

**UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND**

CLAUDIO DE SIMONE and
EXEGI PHARMA, LLC,

Plaintiffs/Counterclaim Defendants,

v.

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

Defendants/Counterclaim Plaintiffs,

v.

DANISCO USA, INC.,

Counterclaim Defendant.

Civil Action No. TDC-15-1356

MEMORANDUM OPINION

Plaintiffs and Counterclaim Defendants Claudio De Simone and ExeGi Pharma, LLC (“ExeGi”) (collectively, “the De Simone Parties”) have filed a Motion for Summary Judgment seeking summary judgment on all of their claims and all counterclaims asserted by Defendants and Counterclaim Plaintiffs VSL Pharmaceuticals, Inc. (“VSL”), Lediand Biosciences, Inc. (“Lediand”) and Alfasigma USA, Inc. (“Alfasigma”) (collectively, “the VSL Parties”). The VSL Parties; in turn, have filed a consolidated Cross Motion for Partial Summary Judgment. Having reviewed the submitted materials, the Court finds no hearing necessary. *See* D. Md. Local R. 105.6. For the reasons set forth below, the De Simone Parties’ Motion for Summary Judgment is GRANTED IN PART and DENIED IN PART, and the VSL Parties’ Cross Motion for Partial Summary Judgment is GRANTED IN PART and DENIED IN PART.

This case centers on disputes among the parties relating to the formulation used in a probiotic known by the tradename VSL#3 and the “Know-How,” developed by De Simone, consisting of a unique biochemical profile, formulae, processes, data, and other technical and non-technical information. Broadly speaking, the parties disagree on which party owns the Know-How; whether De Simone, as the Chief Executive Officer (“CEO”) of VSL, breached a fiduciary duty as he departed the company to launch Visbiome, a probiotic using the same formulation then found in VSL#3 (“the De Simone Formulation”); whether De Simone and his new company, ExeGi, infringed the VSL#3 trademark owned by VSL while launching and marketing Visbiome; and whether either side has engaged in false advertising as each seeks to market the competing probiotics.

Relevant factual background is set forth in the Court’s September 23, 2015 Memorandum Opinion on the First Motion for a Preliminary Injunction, *De Simone v. VSL Pharm., Inc.*, 133 F. Supp. 3d 776, 780-88 (D. Md. 2015), and the June 20, 2016 Memorandum Opinion on the Second Motion for a Preliminary Injunction, *De Simone v. VSL Pharm., Inc.*, No. TDC-15-1356, 2016 WL 3466033 at *1-12 (D. Md. June 20, 2016). Additional facts and procedural history are provided below as necessary.

DISCUSSION

Following the Court’s ruling on the parties’ Motions to Dismiss, the remaining claims generally consist of: (1) claims relating to the ownership of the Know-How; (2) claims relating to the alleged breach of fiduciary duty owed to VSL by De Simone; (3) claims relating to sales of VSL#3 by VSL between 2014 and 2016, after De Simone resigned from VSL; and (4) trademark infringement and false advertising claims under the Lanham Act, 15 U.S.C. §§ 1051–1141n

(2012). The De Simone Parties seek summary judgment on all claims asserted by all parties in this case. The VSL Parties seek summary judgment on the following claims relating to the ownership of the Know-How, the alleged breach of fiduciary duty, the 2014-2016 sales of VSL#3, and ExeGi's claim of false advertising: Counts I, III, IV, V, and VI of the De Simone Parties' currently operative Complaint ("the Complaint"); Counts I, IV, and XXVIII of VSL's currently operative Counterclaim ("the VSL Counterclaim"); Counts I and II of Leadiant's currently operative Counterclaim ("the Leadiant Counterclaim"); and Counts III and IV of Alfasigma's currently operative Counterclaim ("the Alfasigma Counterclaim"). The VSL Parties seek partial summary judgment on the following claims relating to the alleged breach of fiduciary duty, trademark infringement, and false advertising, consisting of: VSL's Counts XXI and XXII; Leadiant's Counts IV, V, VI, VII, and VIII; and Alfasigma's Counts I and II.

I. Legal Standard

Under Federal Rule of Civil Procedure 56, the Court grants summary judgment if the moving party demonstrates that there is no genuine issue as to any material fact, and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). In assessing the Motion, the Court must believe the evidence of the non-moving party, view the facts in the light most favorable to the nonmoving party, and draw all justifiable inferences in its favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

The nonmoving party has the burden to show a genuine dispute on a material fact. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986). "A material fact is one that might affect the outcome of the suit under the governing law." *Spriggs v. Diamond Auto Glass*, 242 F.3d 179, 183 (4th Cir. 2001) (quoting *Anderson*, 477 U.S. at 248). A

dispute of material fact is only “genuine” if sufficient evidence favoring the nonmoving party exists for the trier of fact to return a verdict for that party. *Anderson*, 477 U.S. at 248–49.

“When faced with cross-motions for summary judgment, the court must review each motion separately on its own merits ‘to determine whether either of the parties deserves judgment as a matter of law.’” *Rossignol v. Voorhaar*, 316 F.3d 516, 523 (4th Cir. 2003) (quoting *Philip Morris, Inc. v. Harshbarger*, 122 F.3d 58, 62 n.4 (1st Cir. 1997)).

II. The Know-How Claims

A. Prior Rulings

As part of the First Motion for a Preliminary Injunction, VSL asserted that the Know-How associated with the De Simone Formulation is a trade secret and that VSL owns that secret. VSL traced its claim of ownership to the Mendes Assignment, a September 2000 agreement between VSL and Mendes SRL (“Mendes”), a company owned by De Simone. The Mendes Assignment was signed by De Simone on behalf of Mendes and VSL Chief Financial Officer Antonio Nicolai on behalf of VSL. That agreement transferred to VSL the trademark rights for the term “VSL#3.” It also transferred “any and all rights to any intellectual property owned or licensed by [Mendes] and which relates to” the VSL#3 trademark, as well as “proprietary information,” including “trade secrets” and “know-how” relating to the VSL#3 trademark. *De Simone*, 133 F. Supp. 3d at 790.

In adjudicating whether VSL was likely to succeed on its claims of ownership of the Know-How, the Court found that the language of the Mendes Assignment was ambiguous because it did not “clearly establish that the Know-How relates to the VSL#3 trademark,” such that extrinsic evidence of the parties’ intent needed to be considered. *Id.* Evaluating the available extrinsic evidence, the Court found that other agreements between the parties provided

“specific evidence” that the Mendes Assignment did not transfer the Know-How to VSL. *Id.* at 792. In particular, the 1999 Option Agreement between De Simone and Sigma-Tau Pharmaceuticals, Inc., (“Sigma-Tau”), Leadiant’s predecessor-in-interest, explicitly stated that De Simone had granted to Sigma-Tau an option for an exclusive license relating to the Know-How and thus demonstrated that when De Simone wished to convey rights in the Know-How, he did so expressly, rather than by implication. *Id.* at 792–93. The 1999 Option Agreement also established that as of November 1999, De Simone himself, not Mendes, continued to own the Know-How. *Id.* The Court found that because the Assignment transferred only intellectual property owned or licensed by Mendes, the Know-How could be included in the sweep of the Mendes Assignment only if there were evidence that in the brief period between the 1999 Option Agreement and the 2000 Mendes Assignment, De Simone had conveyed the Know-How to Mendes. *Id.* No such evidence was presented to the Court on that Motion. *Id.* at 793.

The Court also found that the 2001 Patent License Agreement, in which De Simone granted to VSL a license to the patent underlying the De Simone Formulation (“the 615 Patent”), contradicted VSL’s broad characterization of the intellectual property transferred through the Mendes Assignment. *Id.* As the Court noted, if VSL’s reading of the intended scope of the Mendes Assignment were correct, the patent would have been swept up in it, leaving the parties with no need the following year for De Simone to agree to license the patent to VSL. *Id.* at 792–93. Other, later agreements referenced by the parties did not warrant a different conclusion. *Id.* at 793–94.

