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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

EXEGI PHARMA, LLC, a New York limited liability company,

Plaintiff,

vs.

TRUE COMMERCE, INC., a Delaware corporation, HIGHJUMP SOFTWARE, INC., a Delaware corporation, NEXTERNAL SOLUTIONS, INC., a California corporation,

Defendants.

Case No. '19CV0611 AJB MSB

COMPLAINT

Plaintiff ExeGi Pharma, LLC ("ExeGi"), by and through undersigned counsel, as and for its Complaint against Defendants Nexternal Solutions, Inc. ("Nexternal"), True Commerce, Inc. ("TrueCommerce") and HighJump Software, Inc. ("HighJump") (collectively, the "Defendants"), avers as follows:

NATURE OF THE ACTION

1. ExeGi brings this action to put an end to Defendants' illegal role in a well-documented international campaign of false advertising about the probiotic medical food product "VSL#3." ExeGi has repeatedly requested that Defendants stop the false advertisements and explained the legal, moral, health, and safety reasons why Defendants should do just that. However, Defendants, caring only about their own profits, have flatly refused to do so. Defendants' unwillingness to cease their false advertising has revealed their insatiable appetite for corporate profit and displayed an intentional, callous disregard for the rights of ExeGi and the health and safety of consumers.

2. To understand the severe consequences of Defendants' conduct, one must understand the history behind the product sold under the "VSL#3" trademark. Professor Claudio De Simone ("Prof. De Simone") is the inventor of a unique probiotic medical food, which is widely used to manage numerous, persistent gastrointestinal disorders (the "De Simone Formulation"). Between 2002 and 2016, the De Simone Formulation was sold under the brand name "VSL#3" by VSL Pharmaceuticals, Inc. ("VSL Inc."), the company that owns the trademark to VSL#3, and Leadiant Biosciences, Inc. ("Leadiant"), a large pharmaceutical distributor owned by the Cavazza family in Italy (who was also the ultimate majority owner of VSL Inc). By 2016, due to its clinically- and study-proven benefits in managing serious medical conditions, the De Simone Formulation (sold as "VSL#3" at the time) was a major commercial success, with sales of over $35 million per year in the United States alone. However, in early 2016, VSL Inc. and Leadiant lost the right to sell the De Simone Formulation. That right was granted to ExeGi via an exclusive license from Prof. De Simone to market and sell the De Simone Formulation in the United States under the brand name "Visbiome." From 2016 through the present, ExeGi sold, and still sells, Visbiome directly to consumers via the internet as well as through major distributors and retail stores.

3. VSL Inc., viciously unhappy with losing the right to sell the very profitable De Simone Formulation, decided to wage a two-front war to keep the profits flowing. On one front, it engaged in a scorched earth, no-holds-barred litigation seeking to wrest ownership of the intellectual property rights attendant to the De Simone Formulation (the "Know-How") away from its inventor and owner, Prof. De Simone. On the second front, when the first effort failed, VSL Inc. decided to make a counterfeit, poor version of the De Simone Formulation in Italy (the "Fake Product") and simply pass it off to consumers as the real De Simone Formulation by continuing to sell it under the VSL#3 trademark and falsely representing the history of the De Simone Formulation as the history of the Fake Product.

4. Thus, beginning on July 1, 2016, Alfasigma USA, Inc. ("Alfasigma")[1], via a purported license from VSL Inc., began selling the Fake Product—the counterfeit, poor imitation of the De Simone Formulation—under the brand name "VSL#3." This Fake Product remains the product being sold as "VSL#3" by Alfasigma and the Defendants in the United States to this day. Accompanying this Fake Product is packaging and other marketing materials falsely representing to the public that VSL#3 is the same as the original De Simone Formulation that has been sold in the United States market since 2002 and that has been the subject of more than 60 published clinical studies. More specifically, the packaging and other marketing materials for VSL#3 falsely represent that the formula currently being sold as VSL#3 (the Fake Product) contains the same eight distinct strains of bacteria in the same proportions as the original formula, that the Fake Product has been clinically studied and sold successfully for more than 15 years, and cites to many clinical studies actually performed on the De Simone Formulation, and not the Fake Product, as support for its claimed efficacy.

5. These product claims are literally false, as they materially misrepresent the facts about the composition, safety, history, and efficacy of the Fake Product. Not only are they false, they are highly damaging to ExeGi and are endangering consumers of VSL#3, many of whom have relied

[1] Alfasigma is also partially owned by the Cavazza family and is the successor to the distribution rights formerly possessed by Leadiant.

on the De Simone Formulation for years to manage the effects of serious gastrointestinal diseases and conditions.

6. In order to stop this false advertising, ExeGi sued Alfasigma under the Lanham Act in May of 2017 as part of the already existing litigation in the United States District Court for the District of Maryland regarding ownership of the Know-How. On October 9, 2018, the court issued a summary judgment ruling awarding Prof. De Simone ownership of the Know-How and dismissed, with prejudice, VSL Inc.'s claim of ownership of the Know-How.

7. ExeGi's false advertising claim against Alfasigma proceeded to trial. From October 30 to November 20, 2018, the parties conducted a jury trial on that cause of action. At trial, ExeGi presented overwhelming proof of the falsity of Alfasigma's advertisements for the Fake Product. For example, Alfasigma was touting the efficacy of the Fake Product, but extensive documentary and testimonial evidence showed that Alfasigma had no scientific basis for its claims regarding the efficacy and safety of the Fake Product; in fact, there was not even a single clinical study showing that the product was efficacious or safe. On November 20, 2018, the jury unanimously found that Alfasigma[2] had engaged in false advertising [against ExeGi] in violation of the Lanham Act and awarded ExeGi $15 million (representing the jury's determination of Alfasigma's wrongfully earned profits on sales of the Fake Product) as compensatory damages for that false advertising. The Court entered a final judgment on this verdict on November 21, 2018.

8. Despite the finding of false advertising reached in the federal court in Maryland, Alfasigma steadfastly refused to change its advertisements and continues to make the same false statements in its advertisements to this day. However, since the final judgment was entered, most of Alfasigma's partners in the distribution chain have refused to continue participating in Alfasigma's deceit. Recognizing their own potential liability for participating in, and perpetuating, Alfasigma's false advertisements, within weeks of the verdict, most of the U.S. distributors and major national retailers, including McKesson Corporation, Cardinal Health, Inc., CVS Health

[2] The jury also found that Leadiant engaged in false advertising against ExeGi in violation of the Lanham Act for claims it made about the Fake Product.

Corporation, Costco Wholesale Corporation, Walmart Inc., Amazon.com, Inc., and Walgreens Company stopped selling VSL#3 due to Alfasigma's false advertising.

9. As the distributors and major national retailers that refused to continue selling VSL#3 cut off much of the U.S. market for the Fake Product, Alfasigma is left primarily with selling VSL#3 to consumers through the VSL#3 website and "online store" (the "VSL#3 Website").[3] Regrettably, the VSL#3 Website contains numerous false representations about VSL#3. In fact, the VSL#3 Website is using the same marketing claims to sell the Fake Product that were found to violate the Lanham Act in the federal court case in Maryland.

10. Defendants are currently playing a pivotal role in selling the Fake Product (as "VSL#3") to consumers and, upon information and belief, have played this role since Alfasigma began selling the Fake Product (with accompanying false statements) in July 2016. Defendants are the sole eCommerce solution for the VSL#3 Website, where Alfasigma and Defendants falsely advertise and sell the Fake Product as VSL#3 directly to consumers. In fact, Defendants are the central players in selling the fake VSL#3 product, as they tout their platform to "efficiently capture & manage all your orders in one commerce system," to "capture orders from distributors, retailers, and sales reps with advanced customer segmentation," to cause sales to "thrive with our vast array of marketing tools" through "online, mobile, point of sale, subscription, call center, or club order" channels. Defendants, in their own words, allow Alfasigma to "do business in every direction."

11. As Defendants had not disassociated themselves from Alfasigma and the Fake Product like Amazon, Costco, Walgreens, and so many others properly did, counsel for ExeGi sent a letter to Defendants on March 14, 2019 to ensure that they were informed of the results of the trial in Maryland (the "March Letter"). The March Letter included a copy of the judgment (Exhibit 1, attached hereto), the Amended Complaint on which the judgment was based (Exhibit 2, attached hereto), recent media reports about the case (Exhibit 3, attached hereto); and confirmation from the Canadian VSL#3 website that VSL#3 was abruptly discontinued in the whole of Canada (Exhibit 4, attached hereto). In the March Letter, ExeGi requested that, in light of the finding of false

[3] *See* www.vsl3.com and www.shop.vsl3.com/vsl3-c2.aspx (the "VSL#3 Website") (last visited on March 29, 2019).

advertising already reached in the federal court trial in Maryland, Defendants immediately cease the sale and/or distribution of any and all VSL#3 product containing or otherwise associated with false advertising equating the product with the De Simone Formulation or otherwise falsely indicating that VSL#3 consists of 8 strains of bacteria and is supported by clinical studies on the product.

12. Counsel for Nexternal and TrueCommerce, Michael Carrigan ("Mr. Carrigan") of the law firm Holland & Hart, LLP, responded to ExeGi's request on March 22, 2019. In that letter, Mr. Carrigan informed ExeGi that Defendants "decline[d] to agree to the demands in your Letter." Mr. Carrigan further informed ExeGi that that decision was "based on" only two things: (1) that they were not yet required via Court order to suspend sales of VSL#3; and (2) Alfasigma agreed to "indemnify TrueCommerce for any claims brought by [ExeGi]."

13. Clearly, Defendants had only one focus: their own profits. They did not address—or even purport to analyze—the concerns for patient safety arising out of the sale of the Fake Product or the harm to ExeGi from the false advertising. Rather, Mr. Carrigan made it clear that Defendants would keep selling VSL#3 and reaping the profits until forced to do otherwise by a court, with the security of knowing that Alfasigma was guaranteeing the profits and indemnifying TrueCommerce for its wrongdoing. True to Mr. Carrigan's word, Defendants continue to be the sole eCommerce solution for the VSL#3 Website and thus have continued to directly adopt, endorse, facilitate, perpetuate and profit from the false representations about the Fake Product on that website, as they have done since July 2016.

14. ExeGi now brings this action to force Defendants to stop engaging in, and profiting from, false advertisements about the counterfeit version of the De Simone Formulation. These false advertisements materially misrepresent the facts about the composition, safety, and efficacy of the Fake Product. In so doing, these false advertisements have placed the patient population in the United States in grave physical danger and have substantially harmed ExeGi's sales of Visbiome, which is the only genuine version of the De Simone Formulation available in the market. Based on these facts and the averments below, ExeGi seeks to hold Defendants liable for false advertising and unfair competition under the Lanham Act, false advertising and unfair competition under the California Business and Professional Code, and tortious interference with prospective economic

advantage. For these causes of action, ExeGi requests compensatory damages against Defendants to remedy the harms caused by their false advertising as well as punitive damages and comprehensive injunctive relief. ExeGi also asks that the Court order the Defendants to disgorge to ExeGi all profits that they have unjustly gained from their unlawful conduct.

PARTIES

15. ExeGi is a limited liability company organized and incorporated under the laws of New York, with its principal place of business located at 155 Gibbs St., Unit 506, Rockville, Maryland 20850. All members of ExeGi are domiciled in, and are citizens of, Maryland. ExeGi is therefore a citizen of Maryland.

16. Nexternal Solutions, Inc. ("Nexternal") is a corporation organized and incorporated under the laws of California, with its principal place of business located at 560 Carlsbad Village Drive, Suite 204, Carlsbad, CA 92008. Nexternal is therefore a citizen of California. From its corporate headquarters in Carlsbad, California, Nexternal provides an omni-channel commerce platform that serves manufacturers, distributors and retailers.

17. HighJump Software Inc. ("HighJump") is a corporation organized and incorporated under the laws of Delaware, with its principal place of business located at 5600 West 83rd Street 8200 Tower, Suite 600, Bloomington, Minnesota 55437. HighJump is therefore is a citizen of Delaware and Minnesota. HighJump is a leading global provider of commerce-enabled supply chain management solutions. On May 26, 2015, HighJump announced that it had "extend[ed its] omni-channel suite" by acquiring Nexternal, "a leading cloud-based eCommerce platform provider based in California."

18. True Commerce, Inc. ("TrueCommerce") is a corporation organized and incorporated under the laws of Delaware, with its principal place of business located at 400 Northpointe Circle, Suite 201, Seven Fields, Pennsylvania 16046. TrueCommerce is therefore a citizen of Delaware and Pennsylvania. TrueCommerce is a global commerce network company providing technology that enables business to "do business in every direction." TrueCommerce is owned and operated by HighJump. Upon acquiring Nexternal in May 2015, HighJump integrated Nexternal's platform

into its existing TrueCommerce platform to create "TrueCommerce Nexternal." TrueCommerce Nexternal touts itself as the "only provider offering eCommerce and EDI[4] all under one roof."

JURISDICTION AND VENUE

19. Plaintiff ExeGi is a citizen of Maryland, and the Defendants in all claims brought by ExeGi are citizens of Delaware, California, Pennsylvania, and Minnesota. Accordingly, there is complete diversity between the parties to those claims, and this action is between citizens of different states. ExeGi derives substantial revenue from sales of Visbiome in California, including sales via ExeGi's website to consumers in California.

20. As alleged herein, the amount in controversy between the parties substantially exceeds $75,000, exclusive of interest and costs.

21. By virtue of the foregoing facts, this Court has jurisdiction over the subject matter of the claims brought by ExeGi under 28 U.S.C. § 1332(a)(1).

22. This Court also has jurisdiction over the subject matter of the claim brought by ExeGi under 28 U.S.C. §§ 1331 and 1367(a) because ExeGi's claim arises under a federal statute, the Lanham Act.

23. This Court may exercise personal jurisdiction over Defendant Nexternal because Nexternal is incorporated in, and has its principal place of business in, California. Also, ExeGi's claims arise from Nexternal's work from its corporate headquarters in Carlsbad, California, where Nexternal provides its omni-channel commerce platform to Alfasigma.

24. This Court may exercise personal jurisdiction over Defendants TrueCommerce and HighJump because they have purposefully availed themselves of the privilege of conducting business activities in California (*e.g.*, providing, from California, the eCommerce solution for all of Alfasigma's online sales of VSL#3), ExeGi's claims arise out TrueCommerce's and HighJump's provision of eCommerce services from California, and the exercise of jurisdiction over Defendants is constitutionally reasonable. Also, thousands of the sales that resulted from Defendants' false

[4] EDI stands for "electronic data interchange," the electronic interchange of business information using a standardized format. EDI allows one company to send information to another company electronically rather than with paper.

advertising took place in California, as those purchases were made by residents of California on a computer located in California.

25. Venue is properly laid in this judicial district under 28 U.S.C. § 1391(b)(1) because all Defendants are subject to personal jurisdiction in the Southern District of California and therefore are deemed to reside there. Also, venue is proper in this judicial district because Defendants' improper conduct alleged in this Complaint occurred in, was directed from, and/or emanated from, in whole or in part, this judicial district.

