

**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**

At issue in this case is the ownership and use of various intellectual property related to the probiotic VSL#3. That product was originally brought to the United States market through the collaboration of Plaintiff Claudio De Simone (“De Simone”), who patented the formulation, VSL Pharmaceuticals, Inc. (“VSL”), which sold the probiotic, and Sigma-Tau Pharmaceuticals, Inc. (“Sigma-Tau”), which marketed it. In 2014, after serving for over a decade as VSL’s Chief Executive Officer (“CEO”), De Simone stepped down. The parting was not amicable. De Simone believes that his business partners were trying to misappropriate trade secrets related to VSL#3, secrets he then took to ExeGi Pharma, LLC (“ExeGi”) with the aim of launching a

competing, generic version of VSL#3. VSL and Sigma-Tau, for their part, believe that the trade secrets are, in fact, their property, and that it is De Simone who is misappropriating trade secrets.

In 2015, De Simone instructed the lone U.S. manufacturer of VSL#3 to stop supplying VSL with the product. De Simone also filed suit in this Court seeking, among other things, a declaratory judgment that he owns the VSL#3 trade secrets. VSL and Sigma-Tau filed counterclaims and, with the prospect of losing their supply of VSL#3, also each filed a Motion for a Preliminary Injunction. ECF Nos. 55 and 61. On September 1, 2015, the Court heard oral argument on the Motions. For the reasons outlined below, the Motions for a Preliminary Injunction are GRANTED IN PART and DENIED IN PART.

### **BACKGROUND**

In 1998, Plaintiff Claudio De Simone, a Professor of Gastroenterology and Immunology who has done extensive research in the field of probiotics, and two fellow researchers were granted United States Patent number 5,716,615 (the “615 Patent”) for “Dietary and Pharmaceutical Compositions Containing Lyophilized Lactic Bacteria, Their Preparation and Use,” with that patent expiring on February 9, 2015. The 615 Patent was one of a number of patents De Simone secured based on his probiotic research. The 615 Patent consisted of a pharmaceutical combination of eight strains of pure lactic acid bacteria that can be used as treatment for a number of medical conditions, including various gastrointestinal disorders and hypercholesteremia, and was the basis for the probiotic now sold as VSL#3. To produce the specific VSL#3 product under the 615 Patent, De Simone also developed certain “know-how,” a type of trade secret which in this instance consists of a unique biochemical profile, formulae, processes, data, and other technical and non-technical information necessary to make, develop, and use VSL#3 (the “Know-How”).

## I. Establishment of VSL

In 1999, De Simone began discussing the possibility of developing his various patents for market with Claudio and Paolo Cavazza, owners of the Sigma-Tau Group, a large Italian pharmaceutical conglomerate. De Simone and the Cavazzas first agreed on a plan to try to bring the 615 Patent to the U.S. market as a pharmaceutical drug. On November 30, 1999, De Simone and Sigma-Tau entered into an agreement (the “1999 Option Agreement”) specifying that De Simone “co-owns the Patent and fully owns the Know-How” related to that patent, and that he was granting to Sigma-Tau “an exclusive option for an exclusive license related to his right on the Patent and on the Know-How” for the purpose of commercializing the 615 Patent in the United States as a drug. Resp. Opp’n Mot. Prelim. Inj. Ex. 1 ¶¶ A & B, 2.1, Appendix A (specifying the patent as U.S. Patent No. 5716615), ECF No. 76-7.<sup>1</sup> The “Know-How” consisted of “scientific, technical, and commercial information” available to De Simone that relates to the “promotion, manufacturing, and commercialization” of products deriving from the 615 Patent. *Id.* ¶ 1.4. De Simone specifically agreed “not to grant any other option, license and/or other rights on the Patent and the Know-How for the entire duration of this Agreement, neither directly nor through its Affiliates.” *Id.* ¶ 2.1. The 1999 Option Agreement was to last until December 31, 2001.

In July 2000, De Simone and the Cavazzas entered into another business arrangement, this one to pursue bringing products arising from various patents held by De Simone to the U.S. market not as drugs, but as nutritional supplements. To that end, on July 11, 2000, they incorporated VSL in Delaware. As a practical matter, De Simone, Claudio Cavazza, and Paolo Cavazza each owned one-third of the company. However, those ownership interests were routed

---

<sup>1</sup> For ease of reference, all exhibits are numbered in accordance with their ECF filing number, not with the individual numbering systems of the parties.

through various holding companies. De Simone, Claudio Cavazza, and Paolo Cavazza arranged for three companies they individually owned—Mendes, SRL; Taufin International S.A.; and Sinaf S.A.; respectively—to establish collectively another company, CD International, of which each of the three companies owned one-third of the shares. CD International, in turn, established CD Investments, which was then granted 99.7 percent of VSL’s shares. De Simone, Claudio Cavazza, and Paolo Cavazza each individually owned 0.1 percent of the shares. De Simone was installed as the CEO of VSL and was also appointed to its Board of Directors. The other two Directors, Mauro Bove and Antonio Nicolai, were appointed by the Cavazzas, and both had previously served as officers and directors of companies in the Sigma-Tau Group. Under VSL’s by-laws, De Simone agreed that as long as he directly or indirectly owned 4.99 percent of the total voting stock of the company, he would transfer or offer to transfer to the company any intellectual property rights relating to “any inventions” made by him “since the incorporation of [VSL]” relating to “pharmaceutical nutritional compositions and active principles.” VSL Ans. & Countercl. Ex. 2 at 16-17, ECF No. 9-2.

Also on July 11, 2000, the parties executed a Collaboration Agreement (“2000 Collaboration Agreement”) that established a commitment to transfer various intellectual property from De Simone to VSL following the incorporation of VSL. De Simone personally committed to transfer his rights to various patents specified in Annexes B and C to the agreement, with Annex B cataloging patents of which De Simone was the exclusive owner and Annex C cataloging those of which he was a co-owner. De Simone also committed, on behalf of his company Mendes SRL, to transfer Mendes’s rights to the “patents, patent applications, and brands” detailed in Annex A. Notice of Corrected Exhibit Ex. 1 ¶ 2, ECF No. 94-1. The 615 Patent was not included in any of the annexes. Included in Annex A, the intellectual property

being transferred to VSL by Mendes, was the United States trademark “VSL#3,” which is listed as “Pending filing,” as well as the European trademark “VSL#3,” listed with a filing number. *Id.*, Annex A ¶ 9.

On September 18, 2000, the parties executed three additional agreements to carry out the commitments made in the Collaboration Agreement: (1) the De Simone–VSL Assignment, (2) the Mendes–VSL Assignment (“the Mendes Assignment”), and (3) the De Simone–VSL Option Agreement. The Assignments provided that the “Assignor”—De Simone or Mendes—had “sole and exclusive rights to the Transferred Property,” which in turn was specified as “Intellectual Property, Proprietary Products, and the Proprietary Information.” VSL Ans. & Countercl. Ex 4 at 4, ¶ 1.01, ECF No. 9-4. Those terms were then further defined. “Intellectual Property” was defined as “any intellectual property ... which relates to the subject matter set forth in Schedule I, including, without limitation, each and every (a) Patent or Patent Right; (b) trademark ... and the entire business or portion thereof to which the [trademark] pertain[s] as required by 15 U.S.C. § 1060; and (c) other form or nature of proprietary or exclusionary right.” *Id.* “Proprietary Information” was defined as “any trade secrets or confidential business information ... know-how, production processes and techniques ... described, comprised in or relating to the Intellectual Property or Proprietary Products and that is not in the public domain.” *Id.* “Proprietary Products” include “compounds, reagents, assays and other materials arising out of or relating to the Proprietary Information, the Intellectual Property or the subject matter of Schedule I.” *Id.* The agreements then provided that the Assignor “irrevocably assigns . . . all right, title and interest” in the “Intellectual Property (including, without limitation, with respect to the Trademarks, together with the entire business of the Assignor to which the Trademarks pertain) and the Proprietary Information ... and all future rights to any Intellectual Property or

Proprietary Information which is derived from or are based upon any of the Transferred Property.” *Id.* ¶ 2.01(2).

Consistent with the terms of the 2000 Collaboration Agreement, none of the Assignments includes the 615 Patent. However, Schedule I of the Mendes Assignment includes the trademark “VSL#3.” De Simone, through his corporation Mendes SRL, had filed a trademark application in the United States for the name “VSL#3” on June 19, 2000. The application was later granted on November 26, 2002. In VSL’s estimation, this reference to VSL#3 in the Mendes Assignment establishes that the Mendes Assignment transferred to VSL all intellectual property, including the Know-How associated with the 615 Patent, related to the product now known as VSL#3. In De Simone’s estimation, the Mendes Assignment transferred only the trademark VSL#3 and nothing else, as evidenced by the fact that the 615 Patent was expressly carved out of the various 2000 agreements.