Furthermore, considering documentary evidence relating to the VSL#3 trademark, the Court noted that at the time of the Mendes Assignment, VSL#3 was an “unattached signifier” not firmly linked to a probiotic using the De Simone Formulation, such that “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.” *Id.* at 791.

Finally, the Court was unpersuaded by VSL’s argument, made at the hearing on the First Motion for a Preliminary Injunction, that the Know-How necessarily had to be transferred with the VSL#3 trademark because one cannot practice a trademark without its associated goodwill, and that goodwill includes “scientific formulations and methodology such as the Know-How.” *Id.* at 791–92. The Court found no support for that argument in the law, and noted that, regardless, at the time of the Mendes Assignment there was not yet a product branded VSL#3, and thus there could be no goodwill associated with the mark. *Id.* at 792.

In their Motion to Dismiss VSL’s Counterclaim, the De Simone Parties returned to the issue of the Know-How and argued that the Court should decide the question on the pleadings as a matter of law. In declining to do so, the Court explained that although on the First Motion for a Preliminary Injunction it had considered certain extrinsic evidence such as the additional agreements discussed above, it could not be certain that “those materials constitute the only relevant extrinsic evidence” on whether the Mendes Assignment transferred the Know-How to VSL. The Court thus allowed the case to proceed to discovery on that question. *De Simone v. VSL Pharm., Inc.*, No. TDC-15-1356, 2017 WL 66323 at *4 (D. Md. Jan. 7, 2017).

B. Discovery Evidence

Discovery has produced no additional direct evidence of the parties’ intent on whether the Mendes Assignment transferred ownership of the Know-How to VSL. In his deposition, Luca Guarna, VSL’s corporate representative, reiterated the company’s position that VSL owns the Know-How and traces its entitlement to the Know-How to the Mendes Assignment. As for evidence to support VSL’s interpretation of the parties’ intent in the Mendes Assignment and the

other relevant agreements, Guarna admitted that VSL does not have “any other source of information apart from the text of those contracts,” but asserted that “the content of these contracts were very, very clear” and thus should be the source for “what the intentions of the various parties were.” Joint Record (“J.R.”) 134. More generally, Guarna asserted that the Know-How was “valuable” but he stopped short of stating that it was a trade secret, explaining that whether something was a trade secret was a legal determination he did not have the training to make. J.R. 138.

As for circumstantial evidence of the parties’ intent, over the De Simone Parties’ objection, VSL has submitted the Declaration of Mauro Bove, the former Chief Operating Officer of VSL. Bove participated in numerous aspects of the original commercialization of VSL#3. Presumably based on that involvement, he states that “[i]n 2000, when VSL was formed, all of the parties to the various agreements fully understood that any reference to VSL#3 referred to an already existing product that was called ‘VSL#3’ and would be sold by VSL under the ‘VSL#3’ trademark.” J.R. 2463. Asserting that VSL#3 had already been the subject of various clinical studies, he concludes that it is “incorrect to say that the parties did not know to what they were referring in listing VSL#3 in the schedule of the Mendes Assignment Agreement.” *Id.* He further asserts that the 615 Patent is “broader than just the VSL#3 product alone.” J.R. 2464.

The VSL Parties also cite to De Simone’s June 2000 U.S. trademark application for the mark “VSL#3.” In that application, De Simone stated his “bona fide intention” to use the mark VSL#3 in U.S. commerce and defined the product to which the mark VSL#3 would be attached as “pharmaceutical, veterinary and sanitary preparations; dietetic substances adapted for medical use, food for babies; nutraceuticals; food supplements.” J.R. 2459. The VSL Parties also

reference two clinical studies of VSL#3, one published in 1999 and one in 2000. Finally, the VSL Parties include in the record, over the De Simone Parties' objection, a November 1, 2000 letter from Dr. R. Balfour Sartor to Antonio Croppo of Sigma-Tau and an accompanying proposed consulting agreement. Through that consulting agreement, Sigma-Tau retained Dr. Balfour Sartor to conduct a study as part of the "scientific development" of VSL#3. J.R. 3719. The stated estimated completion date for that study was October 2001. In the letter, Dr. Balfour Sartor reported that he and De Simone had "begun" their study into VSL#3 and wished Sigma-Tau and VSL "the very best in your development of VSL #3." J.R. 3718.

The De Simone Parties, in turn, cite an April 2, 2002 Letter of Intent, relating to the export of VSL#3 outside the United States, signed by De Simone and Nicolai. In that letter, De Simone describes VSL#3 as a product "manufactured according to my know how and patent licensed to VSL." J.R. 420.

C. Ownership of the Know-How

VSL maintains that the language of the Mendes Assignment plainly transfers the Know-How to VSL. The Court previously rejected that argument and instead found that the Mendes Assignment was ambiguous on the question of whether the reference to the transfer of the VSL#3 trademark from De Simone to VSL implicitly transferred ownership of the Know-How as well. *De Simone*, 133 F. Supp. 3d at 790. VSL cites no new facts or legal authority on this point, so the Court does not revisit its prior determination as to the ambiguity of the Mendes Assignment. On summary judgment, when a court "determines as a matter of law that the contract is ambiguous, it may yet examine evidence extrinsic to the contract that is included in the summary judgment materials, and, if the evidence is, as a matter of law, dispositive of the interpretative issue, grant summary judgment on that basis." *Washington Metro. Area Transit*

Auth. v. Potomac Inv. Properties, Inc., 476 F.3d 231, 235 (4th Cir. 2007). The Court thus turns to extrinsic evidence of the parties' intent.

Although the parties have submitted additional evidence collected through discovery, the most persuasive extrinsic evidence on the proper interpretation of the Mendes Assignment remains the 1999 Option Agreement and the 2001 Patent Agreement. These agreements bookend the Mendes Assignment and so are particularly probative on the issue of how the parties understood and defined the multiple forms of intellectual property involved in these contractual relationships. Indeed, VSL's corporate representative acknowledged that the language of the parties' various agreements is the best source for the parties' intentions. The Court reaffirms its previous analysis of these agreements:

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. 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, rather than rely on broad definitions of generic terms to effect such a conveyance. ...

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.

De Simone, 133 F. Supp. 3d at 792–93 (internal citations omitted). The various other agreements previously offered by VSL, including the 2002 Confidential Disclosure Agreement, do not alter this analysis. *See id.* at 793-94. Rather, it is bolstered by an additional document offered by De Simone, a 2002 Letter of Intent signed by De Simone and Nicoli, in which De Simone states that he authorizes VSL to “sell and export US product which is manufactured according to *my know how* and patent licensed to VSL.” J.R. 420 (emphasis added). Where this letter was signed by the same individuals who signed the Mendes Assignment, the characterization of the Know-How as belonging to De Simone is consistent with the conclusion that the parties’ did not understand the Mendes Assignment to have transferred ownership of the Know-How to VSL. Finally, the Court’s interpretation is consistent with the numerous later documents in which De Simone’s continuing ownership of the De Formulation or the Know-How are referenced, including the 2006 Confidential Disclosure Agreement that was signed by Maurizio Terenzi, a representative of VSL’s parent companies.

The additional evidence offered by VSL with its Motion fails to undermine the Court’s prior conclusion. The deposition testimony of Guarna, VSL’s corporate representative, establishes that there is no direct, extrinsic evidence of the parties’ intent in entering into the Mendes Assignment. VSL instead relies on the Bove Declaration, the clinical studies, and the 2000 trademark application to advance its argument that the transfer of the trademark VSL#3 was intended to include the transfer of the Know-How.