FACTS COMMON TO ALL COUNTS

A. Prof. De Simone's Groundbreaking Work Inventing Probiotic Formulations

26. Prof. De Simone is a renowned scientist, inventor, physician, and leader in the field of medical research focused on the health benefits of certain "friendly" bacteria that live on and within the human body. He is a Professor of Infectious Diseases and has degrees in Gastroenterology and Immunology, is a Fellow of the American Gastroenterology Association, and is an inventor of bacterial compositions used in the fields of human and veterinary nutrition and hygiene. Prof. De Simone has authored hundreds of clinical studies and scholarly papers in the field of probiotics[5], and he also has developed a series of new probiotic products that have helped thousands of people afflicted with gastrointestinal disorders, such as Inflammatory Bowel Disease ("IBD"), including Ulcerative Colitis ("UC"), Pouchitis and Irritable Bowel Syndrome ("IBS").

27. During the 1980s and early 1990s, Prof. De Simone conducted research into the clinical use of bacterial strains to treat the symptoms associated with IBD, IBS, enteral feeding, liver diseases, and many other conditions. Prof. De Simone's work resulted in the synthesis of several probiotic formulations, which clinical experience and data demonstrated had beneficial effects on those suffering from these maladies. Prof. De Simone obtained several patents (among other

[5] Probiotics are formulations comprised of live microorganisms, most often live bacterial cultures, which may be similar to those normally present in the human gastrointestinal tract and which have a beneficial effect on the host. Probiotics are supplied commercially in a variety of forms including capsules, tablets and sachets containing a powder dosage form, as well as in some foods, such as yogurt. The consumption of probiotics can help to re-establish a healthy balance of bacteria in the intestine by replenishing beneficial bacterial strains.

intellectual property rights) relating to his probiotic work in various countries, including in the United States.

B. VSL Inc. Commercializes the De Simone Formulation

28. Some 19 years ago, Prof. De Simone entered into a joint venture with two brothers, Claudio and Paolo Cavazza, who controlled one of the largest pharmaceutical conglomerates in Italy—the Sigma-Tau Group. The Sigma-Tau Group, a portion of which was recently combined with another Italian pharmaceutical company Alfa Wasserman, is in the business of developing and selling research-based pharmaceuticals and currently employs over 2,500 people worldwide.

29. At the outset of their business relationship, the three men struck a deal by which they combined their various talents, skills, and resources to develop and market some of Prof. De Simone's probiotic inventions to the consuming public. Prof. De Simone agreed to license portions of his intellectual property rights to the enterprise, while the Cavazza brothers agreed to contribute capital and business expertise to establish and fund its activities. To implement their plan, Prof. De Simone and the Cavazza brothers formed a company in the United States, VSL Pharmaceuticals, Inc. ("VSL Inc.").

30. On January 30, 2001, Prof. De Simone and VSL Inc. entered into a Patent License Agreement (the "Patent License Agreement") under which Prof. De Simone granted VSL Inc. exclusive (but temporally limited) rights to manufacture, promote, market, and sell the De Simone Formulation, a highly secret, proprietary formula owned by Prof. De Simone, in the United States in exchange for certain royalties based on net sales of the Product.

31. Relying upon the Patent License Agreement, VSL#3 was first offered for sale in the United States in 2002. From that time until February 1, 2016, the product sold as "VSL#3" was the De Simone Formulation, as manufactured by Danisco USA, Inc., a Missouri corporation whose principal place of business is in Madison, Wisconsin ("Danisco").

32. Over the ensuing years, the De Simone Formulation became the "gold standard" in its therapeutic class. This favorable recognition by the medical and scientific community led to business success for the enterprise created by Prof. De Simone and the Cavazza brothers. Aggregate global sales of VSL#3 are estimated to have grown to more than $60 million.

33. Despite this financial success (or perhaps because of it), however, the friendship and business partnership between Prof. De Simone and the Cavazzas began to show signs of cracking. Prof. De Simone had granted to VSL Inc. rights to use his proprietary information for VSL#3 to market and sell the probiotic food product in the United States for a limited period of time. These rights were contained in two key agreements, a Patent License Agreement, formed in 2001, and a Know How License Agreement, formed in 2010. VSL Inc., in turn, sub-licensed these rights to Leadiant, the Cavazza-owned subsidiary of the Sigma-Tau Group that assumed responsibility for actually distributing and selling the product in this country. Claudio Cavazza died in 2011, and his children inherited his interests in the Sigma-Tau Group's pharmaceutical and nutraceutical empire. After Claudio's death, his brother Paolo, Claudio's heirs, and their surrogates within the Sigma-Tau Group began pressuring Prof. De Simone to extend VSL Inc.'s and Leadiant's licenses (which were set to expire on January 31, 2016 and the end of 2015, respectively) under new terms that would disproportionately benefit the Sigma-Tau Group at the expense of Prof. De Simone and VSL Inc., the business enterprise that he jointly owned with them.

34. A key part of the Cavazzas' plan was to convince, and if that did not work, then to coerce, Prof. De Simone to relinquish his tight control over the manufacturing process and allow the Sigma-Tau Group to produce a "fake" version of VSL#3 with cheaper ingredients, thereby increasing the Cavazzas' profit margins for Leadiant.

35. In or about mid-2013, Andrea Montevecchi ("Mr. Montevecchi"), Chief Executive Officer of the Sigma-Tau Group (which includes Leadiant) and a director of Leadiant, contacted Prof. De Simone on several occasions to attempt to persuade him to agree to renew the license agreement between VSL Inc. and Leadiant for an additional five-year term beyond 2015 and on terms that were extremely favorable to Leadiant but economically unfeasible for VSL Inc.

36. In or about November 2013, Prof. De Simone met with Enrico Cavazza, who, along with his siblings, had assumed management of his father Claudio's businesses after Claudio Cavazza died in 2011. Enrico Cavazza proposed that Prof. De Simone agree to allow VSL Inc. to purchase the strains of lactic acid bacteria to be used in VSL#3 from Biosint, a company controlled by the Sigma-Tau Group, instead of from Danisco. Prof. De Simone rejected this proposal because,

in his view, Biosint's bacterial strains were inferior in quality to the strains used by Danisco and could be detrimental to consumers. In addition, Prof. De Simone worried about increasing the risk that the Cavazzas could misappropriate his Know-How.

37. In or about November 2013, Mr. Montevecchi complained again about the high cost of VSL#3 and how this was causing Leadiant's profit margins to be too low. Mr. Montevecchi proposed reducing VSL#3's production cost (thus increasing profit) by changing the product's composition and substituting cheaper bacterial strains supplied by Biosint. He argued that since VSL#3 was not being marketed as a drug in the United States, no one would notice the change in composition if everyone remained quiet about it.

38. Prof. De Simone would have none of this. He replied that he would never participate in a scheme to dilute or adulterate the product secretly, which would violate the trust that consumers had placed in VSL#3 and could lead to adverse health consequences for very sick consumers. Mr. Montevecchi, however, was not so easily dismissed this time. Disturbingly, he warned that unless VSL Inc. offered Leadiant a better profit margin on VSL#3, Prof. De Simone was risking further confrontation with the Cavazza family.

39. On November 21, 2013, Prof. De Simone met with Paolo Cavazza in Rome. Mr. Cavazza explained that Leadiant would be split into two entities, one for "orphan drug" prescription products and the other for nutraceuticals. Mr. Cavazza stated that the brand VSL#3 would be used to include new formulations with cheaper bacterial strains and concentrations. Mr. Cavazza also again suggested changing the formulation of VSL#3 in order to obtain higher profitability.

40. By the end of 2013, Prof. De Simone reached the frightening conclusion that profitability was the only objective that Paolo Cavazza and Leadiant had with respect to VSL#3 and they gave no consideration to the health risks to consumers and associated legal and ethical implications. It had become clear that undue threats and pressure from the Cavazzas to cooperate in their plans would only grow.

41. By March 2014, the pressure from the Cavazzas and their surrogates had indeed intensified. When Prof. De Simone resisted these pressures because of his concerns for consumer safety and the inherent deceptiveness of the Cavazzas' scheme, the Cavazzas initiated a coordinated

program to intimidate, threaten, and bully Prof. De Simone into complying with their demands. The Cavazzas explicitly threatened to use their massive financial resources to sue him and to bankrupt him and his family through the litigation process. They planned to use their control over the VSL#3 trademark to market a new, adulterated product under the old name in order to deceive the consuming public into thinking that the bastardized version was the same as the original "gold standard." Prof. De Simone became very concerned that if the Sigma-Tau Group succeeded in creating and marketing a fake VSL#3 product, it would put the patients who depend on this product at risk for due to a lack of efficacy and safety. Such a product would not have its efficacy and safety proven in any randomized controlled study, as the genuine product (the De Simone Formulation produced by Danisco) has done repeatedly.

42. By mid-2014, the evidence supporting Prof. De Simone's suspicion that Leadiant and related companies planned to market a "clone" of VSL#3 was mounting and emanated from multiple independent sources. This reckless conduct gravely concerned Prof. De Simone, who considered these actions to be unethical and in disregard for the safety of consumers who are immunosuppressed and rely on VSL#3 to address their serious medical conditions. In the absence of appropriate testing for safety and efficacy, no high concentration bacterial product should be made available to be administered to immunosuppressed consumers, since it can be dangerous and even lethal. This fact is well established in the medical community and was of major concern for Prof. De Simone.

43. Regrettably, the Cavazzas' intimidation scheme did not stop at mere threats. In 2014, they sued VSL Inc. (where Prof. De Simone was a director and officer at the time) and Prof. De Simone in Delaware. The Delaware litigation was principally filed to gain access to VSL Inc.'s books and records (and, in reality, Prof. De Simone's trade secrets), so the ownership of that intellectual property was not directly at issue. It became eminently clear that the Cavazzas had repudiated their contractual acknowledgments of Prof. De Simone's ownership of the Know-How and would stop at nothing to steal what he would not relinquish through negotiation—unilateral control over the valuable De Simone probiotic formulation and all of the profits that his invention had yielded.

44. In September 2014, the Cavazzas installed a new director, James Brady ("Mr. Brady") at VSL Inc. By letter dated October 15, 2014, addressed to the other directors of VSL Inc. and in his capacity as a director of the company, Mr. Brady asserted that VSL Inc. owns or may own all intellectual property rights in VSL#3 and contended for the very first time—falsely and in utter disregard for their repeated previous contractual acknowledgments—that Prof. De Simone's VSL#3-related patent rights and trade secrets actually belonged to them. This was in stark contradiction to the numerous prior agreements entered among the relevant parties in which it was clearly acknowledged that Prof. De Simone, and only Prof. De Simone, is the sole rightful owner of all intellectual property rights relating to the probiotic formulation underlying VSL#3 (as produced prior to February 1, 2016).

45. In November 2014, once the aforementioned Delaware litigation had been settled, Prof. De Simone resigned his positions as a director and officer of VSL Inc. and informed VSL Inc. that he intended to terminate the Know How Agreement. By early February 2015, the Patent License Agreement between Prof. De Simone and VSL Inc. had expired by its own terms. VSL Inc. also was in material breach of its obligations under this agreement as a result of its failure to make royalty payments due for 2014. Although Leadiant's (and its successors') sub-license with VSL Inc. was not formally terminated at that time, VSL Inc. could no longer legally honor that sub-license, and Leadiant (and its successors) could no longer legally make use of it, because VSL Inc.'s own licensing rights from Prof. De Simone were no longer valid.

46. In May 2015, ExeGi signed an agreement with Prof. De Simone to produce the probiotic containing the De Simone Formulation. The license agreement permits ExeGi to have the De Simone Formulation manufactured, as well as to market and sell this formulation, in the United States and elsewhere, based on the trade secrets and know-how owned and possessed by Prof. De Simone. ExeGi launched this product under the name "Visbiome" on February 1, 2016. Since that time, ExeGi has been, and currently is, the only authorized supplier of the De Simone Formulation in the United States and, as of July 2016 when Alfasigma began selling the Fake Product as VSL#3, Visbiome is the only authentic version of the De Simone Formulation in the market.

47. On June 24, 2015, Prof. De Simone sent a letter to Danisco stating that Leadiant could only continue as an Approved Buyer under Schedule A of the DeSimone-Danisco 2008 Agreement until September 15, 2015. On October 1, 2015, this letter was modified such that Leadiant's access to Danisco's supply of VSL#3 was extended to January 31, 2016. Danisco honored Prof. De Simone's instructions and ceased to provide Leadiant with supply of the De Simone Formulation as of January 31, 2016. Prior to the termination and expiration of these rights, the Cavazzas stockpiled the De Simone Formulation through large orders to Danisco, who was the only manufacturer of the De Simone Formulation. Leadiant had enough stock to continue selling the De Simone Formulation as VSL#3 through June 2016, unjustly enriching itself by selling the De Simone Formulation without paying royalties to Prof. De Simone.

48. In addition, as long suspected by Prof. De Simone, the Cavazzas, realizing they would soon be entirely cut off from the De Simone Formulation, intensified their efforts to create and sell a "fake" probiotic product that they could sell under the well-known VSL#3 brand. The Cavazzas hired a team of dairy experts to try to reverse engineer the De Simone Formulation. However, that task proved impossible, as the dairy experts could not ascertain the exact strains used in the product or the correct proportions of the strains they did identify. The best they could do was come up with a bad approximation of the De Simone Formulation and ask a new manufacturer in Italy, Centro Sperimentale del Latte, or "CSL," to make that Fake Product.

C. Leadiant and Alfasigma Foist the Fake Product on the Unsuspecting Public

49. In May 2016, Leadiant publicly announced that production of VSL#3 would be moving from the Danisco facility in the United States to a new manufacturer in Italy but went to great lengths to assure the public that there will be "no effect" on patients due to this change. In reality, Leadiant was converting from selling the De Simone Formulation as VSL#3 to selling the Fake Product as VSL#3, and simply pretended it was merely a change in manufacturing location, nothing more.

50. Nothing could be further from the truth. In the months that followed, independent testing (corroborated by anecdotal reports and complaints from consumers) confirmed that the Fake Product was demonstrably different from the original De Simone Formulation (then being sold by

ExeGi as Visbiome). Since the launch of the Fake Product (first in Europe, then in the U.S. and Canada), multiple investigators in Europe have compared the Fake Product to the De Simone Formulation and found striking differences between them. This data was peer reviewed and initially published in two journals and at two medical conferences, including the *Journal of Cellular Physiology*, *PLOS One*, the 2017 Digestive Disease Week Conference and the 4th World Congress on Targeting Microbiota at Institut Pasteur in Paris. A common theme of all the data sets is that both the quantitative and performance characteristics of the Fake Product versus the De Simone Formulation are fundamentally different.

51. Since September 2016, more articles have appeared in various peer-reviewed scientific journals that have compared the functional and performance characteristics of the De Simone Formulation and the Fake Product, as well as in abstracts at international conferences. All of the articles and abstracts have concluded that there are significant differences between the two products.

52. The first article appeared in the journal *Plos One* in September 2016 and was authored by six scientists. Using an in vitro study, they evaluated a variety of qualitative and performance characteristics. As to both qualitative and quantitative differences between the De Simone Formulation and the Fake Product, these scientists concluded that the average live-to-dead bacteria ratios of the two products were significantly different. When ingested by living organisms, the Fake Product contained 130-150 percent more dead bacteria (which are not inert ingredients) than are found within the De Simone Formulation. Even more importantly, when evaluated for impact on cancer cell activity, the De Simone Formulation had a significantly greater capability than the Fake Product to arrest the proliferation of cancer cells and in inducing the apoptotic cell death of those cancer cells. *See* Benedetta Cinque, *et al.*, *Production Conditions Affect the In-Vitro Anti-Tumoral Effects of a High Concentration Multi-Strain Probiotic Preparation*, PLOS ONE, Sept. 22, 2016.