In January 2001, De Simone and VSL signed a Patent License Agreement (“2001 Patent License Agreement”), the subject of which was the 615 Patent. The 2001 Patent License Agreement provided that De Simone “co-owns the Patent,” including “any other proprietary rights related to” the Patent, and that De Simone is “grant[ing] to VSL an exclusive license related to his co-ownership right on the Patent ... for the production and for the commercialization” in the United States of any product “marketed as dietary supplement or functional food” containing the bacteria described in the Patent. VSL Ans. & Countercl. Ex. 7 ¶¶ A, B, 1.5, 3.1, ECF No. 9-7. The license would “continue in effect until the expiry of the Patent.” *Id.* ¶ 5.1. De Simone also agreed that if he acquired full ownership rights to the 615 Patent, he would give VSL an option to acquire those rights.

In August 2001, VSL partnered with Rhodia, Inc., which would later become Danisco USA, Inc. (“Danisco”), to manufacture a product based on the 615 Patent. In December 2001, VSL then partnered with Questcor Pharmaceuticals, Inc. to market the product in the United States. In mid-2002, that product, branded as VSL#3, was first offered for sale in the United States. In 2003, VSL brought the marketing of VSL#3 in the United States back into the Cavazza family, replacing Questcor with Sigma-Tau, an American subsidiary of the Sigma-Tau Group. That relationship was formalized in a 2003 VSL–Sigma Tau License Agreement. That agreement acknowledged that “VSL has developed and has proprietary rights on the Product and the Trademark and has certain rights to exploit the Patent and the Know-How in the Territory,” and provided that VSL was sub-licensing its rights to Sigma-Tau until December 2010. Mot. Prelim. Inj. Ex. 14 at 1, ¶ 9.1, ECF No. 55-14. The patent at issue was identified as the 615 Patent, and the trademark as VSL#3.

## **II. De Simone Asserts Control over the Know-How**

Over the next several years, VSL#3 became the “gold standard” for probiotics. Compl. ¶ 6, ECF No. 1. According to De Simone, this success strained his relationship with the Cavazzas, who wanted to increase their profit margins by using cheaper ingredients for VSL#3. De Simone asserts that when he rejected such an idea, the Cavazzas began, through their representatives in the Sigma Tau Group, to try to lay claim to the trade secrets—the Know-How—involved in manufacturing VSL#3, with the aim of cutting De Simone out of the business entirely. In response, De Simone set out to clarify the status of his intellectual property.<sup>2</sup> Accordingly, in

---

<sup>2</sup> In 2005, De Simone gained full rights to the 615 Patent. On April 15, 2005, referencing his obligations under the 2001 Patent License Agreement, De Simone officially informed VSL that he had acquired full ownership of the 615 Patent and offered VSL an exclusive license to that patent free of charge.

May 2006, De Simone, Danisco, CD International, and various CD International subsidiaries signed a Confidential Disclosure Agreement (“2006 Confidential Disclosure Agreement”). That Agreement provided that “*it is hereby recognized and agreed that De Simone is the owner of the product formulation referred to as VSL #3 described in U.S. Patent n. 5,716,615*” and that De Simone therefore had the right to discontinue a company’s license to make VSL#3. VSL Ans. and Countercl. Ex. 11 ¶ 6, ECF No. 9-11 (emphasis in original). Danisco was “*to discontinue the use and/or manufacture of VSL #3 for the Company upon receipt of such notice.*” *Id.* That agreement was signed by Danisco’s Business Director of Probiotics; by Maurizio Terenzi, as President of CD International and various other CD International subsidiaries; and by De Simone on his own behalf, and on behalf of VSL and an Indian subsidiary of CD International.

From VSL’s perspective, the 2006 Confidential Disclosure Agreement was an effort by De Simone to wrest back intellectual property that he had already conveyed to VSL. VSL claims that it was thus De Simone, not the Cavazzas, who sought unfairly to capitalize on VSL#3’s success by cutting his partners out of the business. VSL asserts that as part of this effort, De Simone hired a “co-conspirator” to help him take control of the company. VSL Ans. & Countercl. ¶ 92, ECF No. 9. At the end of 2006, the two members of the VSL Board of Directors other than De Simone resigned. One was replaced by Terenzi, a confidant of the Cavazzas. The other was replaced by Dr. Bo Young “Beth” Park, an orthodontist by training who had been doing unpaid work for De Simone to market VSL#3 after it had proven effective for her son. VSL asserts that De Simone installed Park to shift the balance of power at VSL in his favor, a shift that, in VSL’s estimation, enabled De Simone to begin a years-long process of self-dealing. With the new Board in place, De Simone was re-elected CEO, Park was elected Chief Operating Officer, and Terenzi was elected Chief Financial Officer and Treasurer.



In 2007 and 2008, De Simone signed additional agreements designed, from his perspective, to strengthen his control over his intellectual property, and from VSL's perspective, to wrongly try to take back that property. Specifically, in 2007, De Simone and VSL executed a Know-How License Agreement relating to the distribution of VSL#3 in Canada. That agreement, signed by Park on behalf of VSL, provided that De Simone "owns and has developed a secret and substantial know-how" for the manufacturing of VSL#3, and that he was giving VSL a license to use that know-how to distribute VSL#3 in the Canadian market. VSL Ans. & Countercl. Ex. 10 ¶ A, ECF No. 9-10. The Agreement stipulates that VSL owns the trademark "VSL#3." Then, in 2008, De Simone, in his personal capacity, signed a supply agreement with Danisco establishing that he owned and had provided to Danisco "Technical Information" necessary to produce VSL#3 consisting of "trade secrets [and] know-how" relating to the "ratios of the ingredients to be included in VSL#3 ... and the order of the ingredients in specific ratio formations," and that Danisco was to use this information only in the strictest confidence. VSL Ans. & Countercl. Ex. 14 ¶ 1, ECF No. 9-14. That agreement also echoed the provision in the 2006 Confidential Disclosure Agreement, which gave De Simone the power to instruct Danisco to stop supplying particular companies, by giving De Simone the authority to dictate which companies Danisco could supply with VSL#3. According to De Simone, he provided a copy of this agreement to the Cavazzas "immediately after" it was signed. Resp. Opp'n Mot. Prelim. Inj. Ex. 6 (De Simone Decl.) ¶ 67, ECF No. 76-6.

In 2009, De Simone broached the topic of a Know-How agreement governing VSL's distribution of VSL#3 in the U.S. market. At a September 18, 2009 meeting of the Board of Directors, attended by De Simone, Park, and Terenzi, the Board discussed the fact that the 2001 Patent License Agreement would expire with the 615 Patent in February 2015, at which point

“VSL w[ould] no longer have the right to use [the] know-how to manufacture, sell and market VSL#3 in [the] USA.” Mot. Dismiss VSL Countercl. Ex. 9 at 5, ECF No. 53-9. To ensure that VSL could continue to supply the U.S. market after the expiration of the patent, the Board decided to explore a Know-How agreement that would extend VSL’s rights to distribute VSL#3 in the United States to at least until the end of January 2016. That resolution was unanimously approved by Park and Terenzi, VSL’s disinterested board members, with De Simone abstaining.

The resulting Know-How License Agreement (“2010 Know-How Agreement”) between De Simone and VSL was executed on January 28, 2010. In that agreement, De Simone granted VSL “the exclusive right to [De Simone’s] Know How” for the manufacture, production, marketing, and sale of VSL#3 for the U.S. market. Compl. Ex. 3 ¶ 2.1, ECF No. 1-3. “Know-How” was defined as “relevant information related to the Product including but not limited to discoveries, processes, composition, technical and scientific data which are in possession or in control of [De Simone] and are needed in order [to manufacture] VSL[.]” *Id.* ¶ 1.8. The License stipulated that it would become effective upon the expiration of the 2001 Patent License Agreement in February 2015 and would remain in effect until January 31, 2016. The agreement also gave De Simone the right immediately to terminate the license in the event of a change of control at VSL. The 2010 Know-How Agreement was signed by Park on behalf of VSL.

### **III. De Simone’s Departure from VSL**

In mid-2013, De Simone asserts, the Cavazzas renewed their efforts to increase the profitability of VSL#3. Sigma-Tau Group executives proposed a marketing contract for the United States with terms that were “extremely favorable” to Sigma-Tau but “economically unfeasible” for VSL, citing a need to increase Sigma-Tau’s profit margins. Compl. ¶ 115. De Simone rejected the proposal. In November 2013, Enrico Cavazza, Claudio Cavazza’s son, who

had assumed a management role in the Cavazza business after his father died in 2011, began to lobby De Simone to replace Danisco as the VSL#3 manufacturer with a company that was part of the Sigma-Tau Group. A Sigma-Tau Group executive explained that the new manufacturer could make VSL#3 with “cheaper strains of ... bacteria” that would not noticeably affect the product. Resp. Opp’n Mot. Prelim. Inj. Ex. 6 (De Simone Decl.) ¶ 78. De Simone alleges that when he refused this suggestion out of a concern for public safety, the Sigma-Tau Group intensified its efforts to obtain the confidential Know-How by, for example, contacting a regulatory attorney in the United States seeking access to confidential information relating to VSL#3.