At a threshold level, the Bove Declaration’s assertions about the intent of the parties to the Mendes Assignment, such as the claim that “all of the parties to the various agreements fully understood that any reference to ‘VSL #3’ referred to an already existing product that was called

‘VSL#3’ and would be sold by VSL under the ‘VSL#3’ trademark,” are not competent evidence on the Motion. An affidavit submitted in support of a motion for summary judgment “must be made on personal knowledge [and] set out facts that would be admissible in evidence.” Fed. R. Civ. P. 56(c)(4). Where Bove was not a signatory to the Mendes Assignment, and thus is characterizing the intentions of other individuals on both sides of that transaction, he lacks personal knowledge of these assertions. To the extent that his knowledge is based on the statements of those other individuals to him, his statements would constitute inadmissible hearsay. *See* Fed. R. Evid. 801(c), 802 (stating that, except in certain situations not present here, hearsay is inadmissible at trial); Fed. R. Civ. P. 56(c)(2) (stating that parties may object to evidence submitted on summary judgment on the basis that it “cannot be presented in a form that would be admissible in evidence”); *Evans v. Tech. Applications & Serv. Co.*, 80 F.3d 954, 962 (4th Cir. 1996) (stating that Rule 56 requires that “affidavits submitted on summary judgment contain admissible evidence” and thus that they cannot be “based on hearsay”); *Md. Highways Contractors Ass’n, Inc. v. State of Md.*, 933 F.2d 1246, 1251–52 (4th Cir. 1991) (stating that “hearsay evidence, which is inadmissible at trial, cannot be considered on a motion for summary judgment”). VSL’s argument that the Declaration is admissible because, at trial, unnamed witnesses would provide direct testimony as to the parties’ intent is unpersuasive because it runs afoul of the plain language of Rule 56, which requires that declarations “be made on personal knowledge” and “show that the *affiant or declarant* is competent to testify on the matters stated.” Fed. R. Civ. P. 56(c)(4) (emphasis added).

Even if the Court were to consider Bove’s statements, they would not create a material dispute of fact on the parties’ intent. Read in the light most favorable to VSL, Bove’s statements establish, at most, that the trademark “VSL#3” was, at the time of the Mendes Assignment,

already associated with a product that VSL planned to bring to market. But the linking of the trademark “VSL#3” to a particular probiotic does not mean that transferring the trademark necessarily effected the transfer of all rights to the Know-How. VSL has already made, and this Court has already rejected, the argument that as a matter of trademark law, the Know-How necessarily travels with the trademark. *See De Simone*, 133 F. Supp. 3d at 791–92.

Finally, the additional evidence that De Simone filed a U.S. trademark application for VSL in 1999 and that there were clinical studies relating to VSL#3 before the Mendes Assignment does not provide a basis to alter the Court’s interpretation of the Mendes Assignment. The Court previously discussed the relevance of the VSL#3 trademark application and pre-Mendes Assignment studies of VSL#3 to the question whether the transfer of the trademark necessarily included transfer of the Know-How and found neither form of evidence to be probative. *See id.* Although the proffered studies provide more specific evidence that a probiotic known as VSL#3 was under study prior to the Mendes Assignment, they do not necessarily show that VSL#3 was a finished product understood to be synonymous with the trademark, much less that a transfer of the trademark would necessarily include a transfer of the specific Know-How underlying the present-day De Simone Formulation. Indeed, where Dr. Balfour Sartor was hired in November 2000 expressly to aid in the “scientific development” of “VSL#3,” J.R. 3719, it appears that VSL#3 continued to be in development after the Mendes Assignment was executed, thus illustrating the disjuncture between the Know-How and the trademark.

In the end, the most significant flaw in the additional evidence submitted by VSL is that it fails to show in any way that De Simone transferred the Know-How to Mendes prior to the Mendes Assignment. Regardless of what the parties believed the term “VSL#3” to mean, if

Mendes did not own the Know-How at the time of the Mendes Assignment, there is no way to read it as having transferred the Know-How to VSL.

Where the ambiguity of the Mendes Assignment can be resolved by consideration of other, contemporaneous agreements between the parties, specifically, the 1999 Option Agreement and the 2001 Patent License Agreement, and VSL provides no other evidence that fairly draws that interpretation into question, the Court finds those agreements to be “dispositive of the interpretative issue.” *Potomac Inv. Properties, Inc.*, 476 F.3d at 235. The Court thus concludes that, as a matter of contract interpretation, De Simone owns the Know-How.

D. Trade Secrets

Perhaps anticipating the Court’s ruling as to ownership of the Know-How, VSL has sought to re-formulate the question and argue that it should prevail on the Know-How claims because the Know-How was not, and is no longer, a trade secret. A trade secret consists of:

[I]nformation, including a formula, pattern, compilation, program, device, method, technique, or process, that:

- (1) Derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and
- (2) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Md. Code Ann., Com. Law § 11-1201(e) (West 2013); *see also Milgrim on Trade Secrets* Ch. 1, Definitional Aspects, § 1.01 (Matthew Bender 2018). To remain a trade secret, the information must remain “more or less, secret.” *Id.* § 1.03.

Beyond the obvious fact that this argument is squarely contradicted by VSL’s assertion in its pleadings that the Know-How is a trade secret and its allegation that De Simone has misappropriated a trade secret by using the Know-How, *see, e.g.*, VSL Countercl. ¶ 313, ECF

No. 153, the claim that the Know-How does not qualify as a trade secret is not supported by the record. The evidence does not establish that the Know-How is “readily ascertainable,” whether from the packaging of VSL#3 or Visbiome or from testing. Not only did VSL assert in its Counterclaim that the Know-How “is not commonly known or available to the public, is not readily ascertainable by proper means” and is “the subject of extensive efforts” to keep it secret, VSL Countercl. ¶ 315, but Luca Guarna, VSL’s corporate representative, described the Know-How as “a wide amount of information” that is “very complex” and has “value.” J.R. 137–38. In her deposition testimony, Dr. Mary Ellen Sanders stated that since the start of this litigation, she was retained by VSL to conduct a comparative analysis of VSL#3 and Visbiome, the results of which would be “helpful” in an effort to reverse engineer the composition of Visbiome. J.R. 3261. That some aspects of the De Simone Formulation may be publicly available does not render the Know-How readily ascertainable, nor can the Court draw such a conclusion when the record evidence establishes VSL’s own understanding of the complexity of the Know-How and its efforts to decipher that complexity.

More fundamentally, however, whether the Know-How presently remains an enforceable trade secret need not be decided to resolve the Know-How claims. The core issue on the Know-How claims is not whether the Know-How is currently a trade secret, but whether De Simone transferred ownership rights in the Know-How to VSL, and, if he did, whether as a result he is liable to VSL for misuse of rights owned by VSL. The claims for a declaratory judgment in Count I of the Complaint and Count I of VSL’s Counterclaim seek only a declaration on which party owns the rights to the Know-How, not whether the Know-How currently qualifies for protection as a trade secret and whether De Simone can presently enforce such rights against others. As discussed below, the De Simone Parties’ claim of misappropriation of trade secrets in

Count IV of the Complaint can be resolved without reaching this issue. *See infra* part IV.C. Thus, the Court need not evaluate VSL's eleventh-hour assertion that the Know-How lost protection as a trade secret upon the expiration of certain confidentiality agreements.

Accordingly, the De Simone Parties' Motion for Summary Judgment on Count I of the Complaint will be granted, and De Simone will be declared to be the owner of the Know-How. *See* 28 U.S.C. § 2201 (2012) (stating that "any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought). The De Simone Parties' Motion is also granted as to the declaratory judgment claims in Count I of the VSL Counterclaim, Count II of the Leadiant Counterclaim, and Count IV of the Alfasigma Counterclaim, which are all dismissed with prejudice. Because De Simone cannot be held liable for misappropriating intellectual property that he rightfully owned, and because ExeGi licensed the Know-How from De Simone, the VSL Parties' other claims based on their alleged ownership of the Know-How must also be dismissed. The De Simone Parties' Motion for Summary Judgment is therefore granted as to VSL's Counts IX, X, XI, XVII, XIX, and XX; and Leadiant's Count III, all of which are dismissed with prejudice. To the extent that the VSL Parties sought summary judgment on any of the above claims, their Motion is denied. The De Simone Parties' Motion for Summary Judgment is also granted in part as to (1) all claims within VSL's Count III except the claim relating to the 2014 Supply Agreement with Danisco USA, Inc., the U.S. manufacturer of VSL#3 ("the 2014 Danisco Supply Agreement"), which involves issues related to De Simone's fiduciary duty and thus cannot be resolved solely through an adjudication of ownership of the Know-How; and (2) all claims within Leadiant's Count I and Alfasigma's Count III, except those relating to trademark infringement.