53. In October 2016, another group of scientists affiliated with Sapienza University in Rome, Italy, published an abstract in the *Journal of the International Society of Microbiota* describing their findings of how the De Simone Formulation and the Fake Product compared in their effects on the cells of HIV patients. P24 is an antigen which makes up the core of the HIV virus

and should be maintained at the lowest level possible. Donor peripheral blood cells ("PBMCs") infected with the HIV-1 virus were incubated with both the De Simone Formulation and the Fake Product. The scientists concluded that the two formulations had different effects on the HIV-infected cultures. The De Simone Formulation had a marked inhibitory activity on the HIV replication, as measured by p24, while the Fake Product actually increased the levels of p24 by eight percent (8%). This data was presented at the renowned Institut Pasteur in Paris and raised serious safety-related questions for the HIV community, which need to be explored further. *See* Gabriella D'Ettorre, *et al.*, *p24 Levels In Vitro Are Affected Positively or Negatively Depending by the Production Site of the Probiotic*, 3 JOURNAL OF INT'L SOC'Y OF MICROBIOTA 85 (2016).

54. In January 2017, Professor Cinque and her colleagues followed up by conducting a new in vitro study. This one focused on using wound-healing assays to evaluate performance characteristics of the De Simone Formulation and the Fake Product using human, non-transformed, small-intestinal epithelial cell lines (IEC-6). This is a method to assess the product's efficacy in inducing the healing of the intestines of people suffering from inflammatory bowel disease and other chronic intestinal conditions. The key findings of this study identified the following differences in the performance metrics of the products:

- The Fake Product caused clear morphological cell damage on IEC-6 cell lines.
- The De Simone Formulation resulted in an enhanced rate of monolayer healing, while the Fake Product did not influence the closure rate of the wound.
- The De Simone Formulation enhanced the formation of elongated and aligned stress fibers, while the Fake Product had no such effect.
- The De Simone Formulation was able to cause a total inhibition of H2O2-induced cytotoxic effects on the cell lines, whereas the Fake Product was unable to produce such results.

See Benedetta Cinque *et al.*, *VSL#3 Probiotic Differently Influence IEC-6 Intestinal Epithelial Cell Status and Function*, JOURNAL OF CELLULAR PHYSIOLOGY, Jan. 2017.

55. In May 2017, a different group of scientists conducted an in vivo animal (mice) study comparing the De Simone Formulation with the Fake Product. Animal models of gastrointestinal colitis are critical to comparing the performance similarities and differences of the two products,

and mice with an induced colitis are the preferred and accepted standard experimental models. The methods and results are summarized below:

- The study used the classic dextran sulfate sodium ("DDS") induced colitis in mice. This is a classic animal model of intestinal colitis and inflammation, which has been applied in scientific analysis of medicinal compounds for decades.
- Colitis was induced in three groups of mice, who were then fed the De Simone Formulation, the Fake Product, or no treatment, respectively.
- Mice treated with the De Simone Formulation (Batch A) experienced a reduction in weight loss and intestinal inflammation, a reduction in intestinal permeability, and a reduction in severity of the colitis disease activity index (CDAI). Histopathology analysis also demonstrated an amelioration of colitis with respect to the untreated animals.
- Mice treated with the Fake Product (Batch B) showed a worsening CDAI index compared to the mice fed with the De Simone Formulation. Shockingly, the animals treated with Fake Product did worse than the animals with colitis that constituted the control group and had no probiotic treatment at all.
- Fake Product-treated animals had a worsening histopathology analysis and a six to seven-fold increase in intestinal permeability.

See Biagioli *et al.*, *Variability in Industrial Production Affects Probiotic Activity: Identification of Batches of Probiotic VSL#3 that Increases Intestinal Permeability and Worsens Colitis in Rodents*, DIGESTIVE DISEASES WEEK 2017.[6]

56. There are also significant qualitative differences between the Fake Product and the De Simone Formulation. For example, the average live-to-dead bacteria ratios of the two products were found to be significantly different. The Fake Product has a very high quantity of dead bacteria (which is not an inert ingredient and is therefore detrimental for the host). The number of live *streptococcus, bifidobacteium* and *lactobacillus* bacteria species of the two products also is significantly different, showing different ratios of the various species in each product. There are also significant performance differences between the Fake Product and the De Simone Formulation. Thus, when evaluated for impact on cancer cell activity, the De Simone Formulation was

[6] The above-discussed articles and abstracts were discussed during the federal court trial. Subsequent to the conclusion of the trial, additional peer-reviewed data confirming that the two products are different was published.

statistically significantly different from the Fake Product in its capability to arrest proliferation of common cancer cell lines and in inducing apoptotic cell death in those cells.

57. Prof. De Simone's fears that the Cavazzas and their surrogates would follow through on their threats to produce a dangerous, cheaper, inferior copy of his formulation, and seek to confuse consumers and the medical community that it was the same as the original formulation, had now become a reality.

58. Effective June 30, 2016, Leadiant assigned and transferred its rights for the marketing and sale of VSL#3 to Sigma-Tau Health Sciences, Inc., which was then merged into Alfasigma and ceased to exist as an independent company. By July 1, 2016, Alfasigma was exclusively selling VSL#3, which was the Fake Product sold with the VSL#3 trademark.

59. Even though the Fake Product used an entirely distinct formula from the De Simone Formulation and was manufactured using different methods (a key consideration for the efficacy of probiotics), Leadiant, and then Alfasigma, simply started selling it as "VSL#3" without alerting consumers that this new formula was entirely untested. Even worse, Alfasigma engaged in a pervasive and ongoing advertising campaign asserting the false premise that the Fake Product was "the same as" the De Simone Formulation, which was by then exclusively marketed and sold by ExeGi as Visbiome.

60. A key part of this advertising campaign occurred (and is still occurring) on the VSL#3 Website, with the critical and necessary help of the Defendants. On the VSL#3 Website, Alfasigma and the Defendants essentially have usurped the history of the De Simone Formulation and falsely represented it as the history of the Fake Product. For example, for the entire period that Alfasigma and the Defendants have been selling the Fake Product as VSL#3 (July 2016 through today), the VSL#3 Website has touted that the Fake Product VSL#3: (a) has been "[u]sed by physicians for more than 15 years"; (b) is "[w]idely studied in multiple trials"; (c) "provides support for the management of pouchitis"; (d) "contains 8 different strains of good bacteria"; (e) "has been shown in multiple studies to be safe to take every day, with or without certain medications, for the management of UC"; (f) "has been used to manage UC for more than 15 years"; (g) "has been studied in multiple trials and reviews in UC"; (h) "has been demonstrated to be safe to use every

day, with most people experiencing no problems with tolerability"; (i) "has been shown to effectively manage UC when used daily"; (j) "has been used for more than 15 years to manage IBS"; (k) "contains 8 different strains of live bacteria that have been carefully cultivated and proportionally mixed to optimize the probiotic content"; (l) "has been shown to deliver clinical benefits in UC, IBS, and pouchitis, and has demonstrated over 15 years of success in patients with UC, IBS, and pouchitis"; (m) "in clinical studies, patients taking [it] experienced minimal side effects similar to those seen when taking placebo"; (n) is "[t]he advanced probiotic medical food with a 15-year heritage that provides more to help the gastrointestinal tract"; (o) was "widely studied in over 170 clinical, preclinical, and review papers"; (p) was "demonstrated to be safe, with a low incidence of minor side effects, similar to placebo" in "18 different studies conducted over the past 15 years"; (q) "has been the subject of extensive clinical research in the dietary management of IBS, UC and an ileal pouch"; and (r) is supported by numerous cited studies.

61. Each of these statements is demonstrably false. In reality, the statements apply only to the De Simone Formulation, but the De Simone Formulation has been sold exclusively as Visbiome, not VSL#3, since July 2016. The product sold as VSL#3 from July 2016 to today is the Fake Product, which uses different strains, in a different ratio, has a different biological and immunologic profile, is made with different manufacturing methods than the De Simone Formulation, and has none of the attributes described in (a) through (r) of the preceding paragraph.

62. Further, the VSL#3 Website goes on to cite numerous clinical studies in the field of IBS, UC and Pouchitis. For example: Tursi et al. 2010 - Tursi A., et al. Am J Gastroenterol 105:2218-27 (2010); Ng et al. 2010 - Ng S.C., et al. Inflamm Bowel Dis. 16:1286-98 (2010); and Sood et al. 2009 - Sood A., et al. Clin Gastroenterol Hepatol 11:1202-9 (2009). In each case, the study in question is a study performed using the "VSL#3" product produced with the De Simone Formulation, and not the Fake Product VSL#3 produced in Italy by CSL. As noted above, the De Simone Formulation probiotic and the Fake Product probiotic are simply materially different products, making these clinical citations literally false and misleading.

63. Alfasigma and Defendants' false advertising extended to numerous false representations (similar to the claims made on the VSL#3 Website) on the VSL#3 Facebook

platform as well. The VSL#3 Facebook page has a "Shop Now" button, that which, when clicked, takes the user straight to the eCommerce solution provided by the Defendants.

64. Alfasigma and Defendants committed further acts of false advertising by omitting important information about the Fake Product's ingredients to create a false impression that the Fake Product is linked to the De Simone Formulation. As is common practice in the probiotic industry, Leadiant previously labeled its products with the genus, species and strain designation numbers for each of the eight bacterial strains contained in the product. Respected organizations such as the Council for Responsible Nutrition and the International Probiotics Association specifically recommend this practice in its Best Practices Guidelines for Probiotics[7], as individual strains of the same genus and species can have different functional properties. In fact, Leadiant's marketing materials, such as the VSL#3 Patient Brochure," *did include* the specific strain designation numbers, along with the genus and species when it was selling VSL#3 with the De Simone Formulation. In contrast, on the "Product Information" sheet available on the VSL#3 Website and in the product package insert, Alfasigma and Defendants do not include the strain designation numbers along with the genus and species. This is no surprise because if they were to include the strain designation numbers, it would be an admission to consumers that the Fake Product no longer contains the same strains as the De Simone Formulation and is manufactured in a different place.

65. All of the above falsities were squarely at issue in ExeGi's litigation for false advertising against Alfasigma.

D. Professor De Simone and ExeGi Prevail at Trial in Maryland

66. On October 9, 2018, Judge Chuang, the judge presiding over the Maryland federal court litigation, granted Prof. De Simone and ExeGi's motion for summary judgment in many key respects. Judge Chuang granted Prof. De Simone's request for summary judgment on his claim for declaratory relief, whereby Prof. De Simone was awarded sole ownership of the "Know-How."

[7] https://www.crnusa.org/sites/default/files/pdfs/CRN-IPA-Best-Practices-Guidelines-for-Probiotics.pdf

Judge Chuang determined that ExeGi's claim for false advertising under the Lanham Act could not be decided on summary judgment, as issues of material fact remained in dispute, and that claim (amongst others) proceeded to trial.

67. The litigation between ExeGi and Prof. De Simone on one side and VSL Inc., Leadiant, and Alfasigma (collectively, the "Maryland Defendants") on the other culminated in a jury trial in the District of Maryland from October 30, 2018 to November 21, 2018. Extensive testimonial and documentary evidence was elicited at trial that demonstrated the falsity of the above enumerated statements on the VSL#3 Website.

68. For example, the falsity of the statements that the Fake Product has "a 15-year track record of demonstrated clinical benefits and 170 published clinical studies and reviews" and "has been supported by numerous studies" was at issue in the trial. These same claims appeared on the VSL#3 Website prior to the trial and continue to appear on the VSL#3 Website to this day. ExeGi showed the falsity of those statements by showing that it was the De Simone Formulation, not the Fake Product, that enjoyed that history, and that the Fake Product does not get to usurp that history because genetic testing, journal articles, and expert testimony confirmed the two products are neither genetically identical nor functionally equivalent.

69. As expert witness Dr. Patrick Gillevet opined in the trial: "it is clear that the original De Simone strain product has eight strains and … [the] new VSL#3 product that has been tested has only seven strains." That much was equally clear to VSL Inc., who promoted VSL#3 in Canada as a seven-strain product; disclosed to Health Canada that their product only had seven strains; drafted letters to CSL that showed there were only seven strains in the Fake Product; and confirmed that the Drug Master File for the Fake Product listed only seven ingredients. In their best effort to argue that the Fake Product has eight strains, despite their own representations to the contrary, the Maryland Defendants could offer only the testimony of Franco Pirovano, who had never tested the product,[8] and Marco Caspani. However, Mr. Caspani, the CEO of CSL, the manufacturer of the Fake Product, admitted that he merely acted—upon the request of a VSL Inc. affiliate— as if there

[8] Dr. Pirovano only claimed that he gave Dr. Caspani eight vials; he never tested their contents.

were two distinct *B.lactis* strains; however, to him, when tested at CSL, it appeared that there was only one unique *B.lactis* strain. Although Defendants also proffered the testimony of Dr. Barrangou, who had previously opined that VSL#3 had eight strains based on the DeVos study, at trial, Dr. Gillevet analyzed the same reports and concluded (with "100%" confidence) that VSL#3 had seven strains. And Dr. Barrangou did not challenge Dr. Gillevet's conclusion.[9]

70. As Dr. Gillevet concluded, genetically, the two formulas "are very distinct." The De Simone Formulation contains the strains BI-07 and BL-04; the Fake Product only contains BI-07. Accordingly: "They are genetically different. They are missing a piece of DNA." And where, as here, "you have two different genes, you are going to have … different functions." Simply put, the two formulas "have different functions," which "has medical implications" because the two products will not perform identically. Dr. Barrangou agreed with Dr. Gillevet on these points, noting that the genetic testing showed two isolates of the same BI-07 strain in the Fake Product, while two distinct strains in the De Simone Formulation, and that these two different strains had different functional properties.

71. Another expert witness, Dr. Christian Loch, confirmed the same: "the two products [a]re very different." As his proteomic testing revealed: "Of the roughly 4,000 proteins that we identified, about 1,000, [or] 25 percent of them or so, were indeed different."[10] The formulas' "different protiums [sic] will result in different performance." Dr. Alessio Fasano also confirmed that the two products are "very different," and given their "substantial differences," their efficacy "will be very different." Dr. Fasano further detailed the multiple peer-reviewed studies supporting

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[9] At trial, Dr. Barrangou distanced himself from the position he had maintained throughout the litigation—that the DeVos study proved that VSL#3 had eight strains.

[10] Notably, Alfasigma originally pursued a false advertising claim against Prof. De Simone and ExeGi, alleging that Prof. De Simone and ExeGi falsely stated that "VSL#3 had undergone a formula change"; that VSL Inc. "changed the formula of VSL#3"; and that "VSL#3 did not have the same formulation as Visbiome." It is very telling that Alfasigma voluntarily dismissed that claim (with prejudice) during the trial, as that shows Alfasigma was not able to support its claim that such statements are false. Indeed, all of the evidence at trial made it clear that such statements are true; the Fake Product does not have the same formula as Visbiome (the De Simone Formulation).

the same conclusion: "the new formulation from Italy is not … comparable to the formulation that is from United States." Among other things, "the [De Simone] formulation was able to accelerate the process of wound repair and to mitigate the stress in use by this chemical on the cells while [VSL#3] was not."[11]

72. Further supporting the distinction between the two products, there was also uncontroverted evidence that the Fake Product was made via an attempt to reverse engineer the De Simone Formulation, and that attempt failed. By admission of the CEO of VSL Inc., Luca Guarna, VSL Inc. could only determine the amount of each strain used within a 30% margin of error – ***per strain***. In addition to Mr. Guarna, Paolo Cavazza agreed: it would be "impossible" to create an actual replica of the De Simone Formulation "or to copy it." The dairy experts Defendants hired to attempt to reverse engineer the De Simone Formulation reaffirmed as much.