By mid-2014, the working relationship between De Simone and the Cavazzas had completely broken down. From De Simone’s perspective, the Cavazzas had begun an all-out campaign “to harass and threaten” him into acceding to their plans to dilute VSL#3. Compl. ¶ 127. From VSL’s perspective, De Simone was in the thick of a course of self-dealing through which he was endeavoring to take back intellectual property that he had assigned to VSL in 2000. What ensued were efforts by both sides to fortify their positions.

In May 2014, officers from CD Investments—VSL’s majority shareholder—began making requests for corporate records, with which De Simone refused to comply. In June 2014, with no corporate records forthcoming from De Simone, CD Investments officers attempted to access VSL records through the CD Investments computers, only to discover, VSL alleges, that the computers had been “wiped clean.” VSL Ans. & Countercl. ¶ 143. Forensic analysis of the computers showed that they had been connected to several cloud-based file hosting services, at least one of which was in De Simone’s name, and that VSL’s records had been transferred from

the CD Investments computers to De Simone's account. In October 2014, CD Investments filed suit against De Simone in the Delaware Court of Chancery, seeking corporate records.

For his part, De Simone, in his personal capacity, and Park, on behalf of VSL, signed a second supply agreement with Danisco ("the 2014 Supply Agreement"). Although that agreement does not indicate when it was signed, VSL asserts that it was executed in early June 2014. The 2014 Supply Agreement provided that "in the event that the [2010] Know How License Agreement is terminated or expires before the expiration or termination of this Agreement for any reason, [De Simone] shall ... be defined as the 'Buyer' and all references in this Agreement to 'Buyer' shall apply solely to [De Simone] and not to VSL." VSL Ans. & Countercl. Ex. 17 ¶ 2.1. The 2014 Supply Agreement, which was backdated to be effective as of January 1, 2014, thus set De Simone up to take over VSL's supply after the expiration of the 2001 Patent License Agreement, or even earlier should the Know-How License Agreement be terminated. Also in June 2014, De Simone filed a U.S. trademark application for the mark "VSL3 BY DE SIMONE." In September 2014, De Simone filed a second U.S. trademark application, this one for the mark "VSL3TOTAL."

Also in September 2014, a new director was appointed to the VSL Board by CD International: James Brady. On October 14, 2014, Park resigned from her position on the VSL Board; she later resigned as Chief Operating Officer on November 19, 2014. The next day, on October 15, 2014, Brady sent a letter to De Simone asserting that VSL owned the rights to all intellectual property related to VSL#3, citing the Mendes Assignment and the VSL By-Laws provision by which De Simone was required to transfer all inventions made since the incorporation of VSL.

On November 14, 2014, De Simone resigned his position as VSL CEO and also resigned from the VSL Board. Based on the changes to the Board of Directors, De Simone terminated the 2010 Know-How Agreement, citing that agreement's change of control provision, which allowed termination in the event that less than a majority of the current directors held that role on the date that the 2010 Know-How Agreement was executed. In his written notice of termination, De Simone informed VSL that as a result of the termination, VSL "no longer retain[ed]" the necessary expertise to manufacture VSL#3" and explained that he took this action based in part on the Sigma-Tau Group's efforts to "improperly access highly confidential information about the strain selection and the formula" for VSL#3, with the aim of producing an inferior copy of the product. Mot. Prelim Inj. Ex. 20 at 1-2, ECF No. 55-20. De Simone proposed that VSL license the VSL#3 trademark to him, under an arrangement that would "bring basically the same net earnings to the Company." *Id.* VSL ultimately rejected De Simone's licensing proposal, prompting De Simone, in December 2014, to inform Sigma-Tau that when the 615 Patent expired on February 9, 2015, VSL would no longer "have any rights to pass to [Sigma-Tau] to purchase the active ingredient" in VSL#3 from Danisco. Compl. ¶ 148.

On February 9, 2015, the 615 Patent expired, and with it the 2001 Patent License Agreement. From De Simone's perspective, because he had terminated the 2010 Know-How Agreement, VSL was no longer authorized as of that date to continue distributing VSL#3 in the United States, and Sigma-Tau, as VSL's sub-licensee, was no longer allowed to market the product. Nevertheless, VSL continued to order VSL#3 for sale in the United States, and Sigma-Tau continued to market the product in the United States. Danisco, for its part, continued to fill VSL's orders, having received no express instruction from De Simone to cease doing so.

Although it continued to sell VSL#3 in the United States, VSL allegedly stopped paying De Simone any royalties on those sales.

In a letter dated May 18, 2015, De Simone informed Danisco that because the 2010 Know-How License had been terminated, VSL and Sigma-Tau were “no longer authorized purchasers” of VSL#3 and “all references to Buyer in the Supply Agreement shall apply solely to me and **not** to VSL.” Mot. Prelim. Inj. Ex. R at 1, ECF No. 55-21 (emphasis in original). De Simone added that Danisco could, however, fill any VSL/Sigma-Tau orders that had been placed before May 18, 2015, so long as the expected delivery date for those orders was not after July 30, 2015, and those orders were “not for volumes in excess of normal historical volumes.” *Id.*

#### **IV. ExeGi and Visbiome**

Meanwhile, in October 2014, ExeGi was incorporated in New York. ExeGi is headed by Mark Tewey, a former executive at Sigma-Tau who had extensive experience in marketing VSL#3, and whom De Simone trusted. According to VSL, soon after ExeGi was formed, it began to work with De Simone to bring a competing version of VSL#3 to market. On February 27, 2015, a few weeks after the expiration of the 615 Patent, Tewey, on behalf of ExeGi, sent a letter to VSL stating that ExeGi would be launching a generic version of VSL#3 and that De Simone was supporting the venture by supplying ExeGi with his “know-how and supply.” Mot. Prelim. Inj. Ex. 26, ECF No. 55-26.

In May 2015, ExeGi began to promote this product, known as “Visbiome,” on its website, advertising that it had partnered with De Simone, who had “invented the formulation of the probiotic VSL#3.” Mot. Prelim. Inj. Ex. 30, ECF No. 55-30. ExeGi described Visbiome as a “generic formulation of the probiotic marketed under the name ‘VSL#3’” that would “contain the same strains, in the same concentrations and proportions tested and marketed under the brand

name VSL#3,” and would be manufactured in the same facility and with the same “methods and quality standards as the original product.” *Id.* ExeGi’s website and promotional materials, including images of the proposed packaging for Visbiome, referred to the product as the “Original Formula VSL#3 Probiotic Blend” and “Visbiome/VSL#3 blend.” *Id.*, Ex. 31, ECF No. 55-31. Although the mark “VSL#3” is used numerous times in these promotional materials, the mark is nowhere accompanied by a statement that VSL#3 is a registered trademark of VSL.

#### **V. Procedural History**

On May 11, 2015, De Simone filed suit in this Court against VSL and Sigma-Tau seeking (1) a declaratory judgment that he owns the Know-How used to formulate and produce VSL#3, and alleging (2) breach of contract against VSL for failure to pay royalties, (3) unjust enrichment against VSL and Sigma-Tau for their continued selling and marketing of VSL#3 in the United States despite the expiration of the 2001 Patent License Agreement, (4) misappropriation of trade secrets against both defendants, and (5) civil conspiracy against both defendants. ECF No. 1.

On June 3, 2015, VSL filed an Answer, a Counterclaim, and a Third-Party Complaint in which it joined Mendes, ExeGi, and Danisco as defendants. ECF No. 9. In its Counterclaim and Third-Party Complaint, VSL alleged over 20 causes of action, ranging from breach of fiduciary duty against De Simone to trademark infringement against ExeGi, and including numerous business torts as well as a request for a declaratory judgment that VSL, not De Simone, is owner of the Know-How. On June 9, 2015, Sigma-Tau filed its Answer to De Simone’s Complaint, which it followed, on June 19, 2015, with a Counterclaim against De Simone and Third-Party Complaint against ExeGi, seeking declaratory relief and alleging various business torts. ECF Nos. 39 & 50.

On June 24, 2015, VSL filed a Motion for a Preliminary Injunction seeking to enjoin De Simone from (1) interrupting VSL's supply of VSL#3, and (2) imparting the Know-How to ExeGi or to anyone else; to require De Simone to (3) turn over any of VSL's corporate documents in his possession; and to enjoin ExeGi from (4) using any part of the Know-How that it may already possess, and (5) using or otherwise infringing on the VSL#3 trademark. ECF No. 55. That same day, Sigma-Tau also filed a Motion for a Preliminary Injunction in which it adopted the claims and arguments advanced by VSL. ECF No. 61. Also on June 24, 2015, De Simone sent a letter to Danisco extending the deadline for cutting off supply to VSL. De Simone informed Danisco that it could continue to fill VSL's orders until September 15, 2015, again as long as those orders were not for amounts in excess of VSL's typical order.

On July 24, 2015, De Simone and ExeGi filed their Response to the Motions for a Preliminary Injunction. ECF No. 76. On August 7, 2015, VSL and Sigma-Tau each filed a Reply Memorandum. ECF Nos. 79 & 81. Sigma-Tau also amended its Counterclaim and Third-Party Complaint. ECF No. 80. The Court heard oral argument on September 1, 2015, during which the Court was informed that, in the absence of preliminary relief, Danisco would stop supplying VSL with VSL#3 on September 23, 2015.