III. The Fiduciary Duty Claims

VSL asserts that De Simone breached his fiduciary duty as CEO of VSL in a number of ways and has pleaded that breach as part of his claim for a declaratory judgment in Count III of the VSL Counterclaim and as three, additional separate claims: breach of fiduciary duty (Count IV), conspiracy (Count V), and fraud (Count VI). In the breach of fiduciary duty and conspiracy counts, VSL provides a non-exhaustive list of actions it believes amount to malfeasance on the part of De Simone, most of which relate to agreements by De Simone, in his personal capacity, to license the Know-How. In the fraud claim, VSL is more direct, citing three agreements that it asserts were fraudulent transactions designed to enable De Simone to supplant VSL in the marketplace as the supplier of VSL#3 or an equivalent probiotic: the January 2010 Know-How Agreement, an agreement between De Simone in his personal capacity and VSL granting VSL an exclusive license to the Know-How from the period beginning at the expiration of the 2001 Patent License Agreement until January 31, 2016 (“the 2010 Know-How Agreement”); a separate March 2010 Know-How Agreement between De Simone in his personal capacity and VSL granting VSL an exclusive license to distribute the De Simone Formulation in China; a similar 2007 Know-How Agreement relating to Canada; the 2008 Danisco Supply Agreement, between De Simone in his personal capacity and Danisco authorizing Danisco to use De Simone’s trade secrets consistent with various confidentiality requirements; and the 2014 Danisco Supply Agreement, between De Simone in his personal capacity and VSL, providing that if the 2010 Know-How Agreement were terminated, De Simone would take VSL’s place as the buyer of the supply of Danisco-produced VSL#3.

Under Delaware law, which controls the substantive issues on these claims, a corporate officer or director owes a fiduciary duty to the corporation and therefore must exhibit an “undivided and unselfish loyalty to the corporation,” such that there is “no conflict between duty and self-interest.” *Guth v. Loft, Inc.*, 5 A.2d 503, 510 (Del. 1939). 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. *See In re Walt Disney Co. Derivative Litigation*, 906 A.2d 27, 52 (Del. 2006). 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). Self-dealing, or “the rule of corporate opportunity,” includes usurping a corporate opportunity for oneself. *Guth*, 5 A.2d at 510–11.

A. Know-How Claims

To begin, to the extent that certain parts of the claims of breach of fiduciary duty, conspiracy, and fraud are premised on alleged self-dealing arising from De Simone’s improper appropriation of the Know-How, they are dismissed with prejudice because, as discussed above, De Simone owned the Know-How. Because self-dealing requires usurpation of an opportunity that could otherwise have been taken by the corporation, the rule of corporate opportunity is not implicated when “a business opportunity comes to a corporate officer or director in his individual capacity rather than in his official capacity, and the opportunity is one which, because of the nature of the enterprise, is not essential to his corporation, and is one in which it has no interest or expectancy.” *Guth*, 5 A.2d at 510–11. The Court has determined that De Simone rightfully possessed the Know-How, such that the opportunity to license it was necessarily presented to him in his individual capacity and was one in which VSL could have had no expectancy. *See Broz v. Cellular Info. Sys., Inc.*, 673 A.2d 148, 157 (Del. 1996) (“The teaching of *Guth* and its

progeny is that the director or officer must analyze the situation *ex ante* to determine whether the opportunity is one rightfully belonging to the corporation.”); *see also Science Accessories Corp. v. Summagraphics Corp.*, 425 A. 2d 957, 963 (Del. 1980) (holding that a corporate opportunity “was not an opportunity available to” the corporation but one that the defendants “could legally embrace as their own”). Accordingly, the Court will grant summary judgment to the De Simone Parties on the claims in VSL Counts III–VI relating to the formation of the 2008 Danisco Supply Agreement, the January 2010 Know-How Agreement, the March 2010 China Know-How Agreement, and the 2007 Canada Know-How Agreement.

B. Statute of Limitations

Outside of the claims based on the failed argument that De Simone did not own the Know-How, VSL’s breach of fiduciary duty, conspiracy, and fraud claims center on the claims that De Simone breached his fiduciary duty by (1) inserting into the 2010 Know-How Agreement a change-in-control provision that would allow him to terminate the agreement upon the resignation of two of the three directors of VSL; and (2) including in the 2014 Danisco Supply Agreement a provision that allowed him to take over VSL’s position as buyer of the supply of VSL#3 produced by Danisco upon the termination of 2010 Know-How Agreement. As to claims arising from the 2010 Know-How Agreement, the De Simone Parties assert they are time-barred.

While substantive issues on the fiduciary duty and related claims are controlled by Delaware law, procedural issues, such as the running of the statute of limitations, are governed by Maryland law. *See Sherwin-Williams Co. v. Artra Group, Inc.*, 125 F. Supp. 2d 739, 756–57 (D. Md. 2001) (stating that “the statute of limitations of the forum state applies even when that state’s choice-of-law rules require that another state’s substantive law be applied”); *Lewis v. Waletzky*, 31 A.3d 123, 133 (Md. 2011) (holding that Maryland law controls procedural matters

and that “statutes of limitations are procedural for choice-of-law purposes”). In Maryland, civil suits must be filed within three years from the date the action accrues. Md. Code Ann., Ct. & Jud. Proc. § 5-101 (West 2011). Here, VSL filed its original Counterclaim on June 2, 2015, so it can proceed on only those claims that accrued on or after June 2, 2012. In Maryland, a claim accrues when a litigant “in fact knew or reasonably should have known of the wrong.” *See Poffenberger v. Risser*, 431 A.2d 677, 680 (Md. 1981). However, “[i]f the knowledge of a cause of action is kept from a party by the fraud of an adverse party, the cause of action shall be deemed to accrue at the time when the party discovered, or by the exercise of ordinary diligence should have discovered the fraud.” Md. Code Ann., Cts. & Jud. Proc. § 5-203. VSL asserts that as a result of De Simone’s malfeasance, it did not learn of De Simone’s breach of fiduciary duty relating to the change-in-control provision of the 2010 Know-How Agreement until November 2014, when De Simone resigned as CEO of VSL. The De Simone Parties, however, contend that VSL was on notice of the 2010 Know-How Agreement by no later than September 2009, when it was discussed at a meeting of the VSL Board of Directors (“VSL Board”).

In support of this argument, the De Simone Parties rely on the minutes of the September 18, 2009 meeting of the VSL Board (“the Minutes”). As a preliminary issue, VSL objects to consideration of the Minutes because the submitted document is a copy of the Minutes, not the original, and claims that there are “suspicious inconsistencies in spacing and pagination” in these Minutes as compared to the minutes of other VSL Board meetings. VSL Cross-Mot. Summ. J. at 38, ECF No. 562. They also assert, incorrectly, that no notice of the meeting was produced. *See* J.R. 233. The fact that the original Minutes were not provided is not a basis to exclude the copy, “unless a genuine question is raised about the original’s authenticity.” Fed. R. Evid. 1003. However, VSL offers no evidence for its allegations of inauthenticity. Where the Minutes do not

appear to have been altered or modified in any way and bear the signature of the three VSL Directors at the time—De Simone, Dr. Bo Young “Beth” Park, and Maurizio Terenzi—the Court finds no reason to exclude the Minutes from the record. *See Kassel v. United States*, 319 F. App’x 558, 561 (9th Cir. 2009) (rejecting an argument of inauthenticity under Rule 1003 because the appellant “offered only an unsupported assertion of disbelief as to the authenticity of the documents”).