73. Additionally, the testimony at trial established that the claims on the VSL#3 Website of proven clinical benefits and a robust set of studies supporting the claims of efficacy were literally false. Trial testimony clearly established that there is not a single scientific study that has "proven" that the Fake Product is efficacious or safe in any way. Luca Guarna admitted that VSL Inc. conducted no efficacy testing at all, much less testing that could establish the Fake Product as equally efficacious as the De Simone Formulation. Nor did Alfasigma conduct any efficacy testing, although Alfasigma advertised the Fake Product's supposed efficacy and equivalency regardless. Indeed, the lack of efficacy studies on the Fake Product version of VSL#3 was an uncontested fact in that trial.

74. The testimony thus established that the Fake Product was not equivalent to the De Simone Formulation, and all statements on the VSL#3 Website (and elsewhere) that assert the De Simone Formulation's history, characteristics, and efficacy as that of the Fake Product are literally false. In the Maryland litigation, Alfasigma offered no evidence to the contrary, because none

[11] As Dr. Fasano elaborated, that due to the changes in manufacturing, the protein expression would be different, since "the final outcome of the functionality of … probiotics really depends on what you feed them." Dr. Loch confirmed that changes in manufacturing would change the product's proteins. Further, a change in fermentation "would change statistically significant expression of certain proteins."

exists. Instead, Alfasigma relied on a very poor argument. While conceding that neither it, nor VSL Inc., nor Leadiant had performed efficacy testing to compare the Fake Product and the De Simone Formulation and that the two products were not identical, Alfasigma simplistically argued that the two products were similar enough that the jury should find that it was not false for Alfasigma to usurp the history of the De Simone Formulation and pass it off as the history of the Fake Product. This argument was thoroughly destroyed in the litigation and after three weeks of trial, ExeGi's significant evidence of the falsity of the statements made about the Fake Product carried the day. A nine-person federal jury unanimously found in favor of ExeGi against Alfasigma and awarded $15 million to ExeGi as compensatory damages for the false advertising.

75. Unfortunately, the unanimous findings of the nine-person jury, who determined that Alfasigma and Leadiant violated the Lanham Act through their false advertisements and awarded $15 million in damages to ExeGi, did not convince Alfasigma to change its advertisements. To the contrary, Alfasigma took the nonsensical position that because so many falsities were presented to the jury, Alfasigma could not say for certain which falsities were the foundation for the verdict and thus did not need to change its advertisements in any way.

76. Even prior to the jury verdict, the conclusion that the Fake Product was not functionally equivalent to Danisco VSL#3 had wide ranging acceptance and the implications of that conclusion were adopted throughout the world. As examples:

(a) Health Canada canceled the license to sell VSL#3® in Canada for ulcerative colitis and pouchitis, and Ferring (the same company selling the same VSL#3® in Germany) has withdrawn the product from the Canadian market, effective November 15, 2018.

(b) On January 25, 2018, the Court of Justice in Hamburg assessed the VSL# 3® product distributed by Ferring (that is the Fake Product) and concluded: "It is no longer to be considered identical, at least in effect" to the original principle, with respect to the active ingredient to which the Guidelines refer [2]. The German court came to this conclusion, "as the preparation put into circulation by the defendant [Ferring Germany, which distributes the Fake Product] cannot (anymore) be identical to that mentioned in the Guidelines already for the reason, peaceful, that the cultivation methods have changed substantially and the change of the production method changes its effect." The German court concluded that "such misleading indications to the Guidelines are also likely to influence the purchase decision because the special indication to the associations of specialists arouses increased confidence in the effectiveness and seriousness of the product."

(c) The mention of the VSL#3 product was removed from the WGO (World Gastroenterology Organization) and the ESPEN (European Society for Clinical

Nutrition and Metabolism) Guidelines and replaced by the list of bacteria quoted in the referenced papers.

(d) The CEO of VSL Inc, Luca Guarna, is under investigation by the Prosecutor of the Tribunal of Rome, Italy for the crimes referred to in art. 515 (fraud in commerce) and 440 (adulteration or counterfeiting of food substances) of the Italian penal code as well as for all the other offenses related to the distribution of the Fake Product in Italy.

Despite the crystal-clear conclusion by courts, regulators, and international scientific organizations around the world, by peer-reviewed studies, and even by the jury that Alfasigma's advertising claims were false, Alfasigma did not change its advertisements to remove the false statements. Alfasigma has steadfastly refused to change those advertisements and continues to make the same false statements in its advertising, including keeping the exact same statements on the VSL#3 Website, to this day.

77. However, as mentioned above, most of Alfasigma's partners in the distribution chain have refused, since the conclusion of the Maryland trial, to continue participating in Alfasigma's deceit. Recognizing their own potential liability for participating in, and perpetuating, Alfasigma's false advertisements, within weeks of the verdict, most of the U.S. distributors and major national retailers, including McKesson Corporation, Cardinal Health, Inc., CVS Health Corporation, Costco Wholesale Corporation, Walmart Inc., Amazon.com, Inc., and Walgreens Company stopped selling VSL#3 due to Alfasigma's false advertising.

78. Additionally, at the time of the verdict, several major educational institutions in the United States and Europe were conducting clinical trials on "VSL#3," which, unbeknownst to them, was the Fake Product and not the De Simone Formulation. Once the truth became public after the verdict, out of concern for patient safety and on the basis that VSL Inc.'s claim to a robust clinical history was disproven in the federal court case, every one of these institutions, including Stanford University, University of Wisconsin (Madison), University of Louisville, Emory University, Hopitaux de Paris, and Università Cattolica Roma, immediately ceased its clinical trial.

79. With most of its methods of distribution cut off, Alfasigma has primarily resorted to selling the Fake Product through the VSL#3 Website. All of Alfasigma's Web Sales are made via the eCommerce Solution by Nexternal. Upon information and belief, TrueCommerce and HighJump (an affiliate and the owner of Nexternal, respectively) integrated their own software into

Nexternal's eCommerce Solution and, from Nexternal's corporate headquarters in Carlsbad, California, are actively participating in facilitating the sales of the Fake Product.

80. Defendants' eCommerce solution plays a necessary, critical role in every one of the VSL#3 Web Sales. In fact, Defendants are the key players in selling the counterfeit VSL#3 product, as they tout their platform to "efficiently capture & manage all your orders in one commerce system," to "capture orders from distributors, retailers, and sales reps with advanced customer segmentation," and to cause sales to "thrive with our vast array of marketing tools" through "online, mobile, point of sale, subscription, call center, or club order" channels. Defendants, in their own words, allow Alfasigma to "do business in every direction." As active participants in the sales process for the Fake Product, Defendants have adopted and perpetuated the false statements about that product that appear on the VSL#3 Website. As noted above, those false statements have already been found by a jury to be material misrepresentations that violate the Lanham Act. Defendants cannot claim ignorance of the falsity of those statements or of the jury verdict, as the March Letter put them squarely on notice of both. The fact is, they just do not care, so long as the profits keep rolling in.

81. Defendants actions violate both the Lanham Act and California's Unfair Competition Law ("UCL") and False Advertising Law, Business and Professions Code §§ 17200 et seq. and §§ 17500 et seq. respectively. Defendants are actively perpetuating, participating in, endorsing, adopting, and profiting from a variety of false statements on the VSL#3 Website that aim to, and successfully do, divert customers from the De Simone Formulation (Visbiome, sold by ExeGi) to the Fake Product (VSL#3, sold by Alfasigma). In fact, the harm to ExeGi comes directly from Defendants' role in the transaction, as they provide the method for the consumer to make the actual purchase of the Fake Product, rather than Visbiome. During the period where the false representations were displayed on the VSL#3 Website (July 2016 to today), the Defendants have processed many thousands of orders of the Fake Product that resulted from the false representations.

82. To be subject to liability under the UCL, a defendant must only have "somehow participated in, controlled, or adopted" the unlawful practices. Once a participant in the sales process has actual notice that a manufacturer's marketing materials are deceptive, "its decision to

continue to sell the products may raise an inference of participation in or adoption of the deceptive practices." That is clearly the case with Defendants' decision to continue sales after receiving the March Letter.

83. It is noteworthy that the conduct of Alfasigma, Defendants' customer, not only violates the Lanham Act and the UCL, but it breaches express provisions of TrueCommerce's published Terms of Use. Paragraph 9(b) of the Terms of Use require Alfasigma to represent and warrant that "[a]ll merchandise sold by using the Product . . . does not infringe upon the intellectual property or other rights of any third party, and is legal to sell to each customer and in each jurisdiction in which such merchandise is sold or delivered." Paragraph 9(f) requires that "Client will, at all times, comply with all applicable laws and regulations with respect to its activities under this agreement including without limitation the sale of its products and services using the Product." Finally, paragraph 9(g) states that "Client will, at all times, obtain and maintain all necessary licenses, consents, and permissions necessary for Client, its contractors and agents to perform their obligations under this agreement or required to conduct its business activities, including without limitation the sale and distribution of its products and processing of related transactions utilizing the Product." Each of these provisions is violated by Alfasigma's illicit sales and marketing practices, which run afoul of the Lanham Act. So, Defendants are ignoring the Lanham Act, the UCL, and their own policies for the sake of keeping the money flowing from the sales of the Fake Product.

84. ExeGi is directly harmed by Defendants' false advertising. Visbiome (the De Simone Formulation) and VSL#3 (the Fake Product) are directly competitive products in that both products claim to be high-potency, 8-strain, medical food that is effective to manage IBS, UC, pouchitis and other serious conditions. Visbiome and VSL#3 stand alone from any other competitors, as no other probiotic (or any other product) makes similar claims. Doctors and patients seeking to take a probiotic to manage symptoms of IBS, UC, pouchitis and other serious conditions therefore must choose between only those two options, Visbiome and VSL#3. As testimony in the Maryland litigation firmly established, doctors and patients rely on the clinical history, composition, and peer-reviewed studies to determine which probiotic has been deemed safe and effective in order to determine whether to buy Visbiome or VSL#3. By misrepresenting the Fake Product's clinical

history, composition, and supporting peer-reviewed studies, Defendants caused consumers (such as patients and doctors) to purchase VSL#3 rather than Visbiome. This diversion of sales from Visbiome to VSL#3 has caused direct harm to ExeGi, as it is the exclusive provider of Visbiome in the United States. Defendants' false advertisements also caused a loss of good will for ExeGi, as ExeGi is the exclusive provider of the only probiotic that has more than 15 years of clinical history and over 60 clinical trials to support its claims of efficacy, but Defendants' false advertisements falsely tell consumers that Alfasigma has an alternative probiotic, VSL#3, with an equally impressive clinical and trial history. In fact, there is not a single clinical trial that supports the claim that VSL#3 effectively manages any symptoms and the Fake Product has only been on the market since June 2016.

COUNT I

False Advertising Under 15 U.S.C. § 1125(a)

85. ExeGi adopts by reference each and every one of the foregoing factual allegations as if alleged in full in Count I, except as they may be inconsistent with the specific allegations contained in Count I.

86. As alleged herein, Defendants have actively made, perpetuated, participated in, endorsed, adopted, and profited from material false representations about VSL#3 in commercial advertisements in violation of 15 U.S.C. § 1125(a), including but not limited to:

(a) the false representations contained on the VSL#3 Website, as enumerated in Paragraph 60(a)-(r) above;

(b) citing studies performed using the "VSL#3" product containing the De Simone Formulation in discussing the Fake Product version of VSL#3 on the *www.VSL3.com* website and in its package insert;

(c) the false representations made by Defendants on Facebook, with a direct link to the VSL#3 Online Store provided in the advertisement; and

(d) omitting important information about new VSL#3's product ingredients to create a false impression of linkage to the product produced by Danisco with the De Simone Formulation.

87. As described above, the statements listed in Paragraph 86 are literally false or, at best, highly misleading.

88. The false representations by Defendants are material, as consumers, practitioners, and other healthcare providers will believe that they are purchasing, recommending, or prescribing a product containing the De Simone Formulation, which has been the subject of many clinical trials and a lengthy patient history when, in reality, the product they are purchasing is fundamentally different, with a different source and different effects, with little or no testing history, and little or no clinical trial history.

89. These false representations by Defendants are intended to, and have, deceived a substantial segment of consumers, practitioners, and other healthcare providers into mistakenly believing that the Fake Product has the same biochemical and immunological features, the same performance characteristics, and the same supporting clinical data as the original VSL#3 made by Danisco using the De Simone Formulation.

90. Defendants placed these false representations in interstate commerce by publishing them on the VSL#3 Website and on Facebook.

91. ExeGi has been injured, and is likely to be further injured in the future, as a direct and proximate result of the false advertising described herein through both a direct diversion of its sales and by a lessening of goodwill associated with the original De Simone Formulation made by Danisco, which ExeGi currently sells under the brand name Visbiome. Defendants' false representations are intended to divert sales from Visbiome to VSL#3 and have successfully caused that diversion. Furthermore, the goodwill associated with Visbiome, which is made by Danisco using the De Simone Formulation, has been and will be diminished because consumers falsely believe that the Fake Product VSL#3 is the equivalent of the Visbiome product; therefore, consumers have, and will, think less of ExeGi and Visbiome, given that the Fake Product fails to meet the performance standards of Visbiome. As the Fake Product has not undergone a single clinical trial, and independent testing and consumer reaction has revealed material differences with the De Simone Formulation and serious efficacy deficiencies in the Fake Product, it is likely that

the Fake Product will indeed continue to fail to meet the performance standards of the De Simone Formulation, which was heavily tested by clinical trials and has a long user history.

COUNT II

False Advertising Under CA Bus. & Prof. Code §§ 17500, *et seq*.

92. ExeGi adopts by reference each and every one of the foregoing factual allegations as if alleged in full in Count II, except as they may be inconsistent with the specific allegations contained in Count II.

93. As alleged herein, Defendants have actively made, perpetuated, participated in, endorsed, adopted, and profited from material false representations about VSL#3 in commercial advertisements. These acts constitute untrue and misleading advertising, as defined by CA Bus. & Prof. Code Sections 17500, *et seq*. (the "FAL").

94. As described above, Defendants have actively made, perpetuated, participated in, endorsed, adopted, and profited from numerous false representations, including but not limited to:

(a) the false representations contained on the VSL#3 Website, as enumerated in Paragraph 60(a)-(r) above;

(b) citing studies performed using the "VSL#3" product containing the De Simone Formulation in discussing the Fake Product version of VSL#3 on the *www.VSL3.com* website and in its package insert;

(c) the false representations made by Defendants on Facebook, with a direct link to the VSL#3 Online Store provided in the advertisement; and

(d) omitting important information about new VSL#3's product ingredients to create a false impression of linkage to the product produced by Danisco with the De Simone Formulation.

95. As described above, the statements listed in Paragraph 94 are literally false or, at best, highly misleading.

96. The false representations by Defendants are material, as consumers, practitioners, and other healthcare providers will believe that they are purchasing, recommending, or prescribing a product containing the De Simone Formulation, which has been the subject of many clinical trials

and a lengthy patient history when, in reality, the product they are purchasing is fundamentally different, with a different source and different effects, with little or no testing history, and little or no clinical trial history.