## **DISCUSSION**

### **I. Legal Standard**

To obtain a preliminary injunction, moving parties must establish that (1) they are likely to succeed on the merits, (2) they are likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of equities tips in their favor, and (4) an injunction is in the public interest. *Winter v. Natural Res. Defense Council, Inc.*, 555 U.S. 7, 20 (2008); *see Dewhurst v. Century Aluminum Co.*, 649 F.3d 287, 290 (4th Cir. 2011). 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.

Prior to *Winter*, the United States Court of Appeals for the Fourth Circuit followed a “balance of hardship” approach to preliminary injunctions, considering all four *Winter* factors, but “allow[ing] each requirement to be conditionally redefined” in a “flexible interplay” depending on how the other requirements were met. *See 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)). However, *Real Truth* invalidated this approach, and it “may no longer be applied” in the Fourth Circuit. *Id.* As a result, a moving party must satisfy each requirement as articulated. *Id.*

In their Motions for a Preliminary Injunction, VSL and Sigma-Tau ask for nine different forms of relief, some of which relate to De Simone and some of which relate to ExeGi. These multiple requests stem from four central theories of liability: (1) that De Simone and, by extension, ExeGi misappropriated the VSL#3 Know-How, (2) that De Simone breached his fiduciary duty to VSL, (3) that De Simone engaged in conversion by taking and failing to return VSL company records, and (4) that ExeGi infringed VSL’s trademark. The Court thus analyzes the *Winter* factors across this framework.

## **II. Likelihood of Success on the Merits**

To meet the first requirement for a preliminary injunction, moving parties 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). Thus, to succeed in all respects on their Motions for a Preliminary Injunction, VSL and Sigma-Tau must clearly demonstrate that they are likely to succeed on their claims that De Simone, and by

extension, ExeGi, misappropriated the Know-How, that De Simone breached his fiduciary duty to VSL, that he engaged in conversion of corporate records, and that ExeGi infringed VSL's trademark. The Court analyzes each theory of liability in turn.

**A. Misappropriation of a Trade Secret**

VSL<sup>3</sup> asserts that under the terms of the Maryland Uniform Trade Secrets Act ("MUTSA"), Md. Code. Com. Law § 11-1201 *et seq.*, De Simone misappropriated a valid trade secret rightfully belonging to VSL, specifically the Know-How for the production of VSL#3. VSL further asserts that in relying on the Know-How to produce Visbiome, ExeGi is also misappropriating VSL's trade secret. They thus ask this Court to enjoin De Simone and ExeGi from using or disclosing the Know-How, and to require De Simone and ExeGi to return the Know-How to VSL.

To prevail on a misappropriation claim under the MUTSA, a plaintiff must establish that "(1) it possessed a valid trade secret, (2) the defendant acquired its trade secret, and (3) the defendant knew or should have known that the trade secret was acquired by improper means." *Trandes Corp. v. Guy F. Atkinson Co.*, 996 F.2d 655, 660 (4th Cir. 1993). The parties do not dispute that the Know-How is a valid trade secret. Nor do the parties dispute that VSL possessed that trade secret, and that De Simone acquired it. What the parties sharply dispute is whether De Simone acquired it by "improper means." This issue turns on the nature of VSL's possession—whether it owned the Know-How or merely had a license from De Simone to use it. VSL contends that De Simone assigned ownership of the Know-How to VSL, and thus argues that in now contending that he fully owns the Know-How, De Simone is improperly misappropriating

---

<sup>3</sup> When discussing the arguments made in the Motions for Preliminary Injunction, the Court uses the term "VSL" to refer to both VSL and Sigma-Tau. The Court does so both for the sake of simplicity, and because Sigma-Tau's Motion for a Preliminary Injunction adopted VSL's Motion and proffered no additional arguments.

intellectual property that he previously transferred to VSL. De Simone contends that he has not acted improperly because he never transferred ownership of the Know-How to VSL, but instead only granted VSL a license to use that intellectual property.

### **1. Contract Language**

VSL bases its claim of ownership of the Know-How on the Mendes Assignment, which transferred to VSL all intellectual property related to the VSL#3 trademark. Mem. Supp. Mot. Prelim. Inj. at 6, 31. Whether the Mendes Assignment actually transferred ownership of the Know-How is a matter of contract interpretation. The Mendes Assignment states that it is to “be construed in accordance with and governed by the laws of New York.” Mot. Prelim. Inj., Ex. G ¶ 6.05. Under New York law, “[t]he fundamental, neutral precept of contract interpretation is that agreements are construed in accord with the parties’ intent.” *Greenfield v. Philles Records, Inc.*, 780 N.E.2d 166, 170 (N.Y. 2002). Because the best evidence of the parties’ intent is the language of the contract itself, “a written agreement that is complete, clear and unambiguous on its face must be enforced according to the plain meaning of its terms.” *Id.* A contract is unambiguous “if the language it uses has definite and precise meaning, unattended by danger of misconception ... and concerning which there is no reasonable basis for a difference of opinion.” *Id.* If, however, the agreement is ambiguous, the court may consider “[e]xtrinsic evidence of the parties’ intent.” *Id.*

VSL argues that the plain language of the Mendes Assignment shows that De Simone, through Mendes, transferred ownership of the Know-How to VSL. VSL finds textual support for its argument by linking three parts of the Mendes Assignment. The first is the inclusion of the trademark “VSL#3” in Schedule I, which lists the intellectual property being transferred. The second is Section 2.01, which states that De Simone “irrevocably assigns, conveys, sells,

grants, and transfers ... all right, title, and interest of every kind and character ... throughout the world in and to the Intellectual Property ... and the Proprietary Information” being transferred in the agreement, and also conveys “all future rights to any Intellectual Property or Proprietary Information which is derived from or are based on any of the Transferred Property.” *See Mendes Assignment* § 2.01. The third is the definitions of Intellectual Property and Proprietary Information. “Intellectual Property” includes “any and all rights to any intellectual property owned or licensed by . . . Assignor and which relates to the subject matter set forth in Schedule I.” *Id.* § 1.01. “Proprietary Information” includes “trade secrets” and “know-how” that is “described, comprised in or relating to the Intellectual Property.” *Id.* § 1.01. Under VSL’s interpretation, the Know-How is a form of Intellectual Property related to the trademark “VSL#3” listed in Schedule I, or it is a form of Proprietary Information “described, comprised in or relating to” that trademark. VSL’s claim for misappropriation of a trade secret thus rests on the proposition that in conveying to VSL the *trademark* “VSL#3,” Mendes also necessarily conveyed to VSL ownership of Know-How associated with the formulation and production of the *product* now known as VSL#3.

Although VSL argues that under these broad definitions, the Mendes Assignment unambiguously effected the transfer of the Know-How to VSL, the Court concludes that the language of the agreement is ambiguous in that it is susceptible to more than one interpretation. Although “know-how” is plainly listed as a form of Proprietary Information, the agreement is not clear, in the specific context of the Know-How, as to what it means for Proprietary Information to be “described, comprised in or relating to” intellectual property such as the VSL#3 trademark. This is especially so because VSL is forced to route its ownership argument through the trademark “VSL#3” because, as no one disputes, the rights to the 615 Patent—the bacterial

combination that would become the probiotic VSL#3—were not included in the Mendes Assignment. It is not at all evident that in 2000, the Know-How, a methodology for producing a probiotic based on the 615 Patent, was “related to” a trademark that had been applied for but never used in connection with any product on the market. Because the Mendes Assignment is ambiguous in that it does not clearly establish that the Know-How relates to the VSL#3 trademark for purposes of the Assignment, extrinsic evidence on the parties’ intent should be considered. *Greenfield*, 780 N.E.2d at 170.

## **2. The VSL#3 Trademark**

Through that lens, VSL’s efforts to use the VSL#3 trademark to sweep up the Know-How needed to make the VSL#3 product faces significant hurdles. At the time of the Mendes Assignment, the trademark “VSL#3” had not yet been approved and was not yet defined in such a manner that it could be associated with any particular product, much less with the probiotic derived from the 615 Patent that later came to be known as VSL#3. In fact, the June 2000 VSL#3 U.S. trademark application described the mark in very broad terms, stating that it was for:

Pharmaceutical preparations for the treatment of diseases of the digestive system, gynecological diseases and skin diseases, veterinary preparations for the treatment of diseases of the digestive system, gynecological diseases and skin diseases; medical preparations for hygiene, namely, medical preparations for woman’s intimate hygiene; dietetic substances adapted for medical use, namely, food for medically restricted diets; baby food; and food supplements.

VSL Ans. & Countercl. Ex. 20, ECF No. 9-20. The 1999 application for the European VSL#3 trademark, which was also transferred by the Mendes Assignment, similarly described the goods at issue broadly as “pharmaceutical, veterinary and sanitary preparations, dietetic substances adapted for medical use, food for babies; nutraceuticals; food supplements.” Resp. Opp’n Mot. Prelim. Inj. Ex 8, ECF No. 76-8.