The Minutes reflect that on September 18, 2009, the VSL Board discussed the fact that VSL’s right to use the Know-How would terminate with the expiration of the 615 Patent in February 2015, and that in order for VSL to maintain its right to use the Know-How and to sell VSL#3 in the United States, a licensing agreement relating to the Know-How needed to be put in place. As to that agreement, the Minutes state:

De Simone clearly indicated that he will not accept any term longer than beyond January 31, 2016 to protect his interest as an inventor and owner of know-how (including trade secret) related to VSL#3. [De Simone] mentioned that he is already pressure[d] from SINAF and TAUFIN which he considers undue and unfair for the evident conflict of interest. He wants to reserve irrevocable right to terminate know-how license agreement by January 31, 2016 and protection in new license agreement (such as termination clause related to (i) the change of control of VSL, (ii) sales of trademark (VSL#3), (iii) breach of confidentiality, (iv) non payment/lack of performance and etc)[.] Mr. Terenzi expressed that the concerns from Prof. De Simone may be overstated. However, since Prof. De Simone (as a licensor) did not agree on longer term, the Board who can vote on this matter without conflict of interest (Maurizio Terenzi and Boyoung Park) agreed and voted unanimously to accept the terms (by the end of January 2016) and royalty at 5% of sales (sale as defined in the current agreement). The Board who can vote on this matter without conflict of interest agreed and voted that Bo Young Park, COO, will finalize and execute the new Know-How license agreement with Prof. Claudio De Simone based on terms approved today by VSL Board (Mr. Maurizio Terenzi and Boyoung Park).

J.R. 238.

Thus, the Minutes plainly establish that Terenzi, an undisputedly disinterested director, was aware in September 2009 that VSL and De Simone would enter into an agreement that gave

VSL a license to use the Know-How only until January 31, 2016 and contained a change-in-control provision, and that he voted to approve such an agreement. Terenzi's knowledge is fairly imputed to VSL. *See Teachers' Retirement Sys. of Louisiana v. Aidiouff*, 900 A.2d 654, 671 n.23 (Del. Ch. 2006) (“[I]t is the general rule that knowledge of an officer or director of a corporation will be imputed to the corporation.”), *aff'd sub nom Teachers' Ret. Sys. of La. v. Gen. Re Corp.*, 11 A. 3d 228 (Del. 2010). Moreover, the Minutes reflect that Terenzi acted independently, as reflected by his statement that De Simone's concerns about pressure to alter the De Simone Formulation were “overstated.” J.R. 238. From the uncontradicted testimony of Park, a member of the VSL Board and VSL's Chief Operating Officer from 2006 to 2014, it is clear that Terenzi reviewed the 2010 Know-How Agreement and thus was aware of its contents.

Where the record definitively establishes that Terenzi was independent and fully aware of the particular transaction, the Court is unpersuaded by VSL's assertion that Terenzi could not have acted in an informed matter in approving the 2010 Know-How Agreement without an understanding that “the Patent License Agreement contained no survival language that would preclude VSL from using the know-how associated with the Patent after its expiration.” VSL Cross-Mot. Summ. J. at 26. VSL cites no authority for the proposition that a board member is on notice of a claim for purposes of the statute of limitations only if he or she fully understands sophisticated legal questions of contract interpretation.

Nor is the Court persuaded by the VSL Parties' argument that the doctrine of “adverse domination” precludes the accrual of the claim when the 2010 Know-How Agreement was approved. That doctrine provides that for an action by a corporation against its directors for injury to the corporation, the statute of limitations is tolled until there exists a disinterested majority of non-culpable directors. *Hecht v. Resolution Trust Corp.*, 635 A.2d 394, 402, 408

(Md. 1994). Here, the VSL Parties argue that Park was not a disinterested director, such that at the time of the September 2009 Board meeting and the approval of the 2010 Know-How Agreement, no such disinterested majority existed. An interested director is a director with “a personal pecuniary interest” in a particular decision of the board of directors. *Cheff v. Mathes*, 199 A.2d 548, 554 (Del. 1964). VSL cites no provision of the 2010 Know-How Agreement that secured a personal pecuniary benefit to Park. Rather, the evidence in the record aligns Park’s pecuniary interest with VSL’s, as evidenced by her Executive Employment Agreement, which provided that her salary would be significantly higher if any new licensing agreements would result in higher expected gross profits for VSL. *Cf. Unocal Corp. v. Mesa Petroleum Co.*, 493 A.2d 946, 958 (Del. 1985) (emphasizing that board members do not become interested directors “merely because [they] are large stockholders”).

As for whether Park could be deemed culpable for any conspiracy with De Simone to breach a fiduciary duty as early as 2009 or 2010, the VSL Parties have not submitted sufficient evidence to support such a claim. Particularly where the Court has found that De Simone owned the Know-How, the execution of agreements in that time frame reflecting that fact are not evidence of any such conspiracy. Although De Simone identified Park and invited her to join the Board, there is no evidence in 2009 or 2010 of any communications between De Simone and Park relating to such a scheme, or that Park was aware of any plan by De Simone to undermine VSL by starting a company to take over the sales of VSL#3. All the VSL Parties have offered to show that Park was culpable for a breach of fiduciary duty relating to the 2010 Know-How Agreement is her Executive Employment Agreement, which they assert is not commercially reasonable. The VSL Parties cite no factual or legal authority for that assessment. Notably, while it was ultimately De Simone who signed and approved Park’s employment contract, Park’s

uncontroverted deposition testimony establishes that she negotiated the terms of that contract with Terenzi, who assisted VSL in this time frame even during periods he was not a member of the Board, and that Terenzi reviewed and approved the final agreement. Indeed, Terenzi told Park during such negotiations that VSL could not provide her with medical insurance or a retirement plan. Where a disinterested, independent individual with ties to VSL's parent company negotiated and approved Park's Employment Agreement, that agreement cannot fairly be deemed to be evidence of a conspiracy to breach a fiduciary duty. Although VSL argues that Park's testimony need not be believed by a jury, where VSL has not offered evidence to contradict that testimony, such an assertion is not sufficient to create a genuine issue of material fact. *See Anderson*, 477 U.S. at 256 (stating that summary judgment cannot be defeated "by merely asserting that the jury might, and legally could, disbelieve" a party, and that the nonmoving party must produce evidence that would support a verdict in that party's favor).

Finally, the terms of Park's Employment Agreement make abundantly clear that Park's financial interest would be in maintaining VSL's right to sell VSL#3. The VSL Parties' theory that Park was part of a conspiracy to enter into the 2010 Know-How Agreement in order to assist De Simone in usurping that right is therefore undermined, not advanced, by the terms of her Employment Agreement. In the end, the VSL Parties have offered insufficient evidence for a reasonable factfinder to conclude that Park had an interest in, or was culpable for, a breach of fiduciary duty arising from the adoption of the 2010 Know-How Agreement. *See id.* ("The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff."). Accordingly, a majority of disinterested directors, consisting of Park and Terenzi, was aware of the 2010 Know-How Agreement when it was adopted, such that the "adverse domination" doctrine does not

apply. *See Hecht*, 635 A.2d at 402, 408. The Court does not address whether there is sufficient evidence to support a conspiracy involving Park at a later time, such as in 2014.

Thus, any claim that the terms of the 2010 Know-How Agreement, including the change-in-control provision, constituted a breach of fiduciary duty, conspiracy, or fraud accrued when that agreement was signed in January 2010, more than five years before VSL filed its Counterclaim in June 2015. Counts IV, V, and VI of the VSL Counterclaim are therefore dismissed as to this issue because the claims accrued before June 3, 2012.

C. Remaining Breach of Fiduciary Duty Claims

VSL has also asserted breach of fiduciary duty, conspiracy, and fraud relating to events since June 3, 2012. These claims include VSL's assertion that De Simone breached his fiduciary duty to VSL by inserting a provision into the 2014 Danisco Supply Agreement that allowed him to take over VSL's position as the buyer of VSL#3 in the event that the 2010 Know-How Agreement was terminated and then by actually terminating the Know-How Agreement, becoming the buyer in place of VSL, and seeking to cut off the supply of VSL#3 to VSL. They also include claims that while still CEO of VSL, De Simone sought trademarks that infringed on VSL's trademark of VSL#3. Related to these claims is Count IV of the Lediand Counterclaim, which asserts a cause of action for tortious interference with economic relations based on De Simone's disruption of VSL's supply chain.