97. These false representations by Defendants are intended to, and have, deceived a substantial segment of consumers, practitioners, and other healthcare providers into mistakenly believing that the Fake Product has the same biochemical and immunological features, the same performance characteristics, and the supporting clinical data as the original VSL#3 made by Danisco using the De Simone Formulation.

98. ExeGi has been injured, and is likely to be further injured in the future, as a direct and proximate result of the false advertising described herein through both a direct diversion of its sales and by a lessening of goodwill associated with the original De Simone Formulation made by Danisco, which ExeGi currently sells under the brand name Visbiome. Defendants' false representations are intended to divert sales from Visbiome to VSL#3 and have successfully caused that diversion. Furthermore, the goodwill associated with Visbiome, which is made by Danisco using the De Simone Formulation, has been and will be diminished because consumers falsely believe that the Fake Product VSL#3 is the equivalent of the Visbiome product; therefore, consumers have, and will, think less of ExeGi and Visbiome, given that the Fake Product fails to meet the performance standards of Visbiome. As the Fake Product has not undergone a single clinical trial, and independent testing and consumer reaction has revealed material differences with the De Simone Formulation and serious efficacy deficiencies in the Fake Product, it is likely that the Fake Product will indeed continue to fail to meet the performance standards of the De Simone Formulation, which was heavily tested by clinical trials and has a long user history.

COUNT III

Unfair Competition Under 15 U.S.C. § 1125(a)

99. ExeGi adopts by reference each and every one of the foregoing factual allegations as if alleged in full in Count III, except as they may be inconsistent with the specific allegations contained in Count III.

100. As alleged herein, Defendants have actively made, perpetuated, participated in, endorsed, adopted, and profited from material false representations about VSL#3 in commercial advertisements, which constitute unfair competition in violation of 15 U.S.C. § 1125(a), including but not limited to:

(a) the false representations contained on the VSL#3 Website, as enumerated in Paragraph 60(a)-(r) above;

(b) citing studies performed using the "VSL#3" product containing the De Simone Formulation in discussing the Fake Product version of VSL#3 on the *www.VSL3.com* website and in its package insert;

(c) the false representations made by Defendants on Facebook, with a direct link to the VSL#3 Online Store provided in the advertisement; and

(d) omitting important information about new VSL#3's product ingredients to create a false impression of linkage to the product produced by Danisco with the De Simone Formulation.

101. As described above, the statements list in Paragraph 100 are literally false or, at best, highly misleading.

102. The false representations by Defendants are material, as consumers, practitioners, and other healthcare providers will believe that they are purchasing, recommending, or prescribing a product containing the De Simone Formulation, which has been the subject of many clinical trials and a lengthy patient history when, in reality, the product they are purchasing is fundamentally different, with a different source and different effects, with little or no testing history, and little or no clinical trial history.

103. These false representations by Defendants are intended to, and have, deceived a substantial segment of consumers, practitioners, and other healthcare providers into mistakenly believing that the Fake Product has the same biochemical and immunological features, the same performance characteristics, and the supporting clinical data as the original VSL#3 made by Danisco using the De Simone Formulation.

104. Consumers reviewed and relied upon the false and misleading representations in Defendants' VSL#3 advertising when making the decision to buy VSL#3 rather than the alternative product, ExeGi.

105. Defendants' wrongful acts alleged herein have permitted and/or will permit Defendants to earn substantial revenues and profits on the strength of the De Simone Formulation.

106. ExeGi has been injured, and is likely to be further injured in the future, as a direct and proximate result of the unfair competition described herein through both a direct diversion of its sales and by a lessening of goodwill associated with the original De Simone Formulation made by Danisco, which ExeGi currently sells under the brand name Visbiome. Defendants' false representations are intended to divert sales from Visbiome to VSL#3 and have successfully caused that diversion. Furthermore, the goodwill associated with Visbiome, which is made by Danisco using the De Simone Formulation, has been and will be diminished because consumers falsely believe that the Fake Product VSL#3 is the equivalent of the Visbiome product; therefore, consumers have, and will, think less of ExeGi and Visbiome, given that the Fake Product fails to meet the performance standards of Visbiome. As the Fake Product has not undergone a single clinical trial, and independent testing and consumer reaction has revealed material differences with the De Simone Formulation and serious efficacy deficiencies in the Fake Product, it is likely that the Fake Product will indeed continue to fail to meet the performance standards of the De Simone Formulation, which was heavily tested by clinical trials and has a long user history.

COUNT IV

Unfair Competition Under CA Bus. & Prof. Code §§ 17200, *et seq.*

107. ExeGi adopts by reference each and every one of the foregoing factual allegations as if alleged in full in Count IV, except as they may be inconsistent with the specific allegations contained in Count IV.

108. As alleged herein, through their actions in selling and offering for sale the Fake Product, Defendants have actively made, perpetuated, participated in, endorsed, adopted, and profited from material false representations about VSL#3 in commercial advertisements, which

constitute unfair competition, as defined by CA Bus. & Prof. Code Sections 17200 *et seq*. (the "UCL").

109. As described above, Defendants have actively made, perpetuated, participated in, endorsed, adopted, and profited from numerous false representations, including but not limited to:

(a) the false representations contained on the VSL#3 Website, as enumerated in Paragraph 60(a)-(r) above;

(b) citing studies performed using the "VSL#3" product containing the De Simone Formulation in discussing the Fake Product version of VSL#3 on the *www.VSL3.com* website and in its package insert;

(c) the false representations made by Defendants on Facebook, with a direct link to the VSL#3 Online Store provided in the advertisement; and

(d) omitting important information about new VSL#3's product ingredients to create a false impression of linkage to the product produced by Danisco with the De Simone Formulation.

110. As described above, the statements list in Paragraph 109 are literally false or, at best, highly misleading.

111. The false representations by Defendants are material, as consumers, practitioners, and other healthcare providers will believe that they are purchasing, recommending, or prescribing a product containing the De Simone Formulation, which has been the subject of many clinical trials and a lengthy patient history when, in reality, the product they are purchasing is fundamentally different, with a different source and different effects, with little or no testing history, and little or no clinical trial history.

112. The harm to the public from Defendants' business practice described herein is greater than the utility of the practice.

113. These false representations by Defendants are intended to, and have, deceived a substantial segment of consumers, practitioners, and other healthcare providers into mistakenly believing that the Fake Product has the same biochemical and immunological features, the same

performance characteristics, and the supporting clinical data as the original VSL#3 made by Danisco using the De Simone Formulation.

114. Consumers reviewed and relied upon the false and misleading representations in Defendants' VSL#3 advertising when making the decision to buy VSL#3 rather than the alternative product, ExeGi.

115. Defendants are obtaining profits from those sales.

116. ExeGi suffered an injury in fact and lost money and goodwill as a direct and proximate result of Defendants' unfair competition and is likely to suffer further injury in the future.

COUNT V

Contributory False Advertising

117. ExeGi adopts by reference each and every one of the foregoing factual allegations as if alleged in full in Count V, except as they may be inconsistent with the specific allegations contained in Count V.

118. As alleged herein, Defendants knew or should have known that the VSL#3 Website contains numerous false representations, including but not limited to the false representations enumerated in Paragraph 60(a)-(r) above, as does the VSL#3 Facebook page.

119. As described above, Defendants knew or should have known that those false representations were likely to confuse consumers about the Fake Product and cause consumers to divert sales from ExeGi to Alfasigma.

120. Despite this knowledge, Defendants continued to supply the means of infringement upon ExeGi's rights, by providing the eCommerce solution for all of the sales through the VSL#3 Website.

121. Defendants had the means to control and monitor all of the sales through the VSL#3 Website and actively supported those sales through various promotion efforts.

122. ExeGi has been injured, and is likely to be further injured in the future, as a direct and proximate result of Defendants' contributory false advertising, as described herein, through both a direct diversion of its sales and by a lessening of goodwill associated with the original De Simone Formulation made by Danisco, which ExeGi currently sells under the brand name Visbiome.

Defendants' perpetuations of the false representations are intended to divert sales from Visbiome to VSL#3 and have successfully caused that diversion. Furthermore, the goodwill associated with Visbiome, which is made by Danisco using the De Simone Formulation, has been and will be diminished because consumers falsely believe that the Fake Product VSL#3 is the equivalent of the Visbiome product; therefore, consumers have, and will, think less of ExeGi and Visbiome, given that the Fake Product fails to meet the performance standards of Visbiome. As the Fake Product has not undergone a single clinical trial, and independent testing and consumer reaction has revealed material differences with the De Simone Formulation and serious efficacy deficiencies in the Fake Product, it is likely that the Fake Product will indeed continue to fail to meet the performance standards of the De Simone Formulation, which was heavily tested by clinical trials and has a long user history.

COUNT VI

Tortious Interference with Prospective Economic Advantage

123. ExeGi adopts by reference each and every one of the foregoing factual allegations as if alleged in full in Count VI, except as they may be inconsistent with the specific allegations contained in Count VI.

124. ExeGi has developed and maintained valuable and reliable customer relationships with healthcare providers to whom ExeGi has sold and distributed Visbiome and/or to whom ExeGi is likely to sell and distribute Visbiome to in the future. Defendants have knowledge of these relationships, as they sell, or attempt to sell, VSL#3 to many of the same healthcare providers.

125. Since July 2016, Defendants have evidenced their intent to interfere with ExeGi's customer relationships by knowingly and intentionally misrepresenting to ExeGi's customers the characteristics, history, and efficacy of the Fake Product.

126. Defendants showed their intent to interfere intentionally with ExeGi's customer relationships through the false representations on the VSL#3 Website, enumerated in Paragraph 57(a)-(r) above, and on the VSL#3 Facebook page.

127. Defendants' statements and advertising were wrongful, tortious, and made without right, privilege, or justification.

128. Defendants actions constitute tortious interference with ExeGi's legitimate business expectations relating to sales of Visbiome and ExeGi's economic relationship with its existing and prospective customers.

129. As a direct and proximate result of Defendants' false and misleading statements, advertising, and other wrongful conduct alleged herein, ExeGi has suffered the actual loss of advantageous economic relationships, including the loss of customers that would have purchased Visbiome but for Defendants' wrongful conduct.

WHEREFORE, Plaintiffs demand judgment against Defendants:

A. On Count I (False Advertising – Lanham Act), awarding ExeGi all available remedies under 15 U.S.C. § 1117(a) including: (1) compensatory damages in an amount to be proven at trial but in no event less than $15,000,000.00; (2) disgorgement of Defendants' profits in an amount to be proven at trial but in no event less than $3,000,000.00; (3) a permanent injunction prohibiting Defendants from actively perpetuating, participating in, endorsing, adopting, and profiting from making false statements regarding the Fake Product; (4) attorneys' fees and costs; (5) prejudgment and post-judgment interest; (6) enhanced or trebled damages; and (7) such other further and general relief as the Court deems just and proper.

B. On Count II (False Advertising - FAL), awarding ExeGi: (1) compensatory damages in an amount to be proven at trial but in no event less than $15,000,000.00; (2) disgorgement of Defendants' profits in an amount to be proven at trial but in no event less than $3,000,000.00; (3) a permanent injunction prohibiting Defendants from actively perpetuating, participating in, endorsing, adopting, and profiting from making false statements regarding the Fake Product; (4) attorneys' fees and costs; (5) prejudgment and post-judgment interest; and (6) such other further and general relief as the Court deems just and proper.

C. On Count III (Unfair Competition – Lanham Act), awarding ExeGi all available remedies under 15 U.S.C. § 1117(a) including: (1) compensatory damages in an amount to be proven at trial but in no event less than $15,000,000.00; (2) disgorgement of Defendants' profits in an amount to be proven at trial but in no event less than $3,000,000.00; (3) a permanent injunction prohibiting Defendants from actively perpetuating, participating in, endorsing, adopting, and

profiting from making false statements regarding the Fake Product; (4) attorneys' fees and costs; (5) prejudgment and post-judgment interest; (6) enhanced or trebled damages; and (7) such other further and general relief as the Court deems just and proper.

D. On Count IV (Unfair Competition - UCL), awarding ExeGi: (1) compensatory damages in an amount to be proven at trial but in no event less than $15,000,000.00; (2) disgorgement of Defendants' profits in an amount to be proven at trial but in no event less than $3,000,000.00; (3) a permanent injunction prohibiting Defendants from actively perpetuating, participating in, endorsing, adopting, and profiting from making false statements regarding the Fake Product; (4) attorneys' fees and costs; (5) prejudgment and post-judgment interest; and (6) such other further and general relief as the Court deems just and proper.

E. On Count V (Contributory False Advertising), awarding ExeGi: (1) compensatory damages in an amount to be proven at trial but in no event less than $15,000,000.00; (2) a permanent injunction prohibiting Defendants from making or participating in false statements regarding the Fake Product; (3) attorneys' fees and costs; and (4) such other further and general relief as the Court deems just and proper.

F. On Count VI (Tortious Interference), awarding ExeGi: (1) compensatory damages in an amount to be proven at trial but in no event less than $15,000,000.00; (2) punitive damages in an amount to be proven at trial but in no event less than $15,000,000.00; (3) attorneys' fees and costs; and (4) such other further and general relief as the Court deems just and proper

G. Awarding such other, further, and general relief as to the Court seems just and proper.

Dated: April 1, 2019

Respectfully submitted,

BOUTIN JONES INC.

By: /s/ Robert D. Swanson
Robert D. Swanson

SCHULMAN BHATTACHARYA, LLC

By: /s/ Jeremy W. Schulman
Jeremy W. Schulman

Attorneys for Plaintiff ExeGi Pharma, LLC

JURY DEMAND

In accordance with Rule 38(b) of the Federal Rules of Civil Procedure, ExeGi hereby demands a trial by jury on all issues raised by the claims asserted in the foregoing Complaint that are triable as of right by a jury.

Dated: April 1, 2019

Respectfully submitted,

BOUTIN JONES INC.

By: /s/ Robert D. Swanson
Robert D. Swanson

SCHULMAN BHATTACHARYA, LLC

By: /s/ Jeremy W. Schulman
Jeremy W. Schulman

Attorneys for Plaintiff ExeGi Pharma, LLC

EXHIBIT 1

B

UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

CLAUDIO DE SIMONE,

Plaintiff/Counterclaim Defendant,

EXEGI PHARMA, LLC,

Plaintiff,

v.

VSL PHARMACEUTICALS, INC.,

Defendant/Counterclaim Plaintiff,

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

Defendants,

v.

DANISCO USA, INC.,

Counterclaim Defendant.

Civil Action No. TDC-15-1356

ORDER

The jury having returned a verdict on November 20, 2018 after trial in this case, it is hereby ORDERED that:

1. Judgment is entered in favor of Plaintiff Claudio De Simone against Defendant VSL Pharmaceuticals, Inc. ("VSL") on Count II of his Complaint (Breach of Contract), and damages are awarded in the amount of $967,435.00.