Thus, it appears that as of 2000, the VSL#3 trademark was simply a name that was expected to eventually represent an as yet undefined and unfinished product. Indeed, De Simone asserts, and VSL does not contest, that it was not until 2002 that the probiotic now known as VSL#3 was released in the United States or elsewhere, and branded as “VSL#3.” VSL points to only one thing that might attach the VSL#3 trademark specifically to the eventual VSL#3 product in advance of the Mendes Assignment: a 2000 article in a scientific journal discussing clinical trials of “VSL#3.” Reply to Mem. Opp’n Mot. Prelim. Inj. Ex. 2, ECF No. 79-2. De Simone disputes that this article refers to the product formulation now known as VSL#3, and he asserts that at the time, VSL#3 had an independent, scientific meaning, designating a particular genus of “very safe lactic acid” bacteria. Sept. 1, 2014 Hearing at 10:19-10:20 a.m., *De Simone, et al. v. VSL, et al.* (TDC-15-1356). Even if VSL is able to prove that there were clinical studies occurring before the Mendes Assignment that related to the product now known as VSL#3, under that name, the formal description of the trademark, which is so broad as to include the possibility that VSL#3 would refer to a type of “baby food,” does not establish any clear connection between any product under study and that trademark. Rather, the most reasonable conclusion is that the Know-How was not “related” to the VSL#3 trademark at the time of, and within the meaning of, the Mendes Assignment. Thus, because the trademark VSL#3 was apparently an unattached signifier at the time of the Mendes Assignment in 2000, it could not have been the understanding of the parties that in transferring the trademark VSL#3, De Simone was also transferring the Know-How.

VSL’s contention at the hearing that the transfer of the trademark necessarily included the Know-How because one cannot practice a trademark without its associated goodwill does not change this conclusion. To be sure, 15 U.S.C. § 1060(a)(1) makes clear that a trademark “shall

be assignable with the good will of the business in which the mark is used,” and the Mendes Assignment echoes that proposition. See VSL Ans. & Countercl. Ex. 4 (Mendes–VSL Assignment) ¶ 1.01 (defining “Intellectual Property” as including “trademark[s] ... and the entire business or portion thereof to which the Marks pertain as is required by 15 U.S.C. § 1060”); see also *Marshak v. Green* 746 F.2d 927, 929 (2d Cir. 1984) (“[A] trademark cannot be sold or assigned apart from [the] goodwill it symbolizes[.]”). However, “goodwill” means “the legal and economic recognition of buying habits.” 1 J. Thomas McCarthy, *Trademarks and Unfair Competition* § 2.18 (4th ed. 2015). It is the shorthand for what might be called “buyer momentum,” *id.*, or “the tendency of customers to return” to a familiar product, *Burke v. Canfield*, 121 F.2d 877, 880 (D.C. Cir. 1941); see also *Newark Morning Ledger Co. v. United States*, 507 U.S. 546, 555 (1993) (defining “goodwill,” in the context of determining the value of an asset for tax purposes, as “the expectancy of continued patronage” and those “imponderable qualities that attract customers to the business”). Goodwill is thus the term for a brand’s positive relationship and reputation with customers, its “commercial magnetism.” *Mishawaka Rubber & Wollen Mfg. Co. v. S.S. Kresge Co.*, 316 U.S. 203, 205 (1942). VSL has cited no authority for its claim that, in this case, “goodwill” has a meaning beyond its normal, consumer-specific scope such that it includes scientific formulations and methodology such as the Know-How, or that scientific know-how necessarily transfers with goodwill.

Even if one accepts VSL’s proposition that the Know-How travels with the trademark’s goodwill, VSL fares no better. As discussed above, at the time of the Mendes Assignment, the trademark VSL#3 had not yet been used in business and was not specifically identified with any particular product such as the probiotic based on the 615 Patent. Thus, at the time of the Mendes Assignment, it does not appear that there was any goodwill associated with the VSL#3 trademark

that could follow the mark: with no product branded “VSL#3,” there could be no expectation of continued patronage associated with that mark. And if there was no goodwill to transfer, there could be no scientific know-how that traveled with that goodwill.<sup>4</sup>

### 3. Other Agreements

VSL’s assertion that the transfer of the trademark in the Mendes Assignment included the Know-How also cannot be squared with two other agreements: the 1999 Option Agreement and the 2001 Patent License Agreement. Both specifically dealt with the 615 Patent, which was not at issue in the Mendes Assignment. The 1999 Option Agreement specified that De Simone “co-owns the Patent and fully owns the Know-How” related to the 615 Patent, and that he was granting to Sigma-Tau “an exclusive option for an exclusive license related to his right on the Patent and on the Know-How” for the purpose of commercializing the 615 Patent in the United States as a drug. VSL Ans. & Countercl. Ex. 1 ¶¶ A & B, 2.1, Appendix A (specifying the patent as U.S. Patent No. 5716615). This agreement provides specific evidence that the Mendes Agreement did not effect the transfer of ownership of the Know-How for two reasons. First, it establishes that De Simone personally owned the Know-How as of November 1999, and there is no evidence that he transferred it to Mendes prior to September 2000. Because the Mendes Assignment only transferred intellectual property owned or licensed by Mendes, the Know-How could not have been conveyed through that agreement. Second, the 1999 Option Agreement shows that when De Simone, in his dealings with the Sigma Tau Group, wished to convey rights to the 615 Patent and its Know-How, he knew how to do so and would use those specific terms,

---

<sup>4</sup> De Simone suggests that, because there was no goodwill associated with VSL#3 at the time the mark was transferred to VSL, the transfer is arguably void as an assignment in gross. Because the Court need not decide this question in order to resolve the pending Motions, and because De Simone does not ask for that assignment to be voided, the Court does not address this argument.



rather than rely on broad definitions of generic terms to effect such a conveyance. *See William C. Atwater & Co. v. Panama R. Co.*, 159 N.E. 418, 419 (N.Y. 1927) (explaining that in interpreting a contract, a court should look not only at the contract but also at “the relation of the parties and the circumstances under which [the contract] was executed.”).

The 2001 Patent License Agreement, which explicitly granted a license to the 615 Patent, including “any other proprietary rights” relating to it, also undermines VSL’s argument that the Mendes Assignment transferred the Know-How to VSL. Under VSL’s overly broad reading of that Assignment, the 615 Patent would, like the Know-How, constitute “intellectual property” relating to the VSL#3 trademark and therefore would also have been transferred to VSL through that Assignment. If VSL’s interpretation of the Mendes Assignment were correct, then, there would have been no need for the 2001 Patent License Agreement, because VSL would already have obtained De Simone’s ownership interest in the 615 Patent in 2000. The fact that De Simone and VSL entered into a license agreement relating to the 615 Patent in 2001 thus further establishes that De Simone did not transfer the Know-How through the Mendes Assignment.<sup>5</sup>

The various collateral agreements VSL offers as evidence that, through the Mendes Assignment, VSL owned all of the intellectual property related to VSL#3, do not alter this conclusion. For example, at the hearing VSL cited a 2002 Confidential Disclosure Agreement it

---

<sup>5</sup> Later agreements between or among De Simone, VSL, and entities associated with the Cavazzas, in which the parties acknowledged De Simone’s ownership of the Know-How, provide additional support for, but are not necessary to, the conclusion that the Mendes Assignment did not convey ownership of the Know-How to VSL. For example, the 2006 Confidential Disclosure Agreement among De Simone, VSL, CD International, CD Investments, and other entities, acknowledged that “De Simone is the owner of the product formulation referred to as VSL#3 described in [the 615 Patent]” and was signed on behalf of CD International by Maurizio Terenzi, a VSL Board member selected by the Cavazzas who also served as President of CD International and CD Investments, and who had previously been a Director of the Sigma-Tau Group. VSL Ans. & Countercl. Ex. 11 ¶ 6.

executed with a Canadian company as its best collateral evidence that “VSL owned all the intellectual property and confidential information related to VSL#3” as a result of the Mendes Assignment.<sup>6</sup> Mot. Prelim. Inj. at 32. The language of the agreement, however, does not unambiguously establish that VSL owned the Know-How. Although, as VSL points out, that agreement contains the statement that certain “know-how and information are secret and belong exclusively to VSL,” it also contains the statement that “VSL declares to be the owner or to *directly or indirectly control* certain patent rights as well as proprietary know-how and information[.]” Reply to Resp. in Opp’n Mot. Prelim. Inj. Ex. GG ¶ 1, ECF No. 79-4 (emphasis added). The language of that agreement is substantially the same as a number of other collateral agreements that VSL submits as evidence of its ownership of the Know-How. *See, e.g.*, Mot. Prelim. Inj. Ex. 38 at 1 (2012 VSL–Sanofi Secrecy Agreement), ECF No. 55-38. Not only does that language thwart the claim that VSL was clearly the owner of the Know-How, but its inclusion is most reasonably construed to indicate that VSL’s rights were something less than full ownership, such as having a license to use the Know-How. Moreover, given that this agreement, like the vast majority of those that VSL enlists to make its point, is between VSL and a party other than De Simone, it carries significantly less weight than those between De Simone and VSL or Sigma Tau, because, in these collateral agreements, VSL and De Simone shared a common interest to define VSL’s intellectual property rights broadly and robustly in relation to the rights of the parties with whom they were contracting. These agreements therefore do little to strengthen VSL’s argument.