Both sides seek summary judgment on these claims. In resolving VSL's First Motion for a Preliminary Injunction, the Court found that VSL was likely to succeed on its claim for a breach of fiduciary duty because:

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. ...

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, 133 F. Supp. 3d at 795.

In seeking summary judgment on the breach of fiduciary duty and related claims, the VSL Parties largely rely on the same factual landscape that was before the Court on the First Motion for a Preliminary Injunction. In addition, however, they cite to a few buttressing facts, specifically, De Simone's admission that by September or October 2013, De Simone had decided that he wanted to leave VSL; that in September 2014, De Simone began discussions with Marc Tewey, the Chief Executive Officer of ExeGi, about starting a new company to compete with VSL; and that at about the same time, De Simone asked VSL's outside counsel to return to him all documents containing confidential information about the De Simone Formulation and to destroy any remaining copies. Upon consideration of this and other evidence in the record, the Court concludes that the remaining parts of VSL's breach of fiduciary duty claims are viable, and that the De Simone Parties' request for summary judgment on these claims will be denied.

At the same time, summary judgment in favor of the VSL Parties is also not warranted because there remain genuine issues of material fact. In her deposition, Park provided a different

explanation for the changes to the 2014 Danisco Supply Agreement, which she and another individual negotiated on behalf of VSL. In Park's account, De Simone was inserted into the Agreement, which allowed him to take over as the buyer of VSL#3, due to issues of potential liability. Specifically, Park asserted that Danisco had concerns about product liability because some VSL#3 customers were a "high risk" population, so Danisco wanted VSL to bear the risk of product liability claims. J.R. 309. VSL, in turn, did not want the risk because it was only a licensee, not the owner of the De Simone Formulation. According to Park, the resolution of this issue was that De Simone was inserted as a fallback buyer of VSL#3.

Park's account of the reasoning behind contested terms of the 2014 Danisco Supply Agreement is not without support in the language of the contract. There is an entire section of the 2014 Danisco Supply Agreement devoted to parsing out responsibility for product liability, with several of the sections that limit the scope of Danisco's responsibility appearing in all capital letters. No such sections appear in the 2008 Danisco Supply Agreement. The 2014 Danisco Supply Agreement also explicitly states that Danisco is not liable for certain types of claims, such as those based on the marketing of VSL#3: "Buyer shall indemnify and hold Seller harmless from and against and all liability related to any marketing or sale of or claims made with respect to the Products." J.R. 104. Furthermore, the 2014 Danisco Supply Agreement provides that upon taking on the role of "Buyer," De Simone assumed not just rights, but "all obligations of Buyer." J.R. 103.

To be sure, Park's deposition testimony leaves important questions unanswered. For example, the ability to trigger the contract provisions providing for De Simone's role as fallback buyer, by terminating the 2010 Know-How Agreement through its change-in-control provisions, appears to have been at least in part within the control of De Simone. However, where Park's

account is not entirely implausible, the Court must, at this stage, view the facts in the light most favorable to the De Simone Parties and draw all justifiable inferences in their favor. *Anderson*, 477 U.S. at 255. The Court therefore finds that there is a genuine dispute of material fact whether De Simone breached his fiduciary duty by executing the 2014 Danisco Supply Agreement. Because this question needs to be resolved by a finder of fact, and the resolution of this issue is likely to impact the VSL Parties' remaining theories of liability for their breach of fiduciary duty and related claims, the Court concludes that all remaining aspects of these claims should be resolved at trial. *See Forest Hills Early Learning Ctr. v. Lukhard*, 728 F.2d 230, 245 (4th Cir. 1984) (stating that even if summary judgment may be appropriate based on the record at the time of the motion, "a court may properly decline, for a variety of reasons, to grant it"). *Cf. Kuchenbecker v. Northern Wyoming Drilling Co.*, 647 F.2d 836, 839 (8th Cir. 1981) (stating that where there were material disputes of fact as to the liability of one defendant, it was the "much better practice" and "[i]n the interest of judicial economy" for the case to proceed to trial as to all defendants).

Accordingly, as to those claims within Counts III–VI not otherwise addressed above, specifically those claims based on the 2014 Danisco Supply Agreement and subsequent events, the De Simone Parties' Motion for Summary Judgment will be denied. The VSL Parties' Motion for Summary Judgment will be denied as to VSL's Counts IV, V, and VI and Leadiant's Count IV. Those claims, as limited above, will proceed to trial.

D. Conversion

In Count XVIII of the VSL Counterclaim, VSL pleads a cause of action for conversion against De Simone, asserting that upon his departure from VSL, he took with him confidential and proprietary information, such as VSL documents and computers, and that he withheld from

VSL information belonging to the company, such as electronic account information. Conversion is “an intentional exercise of dominion or control over chattel which so seriously interferes with the right of another to control it that the actor may justly be required to pay the other the full value of the chattel.” *United States v. Arora*, 860 F. Supp. 1091, 1097 (D. Md. 1994) (quoting *Restatement (Second) of Torts*, § 222A(1)), *aff’d* 56 F.3d 62 (4th Cir. 1995).

The De Simone Parties seek summary judgment on this claim, asserting that the record contains no evidence to support it. That assertion is incorrect. For example, the record contains a declaration from attorney Diane McColl, counsel to VSL until 2014. McColl asserts that in September 2014, De Simone instructed her to send him all information she possessed on VSL’s behalf that contained confidential information about the formula for VSL#3 and to destroy any remaining copies. De Simone acknowledges destroying the paperwork he received from McColl but claims that it consisted of only publicly available articles. Without determining specifically what documents were actually destroyed, the Court (Sullivan, M.J.), has sanctioned De Simone for spoliation of evidence arising out of this incident. *See* Mem. Op. at 4-17, ECF No. 556. Thus, there are genuine issues of material fact relating to what exactly was sent by McColl to De Simone, and whether any of that paperwork constituted VSL property that was improperly removed and destroyed. The De Simone Parties’ Motion for Summary Judgment as to this claim will therefore be denied.

IV. 2014-2016 VSL#3 Sales Claims

De Simone asserts several claims in the Complaint based on VSL’s sale of VSL#3 after he resigned as the CEO of VSL in November 2014. He asserts that (1) in Count II, VSL breached the 2001 Patent License Agreement by failing to pay royalties on sales after August 2014; (2) in Count III, VSL was unjustly enriched when it continued to acquire and sell VSL#3

after the expiration of the Patent License Agreement on February 9, 2016; and (3) in Counts IV and V, by stockpiling supplies of Danisco-manufactured VSL#3 after the termination of the 2010 Know-How Agreement, the VSL Parties misappropriated a trade secret, specifically, the Know-How.

A. Breach of the Patent License Agreement

In Count II, De Simone alleges that VSL breached a contract, specifically, the 2001 Patent License Agreement, by failing to pay him royalties on sales of VSL#3 beginning in August 2014. De Simone seeks summary judgment on this claim.

The Patent License Agreement required VSL to pay De Simone royalties on sales of VSL#3 at a rate of 3% on net sales up to \$50 million, and at a rate of 5% on net sales above \$50 million. In return for those royalties, De Simone “grant[ed] 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 615 Patent. J.R. 30, 31. The license and requirement to pay royalties would “continue in effect until the expiry of the Patent” on February 9, 2015. J.R. 33. The Patent License Agreement also stated that if and when De Simone acquired full ownership rights to the 615 Patent, he would give VSL an option to acquire those rights. On May 18, 2015, after the natural expiration of the Patent License Agreement, De Simone informed Danisco that VSL and Sigma-Tau no longer had a license to purchase the De Simone Formulation. VSL admits, however, that although it has made no royalty payments to De Simone since August 2014, it sold more than \$10 million of VSL#3 between August 1, 2014 and February 10, 2015.