2. Judgment is entered in favor of Plaintiff De Simone against Defendant VSL on Count III of his Complaint (Unjust Enrichment), and damages are awarded in the amount of $1,874,602.00.
3. Judgment is entered in favor of Plaintiff De Simone against Defendant Leadiant Biosciences, Inc. ("Leadiant") on Count III of his Complaint (Unjust Enrichment), and damages are awarded in the amount of $172,004.00.
4. Judgment is entered in favor of Plaintiff ExeGi Pharma, LLC ("ExeGi") against Defendant Leadiant on Count VI of its Complaint (False Advertising).
5. Judgment is entered in favor of Plaintiff ExeGi against Defendant Alfasigma USA, Inc. on Count VI of its Complaint (False Advertising), and damages are awarded in the amount of $15,000,000.00.
6. Judgment is entered in favor of Counterclaim Defendant De Simone against Counterclaim Plaintiff VSL on Count IV of VSL's Counterclaim (Breach of Fiduciary Duty).
7. Any and all prior rulings made by the Court disposing of any claims against any parties are incorporated by reference herein.

Date: November 21, 2018

/s/
THEODORE D. CHUANG
United States District Judge

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(Southern Division)

CLAUDIO DE SIMONE *
Routte des Chenolettes 51
1660 Château D'oex *
Switzerland

*

– and –

*

EXEGI PHARMA, LLC
155 Gibbs Street, Suite 506 *
Rockville, MD 20850-0392
[Montgomery County] *

Plaintiffs/Counterclaim Defendants, *

v. *

VSL PHARMACEUTICALS, INC. *
13800 Coopermine Road
Herndon, VA 20171 *

– and – * Case No. 8:15-cv-01356-TDC

LEADIANT BIOSCIENCES, INC. *
f/k/a/ Sigma-Tau Pharmaceuticals, Inc.
9841 Washingtonian Boulevard, Suite 500 *
Gaithersburg, MD 20878-7352
[Montgomery County] *

Defendants/Counterclaim Plaintiffs *

– and – *

SIGMA-TAU HEALTHSCIENCE USA, INC. *
9841 Washingtonian Boulevard, Suite 500
Gaithersburg, MD 20878-7352 *
[Montgomery County]

*

Serve on: Mary Ocnean, Resident Agent
9841 Washingtonian Boulevard, *
Suite 500
Gaithersburg, MD 20878-7352, *

– and – *

ALFASIGMA USA, INC. *
4099 Highway 190 East Service Road
Covington, LA 70433-4941, *

Serve on: P. Keith Daigle, Resident Agent *
4099 Highway 190
East Service Road *
Covington, LA 70433-4941,
*
Additional Defendants.
*

AMENDED COMPLAINT
(Filed by consent under the authority of Fed. R. Civ. P. 15(a)(2))

Plaintiffs, Professor Claudio De Simone ("Prof. De Simone") and ExeGi Pharma, LLC ("ExeGi"), by and through undersigned counsel, as and for their Amended Complaint against Defendants/Counterclaim Plaintiffs VSL Pharmaceuticals, Inc. ("VSL Inc.") and Leadiant Biosciences, Inc., f/k/a Sigma-Tau Pharmaceuticals, Inc. ("Leadiant")[1], and Additional Defendants Sigma Tau HealthScience USA, Inc. ("STHS") and Alfasigma USA, Inc. ("Alfasigma"), aver as follows:

NATURE OF THE ACTION

1. Prof. De Simone brings this action to protect his exclusive legal rights over valuable intellectual property consisting of a unique probiotic medical food that he invented to manage rare and persistent gastrointestinal disorders (the "De Simone Formulation"). Prof. De Simone seeks substantial compensatory and punitive damages, as well as comprehensive

[1] Sigma-Tau Pharmaceuticals, Inc. changed its name to Leadiant Biosciences, Inc. effective on February 15, 2017. For the sake of clarity, this Amended Complaint will refer to this entity as Leadiant throughout, although some of the actions referred to herein took place at a time when the entity was then known as Sigma-Tau Pharmaceuticals, Inc.

declaratory and injunctive relief, to remedy gross misconduct committed by his former business partners, as they have misappropriated and profited illegally from his proprietary inventions. Prof. De Simone also asks the Court to stop the former partners—a group of companies controlled by the wealthy and powerful Cavazza family in Italy—from selling an ineffective and untested counterfeit version of Prof. De Simone's invention under the "VSL#3 brand," which may pose a considerable danger to adult and pediatric consumers suffering from ulcerative colitis, pouchitis, and irritable bowel syndrome in the United States and Canada. Upon information and belief, the counterfeit version of VSL#3 currently is being marketed and sold by Alfasigma, which purports to have assumed all rights to the product (albeit without proper legal authority) from Leadiant and STHS through various assignments and a merger occurring over the past year.

2. ExeGi holds an exclusive license from Professor De Simone to market and sell his original probiotic formulation in the United States under the brand name "Visbiome." Visbiome was introduced to the market on February 1, 2016 in accordance with an order of this Court. As the company holding exclusive rights to market and sell the De Simone Formulation in the United States, ExeGi joins as a plaintiff in this action to prevent Alfasigma from continuing to falsely advertise the counterfeit version of the De Simone Formulation as equivalent to the product formerly sold as VSL#3, which had been based on the De Simone Formulation prior to February 1, 2016 but no longer is. These false advertisements materially misrepresent the facts about the composition, safety, and efficacy of the new version of VSL#3. In so doing, these false advertisements have placed the patient population in the United States in grave physical danger and have substantially harmed ExeGi's sales of Visbiome, which is the only genuine version of the De Simone Formulation available in the market. ExeGi seeks compensatory

damages, as well as comprehensive declaratory and injunctive relief, against Alfasigma, as well as its predecessors-in-interest, Leadiant and STHS, to remedy the harms caused by their false advertising.

3. Prof. De Simone is a renowned scientist, inventor, physician, and leader in a new field of medical research focused on the health benefits of certain "friendly" bacteria that live on and within the human body. He is a Professor of Infectious Diseases and has degrees in Gastroenterology and Immunology, a Fellow of the American Gastroenterology Association, and an inventor of bacterial compositions used in the fields of human and veterinary nutrition and hygiene. Prof. De Simone has authored hundreds of clinical studies and scholarly papers in the field of probiotics, and he also has developed a series of new probiotic products that have helped thousands of people afflicted with gastrointestinal disorders.

4. Some 15 years ago, Prof. De Simone entered into a joint venture with two brothers, Claudio and Paolo Cavazza, who controlled one of the largest pharmaceutical conglomerates in Italy—the Sigma-Tau Group. The Sigma-Tau Group, a portion of which was recently combined with the Italian pharmaceutical company Alfa Wasserman, is in the business of developing and selling research-based pharmaceuticals and currently employs over 2,500 people world-wide.

5. At the outset of their business relationship, the three men struck a deal by which they combined their various talents, skills, and resources to develop and market some of Prof. De Simone's probiotic inventions to the consuming public. One of the most important results of this partnership has been the commercial exploitation of a probiotic food product, consisting of live, freeze-dried, pure lactic acid bacteria, which prior to February 1, 2016 had been marketed under

the name "VSL#3." The product is intended to provide dietary management for patients with serious gastrointestinal disorders.

6. Prof. De Simone agreed to license portions of his intellectual property rights to the enterprise, while the Cavazza brothers agreed to contribute capital and business expertise to establish and fund its activities. To implement their plan, Prof. De Simone and the Cavazza brothers formed a company in the United States, VSL Pharmaceuticals, Inc. ("VSL Inc."), which would later come to sell VSL#3 under license from Prof. De Simone. This product was manufactured based on highly secret, proprietary information that Prof. De Simone owns and which is a valuable trade secret (the "De Simone Formulation"). It was also patented in the United States by Prof. De Simone under Patent No. 5,716,615.

7. Over the ensuing years, VSL#3 became the "gold standard" in its therapeutic class. This favorable recognition of VSL#3 by the medical and scientific community led to business success for the enterprise created by Prof. De Simone and the Cavazza brothers. Aggregate global sales of VSL#3 are estimated to have grown to more than $60 million.

8. Despite this financial success (or perhaps because of it), however, the friendship and business partnership between Prof. De Simone and the Cavazza brothers began to show signs of cracking. Prof. De Simone had granted to VSL Inc. rights to use his proprietary information for VSL#3 to market and sell the probiotic food product in the United States for a limited period of time. These rights were contained in two key agreements, a Patent License Agreement, formed in 2001, and a Know How License Agreement, formed in 2010. VSL Inc., in turn, sub-licensed these rights to Leadiant, the Cavazza-owned subsidiary of the Sigma-Tau Group that assumed responsibility for actually distributing and selling the product in this country. At the time the dispute that is the subject of this case arose, VSL Inc.'s license from

Prof. De Simone was set to expire on January 31, 2016, and Leadiant's sub-licensed rights from VSL Inc. were set expire at the end of 2015.

9. Claudio Cavazza died in 2011, and his children inherited his interests in the Sigma-Tau Group's pharmaceutical and nutraceutical empire. After Claudio's death, his brother Paolo, Claudio's heirs, and their surrogates within the Sigma-Tau Group began pressuring Prof. De Simone to extend VSL Inc.'s and Leadiant's licenses under new terms that would disproportionately benefit the Sigma-Tau Group at the expense of Prof. De Simone and VSL Inc., the business enterprise that he jointly owned with them. A key part of the Cavazzas' plan was to convince, and if that did not work, then to coerce, Prof. De Simone to relinquish his tight control over the manufacturing process and allow the Sigma-Tau Group to produce a "fake" version of VSL#3 with cheaper ingredients, thereby increasing the Cavazzas' profit margins for Leadiant.

10. When Prof. De Simone resisted these pressures because of his concerns for consumer safety and the inherent deceptiveness of the Cavazzas' scheme, the Cavazzas initiated a coordinated program to intimidate, threaten, and bully Prof. De Simone into complying with their demands. The Cavazzas explicitly threatened to use their massive financial resources to sue him and to bankrupt him, his family, and VSL Inc. through the litigation process. They planned to use their control over the VSL#3 trademark to market a new, adulterated product under the old name in order to deceive the consuming public into thinking that the bastardized version was the same as the original "gold standard." Prof. De Simone became very concerned that if the Sigma-Tau Group succeeded in creating and marketing a fake VSL#3 product, it would put the patients who depend on this product at risk for serious infections. Such a product would not have had its

efficacy and safety proven in any randomized controlled study, as the genuine product has done repeatedly.

11. Regrettably, the Cavazzas' intimidation scheme did not stop at mere threats. In 2014, they sued VSL Inc. and Prof. De Simone in Delaware and the United Kingdom, respectively, and there contended for the very first time—falsely and in utter disregard for their repeated previous contractual acknowledgments—that Prof. De Simone's VSL#3-related patent rights and trade secrets actually belonged to them. The Delaware litigation was principally filed to gain access to VSL Inc.'s books and records (and, in reality, Prof. De Simone's trade secrets), so the ownership of that intellectual property was not directly at issue. In the UK litigation, by contrast, the question of ownership was at the heart of the Cavazzas' complaint, but the court there dismissed the action for lack of jurisdiction. Regardless, it was now eminently clear that the Cavazzas had repudiated their contractual acknowledgments of Prof. De Simone's ownership of the De Simone trade secrets and would stop at nothing to steal what he would not relinquish through negotiation—unilateral control over the valuable De Simone probiotic formulation and all of the profits that his invention had yielded.

12. In November 2014, once the afore-mentioned Delaware litigation had been settled, Prof. De Simone resigned his positions as a director and officer of VSL Inc. and terminated the Know How Agreement with that company. By early February 2015, the Patent License Agreement between Prof. De Simone and VSL Inc. had expired by its own terms. VSL Inc. also was in material breach of its obligations under this agreement as a result of its failure to make royalty payments due for 2014. Although Leadiant's (and its successors') sub-license with VSL Inc. formally has not been terminated, VSL Inc. no longer can legally honor that sub-

license, and Leadiant (and its successors) no longer can legally make use of it, because VSL Inc.'s own licensing rights from Prof. De Simone are no longer valid.

13. Despite the termination and expiration of these rights, the Cavazzas continued through 2016 to use their voting and managerial control of both VSL Inc. and Leadiant to continue marketing and selling VSL#3 in the United States without paying Prof. De Simone royalties (as they originally had contracted to do) and in reckless disregard of his intellectual property rights in the De Simone Formulation. In addition, as long suspected by Prof. De Simone, the Cavazzas' efforts to commercialize a "fake" probiotic product under the well-known VSL#3 brand were at an advanced stage when the initial Complaint was filed in this case in May 2015.

14. Since the filing of the initial Complaint, Prof. De Simone and ExeGi have confirmed that VSL Inc. and Leadiant did indeed launch an untested, purported copy of the De Simone Formulation, which Leadiant calls "Non Dairy VSL#3." Even worse, the Defendants have engaged in a pervasive and ongoing advertising campaign falsely asserting that Non Dairy VSL#3 is "the same as" the former version of the VSL#3 probiotic produced using De Simone's technical Know-How, *i.e.*, the De Simone Formulation, which is now exclusively marketed and sold by ExeGi as Visbiome.

15. By this Amended Complaint, Prof. De Simone now seeks the intervention of this Court to help extricate himself from VSL Inc. and the Cavazza family, secure unpaid royalties, declare his legitimate ownership of the product know-how rights and ensure that patients in the U.S. are not put at risk with a counterfeit product.

16. By this Amended Complaint, ExeGi seeks to stop the false advertising campaign perpetrated by the Defendants and obtain damages and other relief for the considerable harm that this campaign has caused.

17. Based on the circumstances summarized above and the additional averments set forth below, this Court should declare that Prof. De Simone alone continues to own the trade secrets underlying Visbiome and the version of VSL#3 produced prior to February 1, 2016, enjoin VSL Inc., Leadiant, STHS, and Alfasigma from infringing on Prof. De Simone's exclusive intellectual property rights, and hold them liable in damages for breach of contract, misappropriation of trade secrets, civil conspiracy, and violation of the Lanham Act. The Court also should order the Defendants to disgorge to Prof. De Simone and ExeGi all profits that they have unjustly gained from their unlawful conduct. Moreover, given the malicious course of intimidation pursued by the Defendants in this case, they should be held liable for punitive damages as well.

PARTIES

18. Prof. De Simone is a citizen of Italy who maintains his residence and domicile in Switzerland. Prof. De Simone therefore is a citizen of a foreign state.

19. ExeGi is a limited liability company organized and incorporated under the laws of New York, with its principal place of business located at 155 Gibbs St., Unit 506, Rockville, Maryland 20850.

20. VSL Inc. is a corporation organized and incorporated under the laws of Delaware, with its principal place of business located at [insert Virginia address]. VSL Inc. therefore is a citizen of Delaware and Virginia.

21. VSL Inc., through its corporate hierarchy, is majority-owned and controlled by the Cavazza family and their surrogates.

22. Leadiant Biosciences, Inc. f/k/a Sigma-Tau Pharmaceuticals, Inc. is a corporation organized and incorporated under the laws of Nevada, with its principal place of business located at 9841 Washingtonian Boulevard, Suite 500, Gaithersburg, MD 20878-7352. Leadiant therefore is a citizen of Nevada and Maryland.

23. Leadiant is part of the Sigma-Tau Group of companies and therefore is owned and controlled, directly or indirectly, by the Cavazza family and their surrogates.

24. Sigma-Tau HealthScience USA, Inc. is a corporation that was incorporated under the laws of Delaware. Effective April 1, 2017, on information and belief, STHS was merged into Alfasigma and ceased operating independently. Therefore, for every wrongful act alleged against STHS, Plaintiffs also seek to hold Alfasigma liable under the doctrine of successor liability.

25. Alfasigma USA, Inc. is a corporation organized and incorporated under the laws of Delaware, with its principal place of business located at 4099 Highway 190 East Service Rd., Covington, Louisiana 70433. Alfasigma therefore is a citizen of Delaware and Louisiana.