---

<sup>6</sup> Although VSL identified the 2002 Canadian Confidential Disclosure Agreement as its best example of an agreement with language establishing VSL’s ownership of the Know-How, De Simone has offered evidence that that agreement did not even relate to the VSL#3 product. *See* Second De Simone Declaration ¶ 6, ECF No. 97; Ex. 1, ECF No. 97-1.

VSL thus fails to establish that it is likely to succeed on its claim that it owns the Know-How, and therefore that De Simone, in asserting that he fully owns the Know-How, is misappropriating VSL's trade secret. In turn, VSL necessarily also fails to establish that ExeGi is misappropriating VSL's trade secret by producing Visbiome with the Know-How provided to it by De Simone. Because VSL has failed to establish likelihood of success on the merits on the misappropriation claim, there is no need to address the remaining *Winter* factors relating to this theory of liability. *See Real Truth*, 575 F.3d at 347. The Motions for a Preliminary Injunction on that basis are therefore denied.

**B. Breach of Fiduciary Duty**

VSL contends that De Simone breached his fiduciary duty to VSL by executing various allegedly self-serving agreements that then positioned him to usurp VSL's intellectual property and supply chain, all while still serving as VSL's CEO. VSL asserts that, as a result of De Simone's alleged self-dealing, it faces the possibility of losing access to its source of supply of its only profitable product. They thus ask the Court to enjoin De Simone from cutting off VSL's supply of VSL#3 from Danisco.

A federal court sitting in diversity applies the choice-of-law principles of the forum state, in this case, Maryland. *Klaxon v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941); *Zimmerman v. Novartis Pharm. Corp.*, 889 F. Supp. 2d 757, 761 (D. Md. 2012). On a claim for breach of fiduciary duty, which involves "a matter peculiar to the relationships among and between the corporation and its directors," Maryland courts apply the law of the state of incorporation, in this case, Delaware. *See Storetrax.com, Inc. v. Gurland*, 895 A.2d 355, 372-73 (Md. Ct. Spec. App. 2006), *aff'd* 915 A.2d 991 (Md. 2007) (holding that because the plaintiff corporation was incorporated in Delaware, the trial court erred in not applying Delaware law to its claim that the

defendant had breached his fiduciary duty, but going on to find that such error was harmless); *Restatement (Second) of Conflict of Laws* § 309 (1971) (“The local law of the state of incorporation will be applied to determine the existence and extent of a director’s or officer’s liability to the corporation[.]”).

Under Delaware law, a corporate officer or director owes a fiduciary duty to the corporation and therefore must exhibit an “undivided and unselfish loyalty to the corporation demands,” such that there is “no conflict between duty and self-interest.” *Guth v. Loft, Inc.*, 5 A.2d 503, 510 (Del. 1939). Officers and directors must “refrain from doing anything that would work injury to the corporation, or to deprive it of profit or advantage.” *Id.* Delaware courts have subdivided this fiduciary duty into three component duties: a duty of care, a duty of loyalty, and a duty to act in good faith. Here, the duty of loyalty is implicated, a duty that prohibits a corporate officer or director from deriving “any personal benefit through self-dealing.” *Anadarko Petroleum Corp. v. Panhandle E. Corp.*, 545 A.2d 1171, 1174 (Del. 1988). “The duty of loyalty mandates that the best interest of the corporation and the shareholders takes precedence over any interest possessed by a director [or] officer . . . not shared by the stockholders generally.” *Cede & Co.*, 634 A.2d 345, 361 (Del. 1993). Self-dealing includes usurping a corporate opportunity for oneself. *Guth*, 5 A.2d at 510-11.

VSL has established that it is likely to succeed on its claim for breach of fiduciary duty based on De Simone’s efforts to usurp VSL’s place in the probiotic market. In June 2014, De Simone amended VSL’s Supply Agreement with Danisco to add a provision whereby if the 2010 Know-How Agreement were terminated and VSL was left without a license to produce VSL#3, De Simone would step into VSL’s shoes as the buyer. Through the express terms of the 2014 Supply Agreement, De Simone made VSL’s loss into his own personal gain, by squarely placing

himself as the beneficiary of any termination of VSL's Know-How Agreement. The degree of self-dealing was magnified by the fact that the means by which to terminate the Know-How Agreement—the change of control provision—was something over which De Simone exercised significant influence. Under that provision, the resignation from the Board of Directors of De Simone and his handpicked co-director, Dr. Park, would establish grounds for termination of the Supply Agreement.

Also indicative of self-dealing was De Simone's filing of trademark applications. The same month that De Simone executed the 2014 Supply Agreement, he filed a trademark application for the mark "VSL3 BY DE SIMONE," a mark that, because it essentially juxtaposes the trademark "VSL#3" with De Simone's own name, makes nearly inescapable the conclusion that De Simone was attempting to usurp the VSL#3 brand for himself. Then three months later, in September 2014, DeSimone filed a trademark application for the mark "VSL3TOTAL," another mark that plainly suggests that De Simone was angling to take over VSL's market share.

The nature and timing of the events, including the execution of the 2014 Supply Agreement and the filing of trademark applications, strongly support the inference that, beginning at least in June 2014 through De Simone's resignation as CEO and a Director of VSL, De Simone acted to his personal advantage, and to the detriment of VSL, by positioning himself to usurp VSL's place in the probiotic market. Through the 2014 Supply Agreement, De Simone set himself up to take over VSL's supply and did so in such a way that he had unilateral control over when that takeover would occur. Through his trademark applications, he was poised to market that co-opted supply so as to capitalize on VSL's brand recognition. In essence, De Simone appears to have laid the groundwork to substitute himself for the corporation of which he was the chief executive officer. Such actions likely would violate De Simone's fiduciary duty as

an officer and director of VSL because it “would work injury to the corporation,” “deprive it of profit or advantage,” and constitute self-dealing. *Guth*, 5 A.2d at 510-11.

De Simone’s only explanation for his actions is that he was concerned that the Cavazzas would steal the Know-How and use it to create a diluted, cheaper probiotic that they would continue to market as VSL#3. He thus casts his actions as an effort to ensure that the original VSL#3 formula remained on the shelves and available for consumers, many of whom suffer from serious diseases. But the Cavazzas alleged bad intentions, and De Simone’s purported good intentions, do not absolve De Simone of his fiduciary duty to VSL, an entity that is legally distinct from the Cavazzas. While De Simone remained CEO, he owed VSL his “undivided” loyalty. *Guth*, 5 A.2d at 510. VSL has thus established a likelihood of success on the merits on its breach of fiduciary duty claim.

### **C. Corporate Records**

VSL alleges that when he left the company, De Simone improperly took VSL’s corporate records and has thereby deprived VSL of the ability to manage and operate the business. VSL also asserts that the computers in the office of CD Investments now contain virtually no files, and that two of them had been connected to a dropbox assigned to De Simone. VSL concludes that De Simone’s removal and retention of corporate records constitutes conversion.

A cause of action for conversion requires proof that a party engaged in “a distinct act of ownership or dominion exerted by one person over the personal property of another in denial of his right or inconsistent with it” and that it had “an intent to exercise dominion or control over the goods which is in fact inconsistent with the plaintiff’s rights.” *Darcars Motors of Silver Spring, Inc. v. Borzym*, 841 A.2d 828, 835-36 (Md. 2004). The act of ownership “can occur either by initially acquiring the property or by retaining it longer than the rightful possessor

permits.” *Id.* Here, VSL has offered evidence in the form of an affidavit by VSL Director James Brady that De Simone has not returned VSL records in his possession despite repeated requests for their return. VSL has also provided a report from a forensics company regarding the lack of files on the computers at the CD Investments office.

In De Simone’s 32-page affidavit attached as an exhibit to his Opposition to the Motion for a Preliminary Injunction, De Simone addressed the corporate records issue by labeling VSL’s attempt to secure the return of records as an effort to obtain evidence for litigation purposes and a “fishing expedition.” He also asserted that “the Cavazzas had access to all of VSL, Inc.’s financial information for nearly the entire history of the company’s existence.” Notably, however, De Simone does not deny the allegations that he removed corporate records.

Although VSL’s evidence is not unassailable, particularly where there has been no evidence offered that VSL corporate records were stored on the computers of CD International, De Simone’s failure to deny that he currently possesses VSL corporate records indicates that VSL is likely to prevail on the conversion claim. Moreover, the removal of company records by an officer and director likely constitutes another form of breach of fiduciary duty because it imposes a harm on the company. *See Guth*, 5 A.2d at 510 (stating that officers and directors must “refrain from doing anything that would work injury to the corporation”). Accordingly, VSL has shown a likelihood of success on the merits of its claim that DeSimone has improperly retained corporate records.