“To prevail in an action for breach of contract, a plaintiff must prove that the defendant owed the plaintiff a contractual obligation and that the defendant breached that obligation.”

Taylor v. NationsBank, N.A., 776 A.2d 645, 651 (Md. 2001). De Simone asserts that, on these uncontested facts, he is entitled to summary judgment because VSL was obligated under the Patent License Agreement to make royalty payments to De Simone but, by its own admission, VSL ceased making those payments in August 2014. In response, VSL asserts that De Simone is estopped from claiming a breach of the Patent License Agreement because De Simone himself breached that agreement. VSL provides no explanation for its theory of a prior breach by De Simone and cites no evidence in the record to support it. To the extent that VSL's theory of breach is that De Simone never offered his rights in the 615 Patent to VSL, it would fail for two reasons. First, De Simone has produced a 2005 letter in which he notified VSL that he had acquired full rights to the 615 Patent, but there is no evidence that VSL then sought to exercise the option to acquire his rights. Second, this Court has already determined that any claim of breach based on the failure to offer the 615 Patent to VSL is time-barred. *See De Simone*, 2017 WL 66323 at *6. To the extent that VSL's theory of breach hinges on its assertion that De Simone did not own the Know-How, that theory also fails based on this Court's determination, as a matter of law, that De Simone rightfully owns the Know-How.

The uncontested facts thus establish that VSL had an obligation under the Patent License Agreement to pay De Simone royalties for sales of VSL#3 and that from August 2014 until the expiration of that agreement in February 2015, VSL failed to do so. De Simone's Motion for Summary Judgment as to Count II of the Complaint will therefore be granted on the issue of liability, with damages to be proven at trial.

B. Unjust Enrichment

In Count III, De Simone asserts a claim of unjust enrichment against the VSL Parties based on the orders for VSL#3 that they placed with Danisco after the expiration of the Patent

License Agreement in February 2015. De Simone asserts that, at that point, because he had terminated the 2010 Know-How Agreement in November 2014, there was no longer any operative agreement giving the VSL Parties a license to purchase products made with De Simone's Know-How. De Simone thus argues that any acquisition by the VSL Parties of VSL#3 from Danisco after that date amounts to unjust enrichment for which the De Simone Parties should be compensated.

Both sides seek summary judgment in their favor. Certain facts appear to be undisputed. The VSL Parties continued to purchase VSL#3 from Danisco between February 2015 and January 31, 2016, and for some portion of that time, they purchased the product in amounts greater than their historical volume of purchases. On September 23, 2015, the Court granted the VSL Parties' First Motion for a Preliminary Injunction to the extent that it enjoined De Simone from interfering with VSL's acquisition of VSL#3 from Danisco until January 31, 2016. Concerned that the VSL Parties were increasing the volume of their purchases to stockpile VSL#3, the De Simone Parties filed a Motion for Clarification on the Scope of Preliminary Injunction, seeking a supplemental order from the Court to cap the volume of the VSL Parties' purchases. The Court denied that motion.

A claim of unjust enrichment has three elements:

1. A benefit conferred upon the defendant by the plaintiff,
2. An appreciation or knowledge by the defendant of the benefit, and
3. The acceptance or retention by the defendant of the benefit under such circumstances as to make it inequitable for the defendant to retain the benefit without the payment of its value.

Hill v. Cross Country Settlements, LLC, 936 A.2d 343, 351 (Md. 2007). Based on the undisputed facts, the first two elements of the claim appear to be satisfied: the VSL Parties were able to purchase VSL#3 from Danisco after February 9, 2015, and were certainly aware of

that fact, as they placed the orders with Danisco. It is at the third element that difficulties arise. “The final element of an unjust enrichment claim is a fact-specific balancing of the equities.” *Id.* at 355. Whether the VSL Parties’ acquisition and sale of VSL#3 up to January 31, 2016—the original expiration date of the 2010 Know-How Agreement—was unjust depends significantly on whether De Simone’s November 2014 termination of the 2010 Know-How Agreement was itself unjust, a question that involves a factual dispute. Although De Simone has asserted that he took that and other actions to prevent the VSL Parties from altering the scientific formulation of VSL#3 in a way that would be detrimental to consumers, the VSL Parties have claimed that De Simone’s action was a breach of his fiduciary duty to VSL undertaken in order to usurp the company’s ability to profit from the sale of VSL#3. Because there remains a genuine issue of material fact as to the motivation and necessity for the termination of the 2010 Know-How Agreement, summary judgment on this claim is not warranted. *See id.* at 348 (“The only thing crystal clear about this case is that the grant of summary judgment, on this record, was inappropriate.”). The Motions for Summary Judgment will be denied as to the unjust enrichment claim in Count III of the Complaint.

C. De Simone’s Trade Secrets Claims

In Counts IV and V, the De Simone Parties assert that in stockpiling supplies of Danisco-manufactured VSL#3 after the termination of the 2010 Know-How Agreement, the VSL Parties misappropriated De Simone’s Know-How, in violation of the Maryland Uniform Trade Secrets Act (“MUTSA”), Md. Code Ann., Com. Law. §§ 11-1201–09 (West 2013) and engaged in a civil conspiracy to do so.

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). To establish that a defendant acquired a trade secret, a plaintiff must have proof that the defendant “possesses secret information,” not, as the De Simone Parties assert here, that it merely possesses a product made by virtue of the trade secret. *DTM Research, L.L.C. v. AT & T Corp.*, 245 F.3d 327, 332 (4th Cir. 2001). Because the record contains no evidence that VSL acquired secret information simply by virtue of receiving and shipping VSL#3 product manufactured by Danisco, the VSL Parties will be granted summary judgment on these claims, which will be dismissed with prejudice. The De Simone Parties’ Motion as to these claims is denied.

V. Lanham Act and Related Claims

A. Trademark Infringement

The VSL Parties have pleaded six trademark infringement and unfair competition claims against the De Simone Parties pursuant to the Lanham Act, 15 U.S.C. § 1114 and 15 U.S.C. § 1125(a), as well as section 1-414 of the Business Regulations Article of the Maryland Code, Md. Code Ann., Bus. Reg. § 1-414 (West 2002). This Court has twice found that the VSL Parties are likely to succeed on their trademark infringement claims. *See De Simone*, 133 F. Supp. 3d at 796–99; *De Simone*, 2016 WL 3466033 at *24–26. In now moving for summary judgment on these claims, the VSL Parties cite to no new evidence produced in discovery, but instead rely on the evidence before the Court on the prior Motions for a Preliminary Injunction.

Although the VSL Parties proceed with their trademark infringement claims under several different statutes, the relevant test is the same:

A plaintiff alleging causes of action for trademark infringement and unfair competition must prove (1) that it possesses a mark; (2) that the defendant used the mark; (3) that the defendant’s use of the mark occurred “in commerce”; (4) that the defendant used the mark “in connection with the sale, offering for sale,

distribution, or advertising” of goods or services; and (5) that the defendant used the mark in a manner likely to confuse consumers.