JURISDICTION AND VENUE

26. Plaintiff Prof. De Simone is a citizen of a foreign state, and the Defendants in all claims brought by Prof. De Simone are citizens of Delaware, Nevada, Louisiana, Virginia and Maryland. Accordingly, there is complete diversity between the parties to those claims, and this action is between citizens of a State and a citizen of a foreign state.

27. As alleged herein, the amount in controversy between the parties substantially exceeds $75,000, exclusive of interest and costs.

28. By virtue of the foregoing facts, this Court has jurisdiction over the subject matter of the claims brought by Prof. De Simone under 28 U.S.C. § 1332(a)(2).

29. This Court also has jurisdiction over the subject matter of the claim brought by ExeGi under 28 U.S.C. §§ 1331 and 1367(a) because ExeGi's claim arises under a federal statute, the Lanham Act.

30. Under section 6-102 of the Courts and Judicial Proceedings Article of the Annotated Code of Maryland, this Court may exercise personal jurisdiction over Defendant VSL Inc. because Defendant VSL Inc. maintained its principal place of business in Maryland when this case was commenced.

31. Under section 6-102 of the Courts and Judicial Proceedings Article of the Annotated Code of Maryland, this Court may exercise personal jurisdiction over Defendants Leadiant and STHS because they maintain their principal places of business in Maryland.

32. Under section 6-103 of the Courts and Judicial Proceedings Article of the Annotated Code of Maryland, this Court may exercise personal jurisdiction over Defendant Alfasigma because it transacts business and contracts to supply goods in Maryland.

33. This Court may exercise personal jurisdiction over Defendant Alfasigma because it has purposefully availed itself of the privilege of conducting business activities in Maryland (*e.g.*, marketing and selling VSL#3 in Maryland), Plaintiffs' claims arise out of those activities, and the exercise of jurisdiction over Alfasigma is constitutionally reasonable.

34. Venue is properly laid in this judicial district under 28 U.S.C. § 1391(b)(1) because all Defendants are subject to personal jurisdiction in Maryland and therefore are deemed to reside there.

FACTS COMMON TO ALL COUNTS

A. Prof. De Simone's Groundbreaking Work Inventing Probiotic Formulations

35. This case involves intellectual property and contractual rights relating to the use of live bacterial cultures for consumers with disease states, such as Inflammatory Bowel Disease ("IBD"), including Ulcerative Colitis ("UC"), Pouchitis and Irritable Bowel Syndrome ("IBS"). Therapeutic and dietary formulations which contain such live bacterial cultures are commonly referred to as "probiotics."

36. Probiotics are formulations which comprise live microorganisms, most often live bacterial cultures, which may be similar to those normally present in the human gastrointestinal tract and which have a beneficial effect on the host. Probiotics are supplied commercially in a variety of forms including capsules, tablets and sachets containing a powder dosage form, as well as in some foods such as yogurt.

37. The consumption of probiotics can help to re-establish a healthy balance of bacteria in the intestine by replenishing beneficial bacterial strains. The ingestion of some probiotics has been proven useful for the dietary management of patients with IBD and IBS in particular.

38. During the 1980s and early 1990s, Prof. De Simone, a renowned medical researcher and clinician in Italy, conducted research into the clinical use of bacterial strains to treat the symptoms associated with IBD, IBS, enteral feeding, liver diseases, and many other conditions. Prof. De Simone's work resulted in the synthesis of several probiotic formulations, which clinical experience and data demonstrated had beneficial effects on those suffering from these maladies. Prof. De Simone obtained several patents (among other intellectual property rights) relating to his probiotic work in various countries, including in the United States.

39. Over the ensuing years, one of Prof. De Simone's probiotic formulations, the formulation known as the De Simone Formulation later branded as VSL#3 (the subject of this case), became the "gold standard" in its therapeutic class. Prof. De Simone successfully conducted more than 60 human clinical trials of the De Simone Formulation, the results of which were published in various peer reviewed medical and scientific journals. These trials demonstrated that the De Simone Formulation is effective in the dietary management of IBD, IBS, and a very serious and rare chronic disorder called Pouchitis. With respect to Pouchitis, the De Simone Formulation ultimately was recognized by the world's professional gastroenterology societies as a "standard of care"—an achievement that no other probiotic substance previously had attained.

B. Origins of Prof. De Simone's Business Relationship with the Cavazzas For the Marketing and Sale of Probiotic Products

40. Beginning in December 1992, Prof. De Simone applied for the issuance of a United States patent for the probiotic formulation that he invented to treat gastrointestinal disorders (the "Patent Application").

41. On February 10, 1998, the Patent Application was granted, and United States Patent No. 5,716,615 was issued for the invention entitled "Dietary and Pharmaceutical Compositions Containing Lyophilized Lactic Bacteria, Their Preparation and Use" (the "615 Patent"). The 615 Patent describes an invention of a "pharmaceutical composition containing several different bacteria," which "are present in the composition at a total concentration of 1.times.10.sup.11 to 1.times.10.sup.13 per gram." The 615 Patent describes a composition, which would come to be known in the commercial market (and trademarked) as VSL#3, for "treatment of a gastrointestinal disorder and hypercholesteremia" and "modulating a host's immune response."

42. Although the 615 Patent originally listed Prof. De Simone as one of two co-inventors of the probiotic composition that later was branded as VSL#3 (the other co-inventor was Dr. Renata Maria Anna Cavaliere Vesely), he initiated litigation in 2002 to declare that he is the sole inventor and owner of the 615 Patent. Several years later, that litigation ended in a settlement agreement by which the Vesely heirs, the estate of Dr. Vesely, and Sigma Tau Industrie Farmaceutiche Riunite recognized that Prof. De Simone was the sole and undisputed owner and inventor of the 615 Patent and all related intellectual property and that those defendants never participated in the invention, development and know-how of the formulations described in that patent.

43. On January 22, 2008, the 615 Patent was duly reissued by the United States Patent Office as Patent No. RE40,023 E to list Prof. De Simone as the sole inventor and owner.

44. The 615 Patent expired on February 9, 2015.

45. Although VSL#3 came to be manufactured, marketed, and sold through a somewhat complex corporate structure and set of supply and licensing agreements, all relevant parties to these transactions repeatedly have acknowledged over the years that the probiotic formulation underlying VSL#3 was solely owned by Prof. De Simone, and that all rights conveyed by Prof. De Simone to manufacture, market, and sell the product were temporary and would, at Prof. De Simone's election, ultimately revert to himself.

C. Agreement to Manufacture, Promote, Market, and Sell Products Under the 615 Patent As a Prescription Drug

46. In order to pursue the U.S. development, marketing, and sale of products based on the 615 Patent in the form of a prescription drug, Prof. De Simone and the Cavazza brothers (the latter through one of their existing pharmaceutical companies) formed an agreement in late 1999

by which the Cavazzas first formally acknowledged Prof. De Simone's ownership of and proprietary rights in the probiotic formula that later became known as VSL#3.

47. On December 15, 1999, Prof. De Simone entered into an Option Agreement (the "Option Agreement") with Sigma-Tau Pharmaceuticals, Inc., a New Jersey corporation ("STP New Jersey"), which was a subsidiary of the Cavazza-owned Sigma-Tau Group.

48. The purpose of the Option Agreement was to enable STP New Jersey to develop and distribute products under the 615 Patent in the form of a prescription drug.

49. The Option Agreement defines the "Product" to mean "any pharmaceutical products containing lactic acid bacteria described in the Patent [which is defined as the 615 Patent] and approved by the FDA for marketing in the Territory [which is defined to be the United States], to be used in any formulation and dosage form."

50. The Option Agreement also defines the "Know How" to mean "any scientific, technical and commercial information on the Product that are in the direct or indirect availability of Prof DE SIMONE both at the signature hereof and during the term of this Agreement and related to the promotion, manufacturing and commercialization of the Product in the Territory."

51. The Option Agreement, under which both parties expressly acknowledged that Prof. De Simone "co-owns the Patent and fully owns the Know-How," granted STP New Jersey the right, to be exercised on or before December 31, 2001, to obtain an "Exclusive license under the Patent and the Know-How to manufacture, have manufactured, promote and sell the Product in the Territory, with the right for STPI to grant sub-licenses to its Affiliates and to third parties."

52. The Option Agreement obligated STP New Jersey to pay certain fees to Prof. De Simone in consideration of the Option and to pay him certain royalties if the Option were to be exercised.

53. STP New Jersey exercised the Option, and its exclusive license to use the 615 Patent and the Know How to manufacture, market, and sell probiotic products in the form of a prescription drug remained in effect until 2006, when STP New Jersey notified Prof. De Simone of its intent not to renew the license. As a result, all of these rights previously licensed exclusively to STP New Jersey reverted to Prof. De Simone, and STP New Jersey discontinued its payments to him.

D. A New Initiative: The Creation of VSL Inc.

54. Another collaboration between Prof. De Simone and the Cavazza brothers—VSL Inc.—was effected through certain closely held companies, formed in previous years, that each of them owned and controlled. The purpose of the collaboration was to advance the marketing and commercialization of certain of Prof. De Simone's probiotic inventions.

55. Claudio Cavazza owned and controlled a Luxembourg company named Taufin International, S.A. ("Taufin"), and Paolo Cavazza owned and controlled a Luxembourg company named Sinaf, S.A. ("Sinaf"). Prof. De Simone owned and controlled Mendes, S.r.l., an Italian company ("Mendes Italy"). In order to participate in the new collaboration, Mendes Italy was asked by the Cavazzas to set up a Luxembourg entity, which later was named Mendes International, S.A. ("Mendes International").

56. . Mendes International (representing Prof. De Simone's interests), Taufin (representing Claudio Cavazza's interests), and Sinaf (representing Paolo Cavazza's interests) formed CD International, S.A., a Luxembourg company ("CD International"), in which each of them holds a one-third ownership interest. However, CD Investments, S.r.l., an Italian company ("CD Investments") wholly owned subsidiary of CD International, owns 99.97 percent of the

shares of VSL Inc., exerting the majority control of VSL and Prof. De Simone, Taufin, and Sinaf each own 0.1 percent of such shares.

57. On July 11, 2000, VSL Inc. was incorporated in Delaware. The initial directors of VSL Inc. were appointed by Prof. De Simone, Taufin (representing Claudio Cavazza's interests), and Sinaf (representing Paolo Cavazza's interests).

58. Under the terms of an Agreement for Product Development and Collaboration entered between the parties on July 11, 2000 (the "Collaboration Agreement") and related assignment agreements, Prof. De Simone agreed to assign to VSL Inc. a portion of his intellectual property rights as specifically identified in the Collaboration Agreement, and the Cavazzas, acting through Taufin and Sinaf, agreed to contribute capital to establish and fund the activities of VSL Inc. Significantly, however, the 615 Patent was intentionally not listed or identified among the intellectual property to be assigned by Prof. De Simone to VSL Inc., nor was any other information for the product that later was branded as VSL#3 included in the intellectual property originally conveyed by Prof. De Simone to VSL Inc.

59. Subsequently, the Cavazzas requested that Prof. De Simone license the 615 Patent to VSL Inc. to enable the company to commercialize a "ready to go" probiotic product for use as a nutritional food or dietary supplement, obtain revenues rapidly, and increase its visibility as a biotech company since the product to be marketed under the 615 Patent already had garnered highly favorable published clinical data. This license was later effectuated through a patent license agreement, as described below, and decidedly was not part of the conveyance of intellectual property rights that occurred when VSL Inc. was formed.

E. Agreements to Manufacture, Promote, Market, and Sell Products Under the 615 Patent As a Nutritional Food or Dietary Supplement

i. Patent License Agreement Between Prof. De Simone and VSL Inc.

60. On January 30, 2001, Prof. De Simone and VSL Inc. entered into a Patent License Agreement (the "Patent License Agreement") under which Prof. De Simone granted VSL Inc. exclusive (but temporally limited) rights to manufacture, promote, market, and sell the "Product" in the United States in exchange for certain royalties based on net sales of the Product.

61. A true and correct copy of the Patent License Agreement is attached hereto and incorporated by reference herein as **Exhibit A**.

62. The Patent License Agreement defines the "Product" to mean "any product marketed as dietary supplement or functional food, containing lactic acid bacteria described in the [615 Patent], to be used in any formulation and dosage form and all further developments and improvements thereto."

63. Unlike the Option Agreement between Prof. De Simone and STP New Jersey, the Patent License Agreement does not mention the "Know How" and does not purport to license any such information to VSL Inc.

64. The Patent License Agreement states that it "shall continue in effect until the expiry of the Patent."

65. In the form of a nutritional food or dietary supplement, relying upon the Patent License Agreement, VSL#3 was first offered for sale in the United States in 2002.

66. Prior to February 1, 2016, VSL#3 was manufactured by Danisco USA, Inc., a Missouri corporation whose principal place of business is in Madison, Wisconsin ("Danisco").

ii. Sub-License Agreement Between VSL Inc. and STP New Jersey

67. When VSL#3 made its debut in the United States in 2002, Questcor Pharmaceuticals ("Questcor") was marketing and selling it under a sub-license from VSL Inc. Claudio and Paolo Cavazza had significant ownership interests in Questcor, but this company did not perform well, which resulted in low revenues for the sale of VSL#3. Questcor's sub-license expired at the end of 2003 and was not renewed by VSL Inc.

68. On December 1, 2003, VSL Inc. and STP New Jersey entered into a license agreement (the "2003 VSL-STP License Agreement") by which, in exchange for certain down payments and royalties payable to VSL Inc., STP New Jersey was granted "an exclusive license . . . under the [615 Patent], the Know-How and the Trademark to use, manufacture and have manufactured, promote, distribute offer for sale and sell the Product in the [United States]."

69. The 2003 VSL-STP License Agreement defines the "Know How" to mean "any and all information related to the Product, including but not limited to, discoveries, processes, formulas, clinical, scientific, technical and marketing data, which at the date of execution of this Agreement (i) are in VSL's possession or control, and (ii) VSL considers necessary for [STP New Jersey] in order to use, manufacture or have manufactured, promote, distribute, offer for sale and sell the Product in the [United States]."

70. The 2003 VSL-STP License Agreement defines the "Product" to be VSL#3, which is more specifically defined to mean "a probiotic preparation to be sold in the [United States] not under an approval of FDA [the U.S. Food and Drug Administration] containing [eight enumerated] strains of lactic acid bacteria."

71. The 2003 VSL-STP License Agreement provides that VSL Inc. "shall disclose to [STP New Jersey] the Know-How which is available to VSL and which may be developed or acquired by VSL during term of this Agreement and which VSL is free to disclose."

72. The 2003 VSL-STP License Agreement further provides that STP New Jersey "shall have manufactured the Product at its own cost and expense by a third party manufacturer to be approved in advance by VSL and strictly in accordance with [certain government approvals and permits, the reasonable instructions and suggestions of VSL Inc.], and the terms and conditions of this Agreement."

73. Among other things, the 2003 VSL-STP License Agreement requires STP New Jersey to keep confidential and not to disclose to any other person all "Know How" and other information that it receives under the agreement, except as required by law or as necessary to obtain government approvals or for those involved in the marketing or distribution of the Product (VSL#3).

74. The 2003 VSL-STP License Agreement also provides that the "Product shall be sold by [STP New Jersey] only under the Trademark which is and shall remain the property of VSL." In accordance with VSL Inc.'s rights under the earlier Patent License Agreement, VSL Inc. obtained a registered trademark for VSL#3 as the name under which STP New Jersey would market the Product.

