction”). These cases suggest that the safe distance rule may be applicable only after there has been a determination on the merits that infringement has occurred.

Even if the safe distance rule could be applied based on violation of terms of a preliminary injunction, an issue this Court does not decide, the Court declines to bar the De Simone Parties entirely from using the VSL#3 mark because the circumstances do not yet warrant such a drastic remedy. Nevertheless, expansion of the injunction is required because, as the record on these Motions reveals, the De Simone Parties have demonstrated that, even though a party subject to a preliminary injunction has a “duty to keep a safe distance from the line drawn by the district court’s injunction,” *Oral-B Labs.*, 810 F.2d at 24, they will adopt aggressive and in some instances unreasonable interpretations of this Court’s rulings and go as close as possible to any line drawn by this Court. Because in doing so, the De Simone Parties have either actually gone over the line or have gotten so close to it as to engage in conduct that is likely to infringe, the Court determines that it must redraw the lines it has previously established to maintain the status quo during the pendency of the case. Specifically:

1. The De Simone Parties will be permitted to use the Same Strains Language and the De Simone History Language **only once** on the entire Visbiome website, and the required Disclaimer must be included in the immediately adjacent text, not in a footnote. The images of the three package inserts, which contain such language and currently appear on the website, do not count toward this limitation. Any other phrases using VSL#3 must be approved by the Court and may appear only once on the website, again with the Disclaimer in the immediately adjacent text.
2. The website cannot make any claim that any clinical study using “VSL#3” in the study title constituted a study relating to the “De Simone Formulation” and may not list such studies on the website or the package inserts.
3. The Disclaimer footer must be removed from any page of the website that does not use the trademark “VSL#3.”

4. The De Simone Parties may not use static or dynamic Google AdWords ads containing the term “VSL#3” to advertise Visbiome unless they develop and include text, to be pre-approved by the Court, which contains the substance of the Disclaimer in a form that fits within the Google AdWords character limitations.
5. The DeSimone Parties will deliver to each medical office on its sales list a letter, with language pre-approved by the Court, stating that VSL#3 has not been discontinued or scheduled to be discontinued, that VSL#3 did not change its name to Visbiome, and that Visbiome is a competing probiotic produced by a different company. The letter will not address the status of licensing agreements or rights to produce a probiotic using the same formulation as VSL#3 prior to January 31, 2016.<sup>11</sup>

As part of the February 2016 Order, this Court also required that all promotional and marketing materials be reviewed by ExeGi’s counsel for compliance with the Court’s Orders. Although the attorneys have presumably acted in good faith in seeking to avoid any violations of the Orders, it is clear from the briefs, particularly from the repeated, incorrect, and self-serving attributions of the Court’s intent to explain away ExeGi’s questionable conduct, that leaving this issue in the hands of attorneys does not lend itself to the kind of even-handed approach necessary to avoid both violations of court orders and the incessant litigation that has continued on this matter and delayed consideration of the merits of this case. The Court will therefore also order that during the pendency of this case, all Visbiome promotional and marketing materials, including the website, package inserts, sales scripts, and any other materials to be provided to or used in discussions with potential customers or medical offices will be submitted, first, to VSL’s and Sigma-Tau’s counsel, who will have seven days to review and comment; and, second, if any disputes remain after the De Simone Parties make any revisions to address concerns expressed by the VSL Parties, to the Court for pre-approval before use, with any remaining objections from

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<sup>11</sup> This provision also serves to effectuate the preliminary injunction against false advertising.

the VSL Parties identified. This creates a sizable burden for the Court, but this option appears to be the only way to enforce the preliminary injunction short of the proposed ban on all use of the VSL#3 mark.

### **B. Preliminary Injunction on False Advertising**

Having found that a preliminary injunction against false advertising is warranted, the Court will enjoin the De Simone Parties, during the pendency of this case, from falsely advertising or otherwise misleading customers and medical professionals into believing that (1) VSL#3 is or will in the future no longer be on the market; (2) that the De Simone Parties are the exclusive provider of the De Simone Formulation or the probiotic formulation in VSL#3; (3) that VSL#3's license to sell this formulation has or will expire; (4) that VSL#3 has a new name or that Visbiome is a rebranded version of VSL#3. The injunction applies to communications of any kind, including but not limited to statements made on the Visbiome website, in any press releases, online advertisements, or other promotional materials, in sales representative scripts, and in any oral or written statements made by sales representatives to doctors' offices or any potential customers. The pre-approval process described above will also serve to enforce this preliminary injunction.

### **C. Contempt**

The Court has found ExeGi in contempt of the February 2016 Order for failing to include in its Google AdWords ads that use the term "VSL#3" the disclaimer required by that Order and for the statements on the Visbiome website in February 2016 that (1) the De Simone Formulation is "exclusively available" from ExeGi and (2) as of February 1, 2016 ExeGi was the "exclusive manufacturer of the De Simone Formulation, in both the U.S. and Canada." The website statements have since been removed, and ExeGi is therefore ordered not to reinsert that language

into the website. As for Google AdWords, ExeGi is ordered to disable immediately all static or dynamic Google AdWords ads that contain the term “VSL#3” or any variation on it within the ad text itself or for which such a term has been designated as a keyword to be inserted into the ad. ExeGi will be fined \$1,000 per day for every day after the date of this Order that Google AdWords ads containing the trademark “VSL#3” or any variation on it continue to appear in search results. *See Cromer v. Kraft Foods, N.A., Inc.*, 390 F.3d 812, 821-22 (4th Cir. 2004) (sanctions can be imposed on a finding of civil contempt if those sanctions are “remedial and intended to coerce the contemnor into compliance with court orders”) (internal quotation marks and citation omitted). In addition, the Court will schedule a Case Management Conference to discuss the appropriate means by which to determine how “to compensate the complainant for losses sustained as a result of the contumacy.” *Id.* at 821.

#### **D. Bond**

The VSL Parties lastly ask this Court to order ExeGi to post a bond “that shall be forfeited in the event that the De Simone Team violates this Court’s orders again.” VSL Mem. Supp. Second Mot. Prelim. Inj. at 40. The VSL Parties cite no authority for the proposition that the party being enjoined should be required to post a bond as insurance against its possible non-compliance with the injunction. The Federal Rules of Civil Procedure instead require a bond be posted by the *prevailing* party, “for the payment of such costs and damages as may be incurred or suffered by any party who is found to have been wrongfully enjoined or restrained.” Fed. R. Civ. P. 65(c). “This rule is mandatory and unambiguous.” *Hoechst Diafoil Co. v. Nan Ya Plastics Corp.*, 174 F.3d 411, 421 (4th Cir. 1999). The Court thus declines to order the De Simone Parties to post a bond, but will require the VSL Parties to post an additional bond in the amount of \$50,000 for the injunction as to the false advertising claims, to be added to the




\$250,000 already posted as to the trademark claims. The injunction as to the false advertising claims will go into effect only once that bond is posted.

**CONCLUSION**

For the foregoing reasons, VSL's Second Motion for a Preliminary Injunction, ECF No. 144, and Sigma-Tau's Second Motion for a Preliminary Injunction, ECF No. 145, are GRANTED IN PART and DENIED IN PART. A separate Order shall issue.

Date: June 20, 2016

  
THEODORE D. CHUANG  
United States District Judge