#### **D. Trademark Infringement**

VSL asserts that ExeGi’s original press release, website depiction of Visbiome packaging, and product leaflet (collectively, the “Visbiome materials”) repeatedly violated the VSL#3 trademark in violation of the Lanham Act, 15 U.S.C. 1051 *et seq.* In its Motion, VSL

described the Visbiome materials and the ways in which they infringed the VSL#3 trademark. In response to VSL's concerns, ExeGi altered its Visbiome marketing materials, but did not concede that the original materials infringed VSL's trademark. VSL acknowledges that those changes "lessen the egregiousness of ExeGi's infringement," but asserts that the altered materials "continue to willingly infringe." VSL Reply to Resp. in Opp'n Mot. Prelim. Inj. at 21. VSL does not explain what it finds objectionable about the altered materials, but nevertheless asks the Court to enjoin ExeGi from continuing to infringe the VSL#3 trademark and falsely represent ExeGi's product in connection with, or as equivalent, to VSL#3.

Although ExeGi has voluntarily altered the Visbiome materials, the question of whether the original packaging violated the VSL#3 trademark is not moot. *See Knox v. Service Employees Intern. Union, Local 1000*, \_\_\_ U.S. \_\_\_, 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."). The Court thus analyzes whether the original Visbiome materials infringed on VSL's trademark.

To prevail on its trademark infringement claim, VSL must show (1) that its mark was used in commerce by ExeGi without VSL's consent "in connection with the sale, offering for sale, distribution, or advertising of any goods," and (2) that the unauthorized use was likely to cause confusion. *See* 15 U.S.C. § 1114(1)(a). On the first element, use in commerce, the uncontested facts establish that the original Visbiome materials, particularly the product leaflet, described Visbiome, multiple times, as the "Original Formula VSL#3 Probiotic Blend" or "Visbiome/VSL#3 blend," without indicating that "VSL#3" was a registered trademark belonging to VSL. Mot. Prelim. Inj. Ex. 31, ECF No. 55-31. ExeGi also featured images of the



original Visbiome packaging on its website with the description “Original Formula VSL#3 Probiotic Blend.” *Id.* That website included a link to a form that customers could fill out “to be alerted when Visbiome becomes available.” VSL Ans. & Countercl. Ex. 36, ECF No. 9-36. Thus, while ExeGi has yet to actually sell any Visbiome, it has publicly advertised those goods on its website and has used the VSL#3 trademark in that advertising. Because the Lanham Act does not require actual sales of an allegedly infringing product, only the “advertising of any goods” that allegedly infringe, the “use in commerce” element appears to be satisfied. *See Bertolli USA, Inc. v. Filippo Bertolli Fine Foods, Ltd.*, 662 F. Supp. 203, 205 (S.D.N.Y. 1987) (finding that although the alleged infringer’s product had “not been advertised or sold to the general public,” because two samples of the product had been sent to distributors and “labels and cartons” for the product had been printed, the product had been “use[d] in commerce” within the meaning of the Lanham Act). Furthermore, ExeGi plans to bring Visbiome to the market in just over a month using packaging that VSL asserts continues to infringe the VSL#3 trademark. Because actual sales of Visbiome are imminent, VSL’s request for a preliminary injunction arising from its trademark infringement claim is ripe. *See Commonwealth of Pennsylvania v. State of West Virginia*, 262 U.S. 553, 593 (1923) (“One does not have to await the consummation of threatened injury to obtain preventive relief. If the injury is certainly impending, that is enough.”).

On the second element of whether that allegedly infringing use was likely to cause confusion, the Fourth Circuit has identified nine factors that courts may consider when determining whether an allegedly infringing use of a trademark is likely to cause confusion: (1) the distinctiveness of the allegedly infringed mark, (2) the similarity of the new mark to the allegedly infringed mark, (3) the similarity of the goods or services that the marks identify, (4)

the similarity of the facilities employed by the parties to transact their business, (5) the similarity of the advertising used by the parties, (6) the defendant's intention in adopting the same or similar mark, (7) actual confusion, (8) the quality of the defendant's product, and (9) the sophistication of the consuming public. *Sara Lee Corp. v. Kayser-Roth Corp.*, 81 F.3d 455, 463-64 (4th Cir. 1996). As the Fourth Circuit has recognized, "[c]ertain factors may not be germane to every situation," and "some factors may, depending on the case, be more important to others." *Id.* Here, the alleged infringement turns on the second, third, and sixth factors: the similarity of the two marks, the similarity of the goods, and the defendant's intention in employing the mark "VSL#3."

Evaluating the original Visbiome materials through the lens of those three factors, VSL appears likely to succeed in establishing that the use of the trademark "VSL#3" was likely to confuse consumer and therefore infringed VSL's trademark rights. On the second factor, the Visbiome materials used descriptive phrases that actually incorporated the VSL#3 trademark, such as "Original Formula VSL#3 Probiotic Blend," and "Visbiome/VSL#3 blend," without clearly distinguishing Visbiome and VSL#3 as different products or brands. At the same time, on the third factor, the products were substantially similar if not identical: both are probiotics derived from the same Know-How and the same manufacturer. Although some of the uses of "VSL#3" in the Visbiome materials arguably could be deemed "fair use," the two phrasings "Original Formula VSL#3 Probiotic Blend" and "Visbiome/VSL#3 blend" are not used simply to describe the goods in a fair manner, but rather unfairly obfuscate the fact that Visbiome and VSL#3 are offered for sale by different companies. 15 U.S.C. 1115(b)(4); *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).

As for the sixth factor, the Visbiome materials are not only likely to cause confusion, but are also intended to cause confusion, in order to enable Visbiome to “profit from [VSL#3’s] reputation.” *Pizzeria Uno Corp. v. Temple*, 747 F.2d 1522, 1535 (4th Cir. 1984). De Simone, in his account of the events that led him to part ways with VSL and to partner with ExeGi, essentially admitted that the purpose of bringing Visbiome to market was to ensure, in light of the perceived threat that VSL#3 would be diluted and adulterated by the Cavazzas, that the original VSL#3 remained available to consumers, albeit under a different name. The original Visbiome materials strongly reflect this perceived continuity between VSL#3 and Visbiome, so much so that it is difficult to discern that these are two different brands. *See id.* (noting that “[t]he intent of the defendant is sometimes a major factor in infringement cases” because an “intent to confuse ... is strong evidence establishing likelihood of confusion”). VSL has therefore made a clear showing that it is likely to succeed on its claim that the original Visbiome materials infringed the VSL#3 trademark.

As for VSL’s claim that the altered packaging continues to infringe the VSL#3 mark, the Court must defer its decision. The Court may not have the current packaging, and the parties have not fully briefed the issue of infringement involving the altered packaging and marketing materials, including whether the altered materials’ references to VSL#3 are permitted under the law as fair use. The Court thus lacks adequate information to make a determination on this aspect of the trademark infringement claim. The Court will return to this issue after supplemental briefing by the parties, on terms and on a schedule set forth in the accompanying Order.

### **III. Likelihood of Irreparable Harm**

Having found a likelihood of success on the merits on three of VSL's claims, breach of fiduciary duty, conversion, and trademark infringement, the Court will evaluate the remaining *Winter* factors as to those claims. 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 969, 975 (2d Cir. 1989)).

#### **A. Breach of Fiduciary Duty**

VSL has clearly demonstrated that it is likely to succeed on its claim that De Simone breached his fiduciary duty to VSL by setting himself up to usurp VSL's supply of VSL#3. On the issue of irreparable harm, VSL asserts that De Simone's present plan to instruct Danisco to cut off supplies to VSL as of September 23, 2015, a plan De Simone can implement because of his apparent self-dealing in entering into the 2014 Supply Agreement, will mean that VSL#3, the core of VSL's business and its only profitable product, will be off the shelves by the end of December. While VSL has apparently found a new manufacturer, the earliest the manufacturer will be able to start production is January 2016. Because it takes 8 to 12 weeks to manufacture the product, VSL thus faces the possibility of a three-month period where its only profitable product is not on store shelves. That three-month period will also largely overlap with the launch of Visbiome, which ExeGi believes will be ready for market as early as late October. De Simone and ExeGi are thus poised to launch their competing product just as VSL#3 disappears from store shelves, leaving consumers with no choice but to turn to Visbiome.

Under these facts, there is a substantial likelihood that, if and when VSL#3 is back on the shelves, some of those consumers will never switch back, and that, as a result of the disruption in supply, VSL will lose the goodwill of some of its customers, particularly those who, as De Simone and ExeGi point out, depend on VSL#3 to manage serious and chronic conditions. Under these circumstances, VSL has established that it is likely to suffer irreparable harm as a result of De Simone's self-dealing and usurpation of its supply of VSL#3. See *Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 552 (4th Cir. 1994) (stating that the "threat of a permanent loss of customers to a competitor and the potential loss of goodwill" can support a finding of irreparable harm), *abrogated on other grounds by Winter*, 555 U.S. 7 (2008); *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Bradley*, 756 F.2d 1048, 1055 (4th Cir. 1985) (holding that the district court's issuance of a preliminary injunction was not an abuse of discretion in part because the movant "faced irreparable, noncompensable harm in the loss of its customers"); *Blackwelder Furniture Co. of Statesville, Inc. v. Seilig Mfg. Co., Inc.*, 550 F.2d 189, 197 (4th Cir. 1977) (holding that the district court's finding that the movant would suffer no irreparable harm was erroneous because "[t]he harm posed to [a company's] general goodwill by its inability to fill outstanding and accumulating orders ... is incalculable"), *abrogated on other grounds by Winter*, 555 U.S. 7 (2008).