People for the Ethical Treatment of Animals v. Doughney, 263 F.3d 359, 364 (4th Cir. 2001) (adjudicating trademark infringement claims under both 15 U.S.C. § 1114 and § 1125(a)); see *Community First Bank v. Community Banks*, 360 F. Supp. 2d. 716, 722 (D. Md. 2005) (“Maryland courts have recognized that trademark infringement cases under either the Maryland statute or the federal Lanham Act are based on the same legal theory and require the same proof.”) (internal citations omitted)). Assessing the final element, likelihood of confusion, is a complex enterprise. The Fourth Circuit has identified nine factors to be considered 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.*

Unsurprisingly, in light of the complexity of assessing the likelihood of consumer confusion, the Fourth Circuit has also emphasized that “determining the likelihood of confusion is an inherently factual issue that depends on the facts and circumstances of each case.” *Anheuser-Busch, Inc. v. L & L Wings, Inc.*, 962 F. 2d 316, 318 (4th Cir. 1992) (citation omitted). In particular, likelihood of confusion “has long been recognized to be a matter of varying human

reactions to situations incapable of exact appraisal” and thus is “frequently a fairly disputed issue of fact on which reasonable minds may differ.” *Id.* While on a motion for a preliminary injunction, the Court is required to assess the relative strength of the parties’ evidence, such factual assessments are inappropriate on a motion for summary judgment. *Anderson*, 477 U.S. at 249 (“[A]t the summary judgment stage the judge’s function is not himself to weigh the evidence and determine the truth of the matter.”). That is particularly true here where, contrary to the suggestion of the VSL Parties, a substantial portion of the evidence relating to alleged trademark infringement deals with the De Simone Parties’ marketing efforts to a sophisticated buying audience of medical professionals, who could be presumed to be less susceptible to confusion. *See Perini Corp. v. Perini Constr., Inc.*, 915 F.2d 121, 127–28 (4th Cir. 1990) (finding that the district court erred in granting summary judgment on a trademark infringement claim where the court had made no inquiry into the sophistication of the purchasers, noting that consumer confusion cannot be presumed where the purchasers are “highly trained” professionals in the field). The fact that the parties are vigorously contesting the quality of their respective products, with De Simone asserting that Visbiome is superior to VSL#3, further supports the conclusion that confusion has not been established as a matter of law. *See Arrow Fastener Co., Inc. v. Stanley Works*, 59 F.3d 384, 398 (2d Cir. 1995) (noting that the “quality of defendant’s product factor” “is primarily concerned with whether the senior user’s reputation could be jeopardized by virtue of the fact that the junior user’s product is of inferior quality”). The VSL Parties’ trademark claims are thus properly left for a jury. Both the VSL Parties’ Cross Motion for Partial Summary Judgment as to these claims, and the De Simone Parties’ Motion for Summary Judgment on these claims, will be denied. VSL’s Counts XII, XIII, XXI, and XXII and Leadiant’s Counts V and VI will proceed to trial.

B. False Advertising

In their Counterclaims, VSL, Leadiant, and Alfasigma have each asserted false advertising claims against De Simone and ExeGi under 15 U.S.C. §1125(a). In Count VI of the Complaint, ExeGi asserts its own claim of false advertising under the same statute against Leadiant and Alfasigma. Leadiant and Alfasigma have also each asserted a related claim for tortious interference with prospective economic advantage.

In ruling on the Second Motion for a Preliminary Injunction, the Court previously found that VSL and Leadiant's predecessor were likely to succeed on their false advertising claims. *See De Simone*, 2016 WL 3466033 at *18–23. To the evidence before the Court on that motion, the VSL Parties have added evidence of efforts by the De Simone Parties to disseminate information, allegedly false, that VSL#3 is no longer composed of the De Simone Formulation and no longer offers the same clinical benefits. This evidence includes posts to online listservs by Susan Linke, a dietician and an expert witness for the De Simone Parties. On the issue of the composition of VSL#3, the VSL Parties cite to their own experts as to the continued clinical equivalence between VSL#3 and Visbiome. The De Simone Parties, in turn, assert that the VSL Parties' continued insistence on the equivalence between VSL#3 and Visbiome is scientifically false, backing up their assertion with their own bevy of experts and articles.

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

To prevail on a claim of false advertising, a plaintiff must establish that:

- (1) The defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about its product or the product of another;
- (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 defendant placed the false or misleading statement in interstate commerce; and
- (5) The plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its 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. However, “if a plaintiff’s theory of recovery is premised upon a claim of implied falsehood, a plaintiff must demonstrate, by extrinsic evidence, that the challenged advertisements tend to mislead or confuse consumers.” *Id.*

In resolving the Second Motion for a Preliminary Injunction, the Court found that statements in the following passage that appeared on the Visbiome website as of February 10, 2016 were likely literally false:

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.

See De Simone, 2016 WL 3466033 at *19. The Court reasoned that because VSL had been allowed to purchase VSL#3 from Danisco up until January 31, 2016 and had been, over the De

Simone Parties' objections, apparently stockpiling the product, it was almost certainly "simply untrue" to assert, only 10 days later, that the De Simone Formulation was available exclusively from Visbiome. *Id.* The parties have submitted no new evidence on summary judgment that calls this initial determination into question. The record has not, however, been augmented with evidence clearly establishing the final element of a false advertising claim: that the VSL Parties have been or are likely to be injured as a result of this misrepresentation on the website, either by direct diversion of sales or by a lessening of goodwill associated with their product. Rather the record is somewhat inconclusive. The total volume of sales of VSL#3 appears to have increased from 2015 to 2016. From 2016 to 2017, the net sales of VSL#3 dropped, but the overall volume of sales for VSL#3 increased during that same period. Although VSL points to evidence that various doctor's offices now prescribe or recommend Visbiome instead of VSL#3, that lessening of goodwill appears to have been effected by sales representatives or information disseminated through internet listservs, not website statements.

As for the alleged false advertising arising from statements by sales representatives, there remain genuine issues of material fact as to whether ExeGi sales representatives made false statements, and the Court previously found in resolving the Second Motion for a Preliminary Injunction that those statements, even if made, likely did not amount to commercial advertising or promotion within the meaning of the statute. *See De Simone*, 2016 WL 3466033 at *22–23. The VSL Parties have not revisited that argument in their Motion. Likewise, there remains a factual dispute whether Linke was affiliated with ExeGi and thus acting as its agent in sending such communications. The evidence in the record therefore does not warrant a finding that the VSL Parties are entitled to summary judgment on the false advertising claims based on alleged false statements that stated or implied that VSL#3 was no longer on the market.

Nor is there cause to grant summary judgment either to the VSL Parties or the De Simone Parties on the new issue of whether VSL#3 and Visbiome are clinically equivalent. The VSL Parties allege that the De Simone Parties have engaged in false advertising by claiming that the current version of VSL#3 made in Italy no longer uses the De Simone Formulation; the De Simone Parties counter with the claim that the VSL Parties have engaged in false advertising by claiming that the new version of VSL#3 is exactly the same as the prior version that used the De Simone Formulation. Each side has submitted extensive, conflicting evidence on the scientific question whether VSL#3 and Visbiome use the same formulation which, on its own, precludes summary judgment. *Anderson*, 477 U.S. at 249. Furthermore, there are significant questions about whether the challenged representations are actionable advertising. It is by no means clear that scientific publications on this issue, or Linke's emails to listservs forwarding such studies, amount to commercial advertising or promotion by ExeGi. *See* Mem. Op. 3d Mot. Prelim. Inj. at 8–10, ECF No. 674 (finding that scientific articles are not actionable under the Lanham Act). Nor is it clear whether VSL's claim on its website to have eight strains of bacteria, rather than seven, even if that statement is determined to be false, is one likely to injure the De Simone Parties.

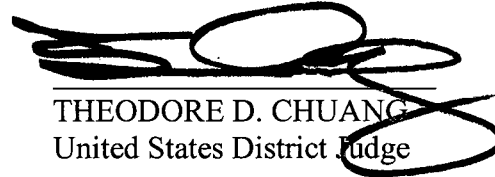
Accordingly, the Parties' false advertising claims, as well as the related tortious interference with prospective economic advantage claims asserted by Leadiant and Alfasigma, must therefore be resolved at trial. *See Kuchenbecker*, 647 F.2d at 839. The Parties' Motions for Summary Judgment on the Lanham Act and related claims will therefore be denied.

CONCLUSION

For the foregoing reasons, and in accordance with the determinations set forth above, the DeSimone Parties' Motion for Summary Judgment is GRANTED IN PART and DENIED IN

PART, and the VSL Parties' Cross Motion for Partial Summary Judgment is GRANTED IN PART and DENIED IN PART. A separate Order shall issue.

Date: October 9, 2018



THEODORE D. CHUANG
United States District Judge