#### **B. Corporate Records**

Having established a likelihood of success on its conversion of corporate records claim, VSL asserts that it will be irreparably harmed if De Simone is not immediately ordered to return VSL company records because VSL will be unable to operate the company. Although the removal of certain corporate records by an outgoing officer or director would not ordinarily cause irreparable harm, in this instance, when De Simone and Park departed the company, VSL

lost its entire management team and apparently lost a substantial amount of corporate records. The remaining director, Brady, joined the Board in September 2014, so there is little to no institutional memory still with VSL. Without company records, VSL likely will be unable to operate effectively, a handicap that is particularly problematic at the moment, since VSL faces the loss of its original supplier and the launch of a direct competitor company. Given the clear efforts by De Simone to deprive VSL of its supply chain, VSL is at a crucial crossroads and faces the real possibility that it may not survive as a going concern if it is not managed effectively over the next several months. Under these circumstances, the Court finds a likelihood of irreparable harm. *Cf. Wisdom Imp. Sales Co. v. Labatt Brewing Co.*, 339 F.3d 101, 114-15 (2d Cir. 2003) (“Conduct that unnecessarily frustrates efforts to obtain or preserve the right to participate in the management of a company may . . . constitute irreparable harm.”).

However, the request for an injunction requiring De Simone to return all corporate records is overbroad. Not every VSL company record is necessary to keep the company operational. In particular, historical records relating to past activities are unlikely to impact current operations. Thus, to the extent there has been a showing of a likelihood of irreparable harm, it relates only to those records essential to allow VSL to function as a going concern.

### **C. Trademark Infringement**

VSL has also clearly demonstrated that it is likely to succeed on its claim that ExeGi infringed the VSL#3 trademark through the original Visbiome marketing materials because those materials were likely to create confusion between the VSL#3 and Visbiome brands. They also have established a likelihood of irreparable harm because in trademark infringement cases, “a presumption of irreparable injury is generally applied once the [movant] has demonstrated a likelihood of confusion.” *Scotts Co. v. United Industries Corp.*, 315 F.3d 264, 273 (4th Cir.

2002). Other than generally denying that the Visbiome materials infringed the VSL#3 trademark, ExeGi has presented no evidence to rebut that presumption. Thus, VSL has satisfied the irreparable harm prong.

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

VSL has also satisfied, for the breach of fiduciary duty, corporate records, and trademark infringement claims, the two remaining preliminary injunction factors: whether the balance of equities tips in favor of the moving party, and whether an injunction is in the public interest.

##### **A. Breach of Fiduciary Duty**

On the breach of fiduciary duty claim, the equities weigh in VSL's favor. VSL has provided strong evidence that De Simone, while still CEO of VSL, engaged in self-dealing by positioning himself to usurp VSL's supply of VSL#3 through the self-serving 2014 Supply Agreement and his orchestration of a change of control at VSL that justified early termination of the 2010 Know-How Agreement. As a result of that breach of fiduciary duty, De Simone is able to, and intends to, cut off VSL's supply of VSL#3 as of September 23, 2015, over four months before the original January 31, 2016 expiration date of the 2010 Know-How Agreement. Meanwhile, De Simone, together with ExeGi, will then divert that supply to their new venture, enabling them to launch Visbiome while potentially crippling VSL. Equity demands that De Simone not be allowed to so profit from his apparent self-dealing. For much the same reason—that people should not profit from their bad acts—the public interest weighs in favor of VSL. *See Fed. Trade Comm'n v. Sinclair Refining Co.*, 261 U.S. 463, 476 (1923) (remarking, in the context of securities regulation, on the “public interest” in “securing fair opportunity for the play of the contending forces ordinarily engendered by an honest desire for gain”).

## **B. Corporate Records**

VSL has also shown that the balance of equities and consideration of the public interest support an injunction to require to the return of those corporate records necessary to allow for the operation of its business. While a failure to return such records could jeopardize the economic viability of VSL, there would be no adverse effect on De Simone, other than the continued existence of a competitor to ExeGi, an impact that he has no right to avoid. The public interest is benefited by having corporations continue to operate in the marketplace, particularly companies offering products designed to promote health, and would be adversely affected if individual officers or directors were permitted to remove corporate records, for competitive reasons, that are necessary to continue such operations.

## **C. Trademark Infringement**

The equities and the public interest also weigh in VSL's favor on the trademark infringement claims relating to the original Visbiome materials. As discussed above, those materials failed to draw adequate distinctions between the Visbiome brand and the VSL#3 brand, and thus made it likely that consumers would confuse one for the other, enabling Visbiome to profit from its unauthorized use of the VSL#3 mark. Equity again demands that ExeGi not be allowed to so profit from its apparent infringement. Nor is it in the public interest to let that apparent infringement continue. One of the purposes of trademarks is "to protect purchasers from being misled as to the identity of the enterprise from which goods and services are obtained," which is precisely the harm threatened here. *AMP Inc., v. Foy*, 540 F.2d 1181, 1185 (4th Cir. 1976).



## V. Injunctive Relief

On the four claims at the core of the Motions for Preliminary Injunction, VSL and Sigma-Tau have failed to make a showing that they are likely to succeed on their misappropriation of trade secrets claim and therefore are not entitled to have this Court enjoin De Simone and ExeGi from moving forward with the production of Visbiome.

As for the remaining three claims, VSL and Sigma-Tau have adequately established that they are entitled to preliminary injunctive relief. VSL has sufficiently shown that De Simone likely breached his duty to VSL by setting himself up to usurp VSL's supplies of VSL#3 by executing the 2014 Supply Agreement and then terminating the 2010 Know-How Agreement. VSL and Sigma-Tau are thus entitled to have this Court enjoin De Simone from cutting off that supply before January 31, 2016, the date that 2010 the Know-How Agreement was scheduled to expire in the absence of De Simone's self-dealing.

VSL is also entitled to a preliminary injunction relating to corporate records, but the Court will limit the injunction to require the return of only those records essential to the day-to-day operation of the company, because those are the only records for which there is a likelihood of irreparable harm. The procedures for determining which documents De Simone must return are set out in the accompanying Order.

Finally, because VSL has adequately demonstrated that the original Visbiome materials likely infringed the VSL#3 mark, they are entitled to have this Court enjoin ExeGi from using the original Visbiome materials, and from using the phrasing "Original Formula VSL#3 Probiotic Blend" and "Visbiome/VSL#3 blend." As for Visbiome's current packaging and marketing materials, ExeGi will be temporarily enjoined from using the "VSL#3" mark in its packaging or marketing materials, to enable the Court to entertain supplemental briefing, as

described in the accompanying Order, on any alleged trademark infringement arising from those materials.

## **VI. Bond**

Under Federal Rule of Civil Procedure 65, a court may issue a preliminary injunction “only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained.” Fed. R. Civ. P. 65(c). In order to ensure that there are funds to compensate De Simone and ExeGi should they successfully establish that the preliminary injunction should not have issued, and that they wrongfully sustained damages as a result of the injunction, the Court requires VSL and Sigma-Tau to post a bond of \$250,000. The injunction will go into effect only once that bond has been posted.

## **CONCLUSION**

For the reasons set forth above, VSL’s Motion for a Preliminary Injunction, ECF No. 55, and Sigma-Tau’s Motion for a Preliminary Injunction, ECF No. 61, are GRANTED IN PART and DENIED IN PART. Specifically, the Motions are DENIED as to the requests that (1) De Simone be enjoined from imparting the Know-How to others, and that (2) De Simone and ExeGi be enjoined from using the Know-How. The Motion is GRANTED as to the requests that (1) De Simone be enjoined from interrupting VSL’s supply of VSL#3, to the extent that De Simone must allow VSL to obtain supply from Danisco through January 31, 2016, the original expiration date of the 2010 Know-How Agreement; (2) De Simone be required to return VSL corporate records, but only with respect to records essential to the day-to-day operations of the business; and (3) ExeGi be enjoined from using its original Visbiome marketing materials and the identifiers “Original Formula VSL#3 Probiotic Blend” and “Visbiome/VSL#3 blend.” In

addition, ExeGi is enjoined for 21 days from using the “VSL#3” mark on any Visbiome materials, to enable the Court to consider supplemental briefing on the trademark infringement issue relating to ExeGi’s revised marketing materials. A separate Order follows.

Date: September 23, 2015

  
THEODORE D. CHUANG  
United States District Judge