75. STP New Jersey further promised under the 2003 VSL-STP License Agreement "not to register or, in connection with the sale of any product, use any trademark which is identical to or confusingly similar to the Trademark, either outside or inside the [United States]."

76. The term of the 2003 VSL-STP License Agreement expired on December 31, 2010. The agreement was renewable for successive two-year terms unless notice of termination was given at least six months prior to the expiration of the initial term.

77. On October 31, 2007, STP New Jersey merged into a Nevada corporation named Sigma-Tau Holding America, Inc. ("ST Holding"), whose headquarters was located in Gaithersburg, Maryland. Immediately after the merger, ST Holding changed its name to Sigma-Tau Pharmaceuticals, Inc. (defined earlier in this Complaint as Leadiant), which is a Defendant in this action.

78. Under the Plan of Merger between STP New Jersey and Leadiant, Leadiant succeeded to all of STP New Jersey's rights, privileges, property, and debts, presumably including STP New Jersey's rights and duties under the 2003 VSL-STP License Agreement. The Plan of Merger also provided that the initial officers and directors of Leadiant would consist of the officers and directors of ST Holding immediately prior to the merger.

iii. Confidentiality Agreement Among Prof. De Simone, Danisco, VSL Inc., and Cavazza Entities

79. Beginning in or about 2005, unbeknownst to Prof. De Simone, individuals acting on behalf of the Sigma Tau affiliate company in Italy ("STP Italy")—which was selling the product VSL#3 in Italy at that time—and STP New Jersey were seeking to obtain information about the De Simone Formulation, to enable them to make a "clone" product of VSL#3. The attempt to "clone" VSL#3 was part of a strategy of the Cavazzas to free themselves from their obligations to Prof. De Simone and to use Prof. De Simone's property for their own purposes and personal gain. The Cavazzas previously had acted in a similar fashion in connection with a product sold under the tradename Yovis®, which Prof. De Simone had licensed to STP Italy and for which Prof. De Simone is still entitled to receive royalty payments. However, after a period

of time, STP Italy launched a modified product formulation under the same overall Yovis brand (Yovis®travel; Yovis®regular) and STP Italy resisted paying royalties on those products.

80. In or about early 2006, the Cavazzas, acting through the management of VSL Inc. whom they controlled, insisted that more information about VSL#3 and other probiotics that VSL Inc. was planning to develop should be shared with STP Italy and STP New Jersey. In response to this demand, and not yet knowing about the Cavazzas' plans to make a clone product based upon Prof. De Simone's proprietary know-how, Prof. De Simone agreed to enter a confidentiality agreement with VSL Inc. (as licensee), certain VSL Inc. affiliates, and Danisco (as supplier). The purpose of the confidentiality agreement was to allow for the confidential sharing with STP Italy and STP New Jersey of certain limited information relating to VSL#3 and other probiotic projects to facilitate the marketing and sale of probiotic products around the world, while at the same time preserving Prof. De Simone's exclusive rights in the know-how and patents underlying VSL#3.

81. More specifically, on May 10, 2006, a Confidential Disclosure Agreement was signed. In paragraph 6 of the Confidential Disclosure Agreement, the parties expressly recognized and agreed to Prof. De Simone's sole ownership of and control over the De Simone Formulation which was then known as VSL#3:

> Furthermore, 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 has licensed such product to [VSL Inc. and other parties, which] hereby confirms and instructs Danisco that De Simone shall have the right to provide notice of termination of such licenses to Danisco on behalf of [VSL and other parties and they] hereby instruct[] Danisco to discontinue the use and/or manufacture of VSL#3 . . . upon receipt of such notice.

82. The Confidential Disclosure Agreement was signed on behalf of certain of the Cavazza-owned companies by Maurizio Terenzi, who at the time was President of CD

Investments (99.7-percent shareholder of VSL Inc.) and also President of CD International (100-percent owner of CD Investments). Mr. Terenzi was also a close financial advisor to the Cavazza family.

83. Soon after the Confidential Disclosure Agreement was signed, Prof. De Simone learned of efforts by managers of the Sigma-Tau Group to access the proprietary formula for making VSL#3, which was known only to Danisco and Prof. De Simone. More specifically, within a few months, Prof. De Simone was contacted by Scott Bush (Business Director, Cultures Division and Probiotics for Danisco) who informed Prof. De Simone that he had been contacted by managers of STP Italy who: (a) sought information about the VSL#3 formulation; and (b) requested access to the bacterial strains of VSL#3, which would allow them to make a fake version of the product without the participation of Prof. De Simone. The ability to make such a probiotic product would allow the Cavazzas to evade their obligation to pay royalties to Prof. De Simone for his know-how under the relevant agreements for VSL#3. On information and belief, the actual sale of this contemplated "fake" product would be potentially dangerous to the health of consumers since this product necessarily would not have undergone any safety or efficacy tests in humans.

84. It was well understood and agreed among the Cavazzas, VSL Inc. and Prof. De Simone that supply of the VSL#3 product was under the control of Prof. De Simone. Such an understanding was confirmed and evidenced by, among many other things, the absence of any supply agreement between Danisco and any entities (including STP New Jersey and Leadiant) that were selling the product. In view of this understanding, Prof. De Simone brought his concerns about the attempts to make a "fake" product and misappropriate the know-how and trade secrets to the attention of Claudio Cavazza and indicated that he was considering

terminating their collaboration since he no longer trusted the managers appointed by the Cavazzas. Prof. De Simone also informed the Cavazzas that he would act to strengthen the protection of his proprietary know-how related to VSL#3 by putting an additional written agreement in place between himself and Danisco.

iv. Supply Agreement Between Prof. De Simone and Danisco

85. On June 1, 2008, Prof. De Simone entered into a written agreement with Danisco for the purpose of memorializing the terms and conditions under which Danisco would continue to manufacture VSL#3 (the "2008 De Simone-Danisco Agreement").

86. Thus, among the recitals of the 2008 De Simone-Danisco Agreement is the statement that "DANISCO's manufacture of the product currently sold as VSL#3 or VSL #3 DS in [United States and certain enumerated other countries] has involved the use by DANISCO of [Prof. De Simone's] 'Technical Information' (as defined herein), including trade secrets, know-how, and other confidential information." The recitals also indicate that "DANISCO's use of [Prof. De Simone's] Technical Information to date to blend final composition of, ship and/or sell the product sold as VSL#3 or VSL#3 DS in the [United States and other countries] has been with the permission of [Prof. De Simone] and with the agreed understanding that [Prof. De Simone's] Technical Information is owned by [Prof. De Simone] and is to be maintained in strict confidence by DANISCO."

87. The recitals also state that the 2008 De Simone-Danisco Agreement "sets forth the terms and conditions under which CDS is willing to allow DANISCO's continued use of [Prof. De Simone's] Technical Information for the purposes of allowing DANISCO to continue to blend final composition of, ship and/or sell the product sold as VSL#3 or VSL#3 DS in the [United States and certain other countries] to those entities designated by [Prof. De Simone] on

Schedule A to this Agreement." Among those designated entities allowed to receive VSL#3 from Danisco was STP New Jersey (for the United States but only until 2010) and VSL Inc. (for Canada, but only until 2012, and Israel until the expiration of the 2008 De Simone-Danisco Agreement).

88. Under paragraph 2 of the 2008 De Simone-Danisco Agreement, Prof. De Simone granted Danisco "a non-exclusive, royalty free, fully paid up worldwide license to make, have made, use, offer to sell, export and import [VSL#3], incorporating [Prof. De Simone's] Technical Information for the benefit of Danisco's customers under those discoveries or inventions exclusively owned or controlled by [Prof. De Simone]."

89. Paragraph 2 further provides that, except as necessary to enable Danisco to perform its obligations under the agreement, Danisco promised to "hold all of [Prof. De Simone's] Technical Information in strict trust and confidence for [him] in perpetuity."

90. Paragraph 8(a) of the 2008 De Simone-Danisco Agreement sets the term of the agreement as the period from June 11, 2008 through December 31, 2012. The agreement was, however, automatically renewable for two additional five-year periods unless terminated earlier by giving written notice at least 180 days prior to the expiration of the term.

91. Soon after the 2008 De Simone-Danisco Agreement was signed, Prof. De Simone shared it with the Cavazzas to ensure that they and all their surrogates were aware of its strict limits on who could receive and distribute VSL#3 as a finished, consumable product.

92. At this point, Claudio Cavazza attempted to convince Prof. De Simone to sign another agreement with a second supplier and suggested that a factory owned by the Sigma-Tau Group could be involved to make the VSL#3 product. Given the previous attempts by Sigma-

Tau managers to access Prof. De Simone's proprietary formula, he rejected Claudio Cavazza's proposal.

v. Know How License Agreement Between Prof. De Simone and VSL Inc.

93. After STP New Jersey merged into Leadiant in late 2007, Prof. De Simone and VSL Inc. were planning for how the company lawfully could continue overseeing the development, production, and distribution of VSL#3 once the Patent License Agreement expired in early 2015.

94. On September 18, 2009, the board of directors of VSL Inc., comprising Prof. De Simone, Dr. Beth Park ("Dr. Park"), and Mr. Terenzi (who represented the interests of the Cavazza family and the Sigma-Tau Group), met in Rome, Italy to discuss this important issue. During this meeting, Prof. De Simone made it clear that VSL Inc. would need to enter into a new agreement with him if it wished to continue marketing and selling VSL#3 because he could not risk losing control over his proprietary rights in the VSL#3 formula once the Patent License Agreement expired. The Board then proceeded to vote (Dr. Park and Mr. Terenzi voting in favor with Prof. De Simone abstaining) to authorize Dr. Park to negotiate a "Know How" agreement that would expire on January 31, 2016 and would obligate VSL Inc. to pay Prof. De Simone a five-percent royalty on net sales of VSL#3.

95. Given Mr. Terenzi's participation in this board meeting, his representation of the Cavazza family's and the Sigma-Tau Group's interests, and his vote in favor of the proposed new "Know How" agreement, Leadiant had knowledge that its rights to market and sell VSL#3 depended exclusively on VSL Inc.'s agreements with Prof. De Simone.

96. As a result of these negotiations, on January 28, 2010, Prof. De Simone and VSL Inc. entered into a Know How License Agreement (the "Know How Agreement") by which, in

exchange for certain royalties payable to Prof. De Simone, he granted VSL Inc. (as stated in paragraph 2.1) "the exclusive right to his Know How and all good will associated with therewith, with the right to grant sublicenses, to manufacture, promote, market and sell [VSL#3] in the [United States]."

97. A true and correct copy of the Know How Agreement is attached hereto and incorporated by reference herein as **Exhibit B**.

98. Recital paragraphs A and B of the Know How Agreement acknowledge the existence of the 2001 Patent License Agreement between Prof. De Simone and VSL Inc. and that the Patent License Agreement would expire on February 10, 2015.

99. Recital paragraph C of the Know How Agreement states Prof. De Simone's intention to grant VSL Inc. "an exclusive license related to all goodwill and Know How owned or controlled by [Prof. De Simone] associated therewith for the production and commercialization of [VSL#3] in the [United States] upon the terms and conditions set forth herein."

100. Section 1.8 of the Know How Agreement defines the "Know How" to mean "relevant information related to [VSL#3] including but not limited to discoveries, processes, composition, technical and scientific data which are in possession or in control of [Prof. De Simone] and are needed in order for VSL [Inc.] to have manufactured, promote, offer for sales and sell [VSL#3] in the [United States]."

101. Under Section 3 of the Know Agreement, in exchange for VSL Inc.'s license to use the Know How, it agreed to pay Prof. De Simone "a royalty of 5% on Net Sales of the Product sold in the [United States]." Payment of this royalty would be due "on the last day of April, July, October and January for the immediately preceding calendar quarter of each month."

102. Section 4.1 of the Know How Agreement provides that it "shall be effective as of the date [the] Patent License Agreement expires and shall continue in effect until January 31, 2016."

103. Section 4.2 of the Know How Agreement gives each party "the right to terminate this Agreement in the event that other Party does not fulfill one or more of its obligations provided hereunder within sixty (60) days of notice by the other Party of such breach(s)."

104. Sections 4.3 through 4.6 of the Know How Agreement give Prof. De Simone rights to terminate the Know How Agreement "immediately with written notice" if: (a) "there is Change of Control of VSL"; (b) "VSL no longer owns Trademarks [VSL#3 and VSL#3 DS]"; (c) the "royalty from any given year is less than the royalty from the previous year"; or (d) "there is a breach of Confidentiality Obligations envisaged in section 5 of this Agreement."

105. Section 5.1 of the Know How Agreement defines "Confidential Information" to mean "[a]ny and all information related to the Product received by VSL or its Affiliate," including "any and all information disclosed to VSL, or its Affiliate by [Prof. De Simone] during the term of Patent License Agreement."

106. Section 5.1 of the Know How Agreement further obligates VSL Inc. and its affiliates ("affiliates" being defined as those entities owning 50 percent or more of VSL Inc.'s capital stock or having the ability to direct its management and operations) to keep such information "in strict confidence," subject to certain specified exceptions.

107. Thus, under Section 5, "VSL [Inc.] acknowledges that any Confidential Information made available to VSL is to be used only in the [United States], only for [VSL#3 in the form of a "medical food"], and solely in connection with VSL[Inc.]'s performance of its obligation of this Agreement" and that "[a]ny other use of the Confidential Information shall be

considered as a material breach of this Agreement," giving Prof. De Simone the "right to terminate the Agreement immediately with written notice to VSL [Inc.]." Section 5 further provides that its confidentiality obligations "shall survive any termination of this Agreement."

108. Section 7 of the Know How Agreement contains mandatory choice-of-law and choice-of-forum provisions. Thus, Article 7 provides:

> This Agreement shall be construed in accordance with and governed by the laws of Maryland, without regard to principle of conflict of law. Process in any such suit, action or proceeding may be served on any party anywhere in the world whether within or without the jurisdiction of any such court. All issues and controversies arising hereunder will be brought in the Federal District Court of Maryland if jurisdiction exists, otherwise, in the State Courts of Maryland. Both Parties hereby submit to the jurisdiction of the Federal and State Courts of Maryland.

vi. Renewal of Sub-License Agreement Between VSL Inc. and Leadiant

109. On March 17, 2010, VSL Inc. notified "Sigma-Tau Pharmaceuticals, Inc." (now Leadiant) at its Gaithersburg, Maryland headquarters that VSL would be terminating the 2003 VSL-STP License Agreement at the end of the agreement's initial term on December 31, 2010.

110. Leadiant acknowledged the termination and invited VSL to begin negotiating a new license agreement that would allow Leadiant to continue marketing and selling VSL#3 in the United States beyond 2010.

111. As a result of these negotiations, on or about May 1, 2010, VSL and Leadiant entered into a License Agreement (the "2010 VSL-STP License Agreement") by which, in exchange for certain royalties payable to VSL Inc., Leadiant was granted an exclusive license (as stated in Section 2.1) "to have manufactured, promote, distribute offer for sale and sell" VSL#3 as a "medical food" in the United States, "without the right to sublicense . . . ." Leadiant also promised that it would "not make any active endeavors to solicit orders for the Product" outside

the United States and that it would "not establish any center for the distribution" of VSL#3 outside the United States.

112. Section 1.8 of the 2010 VSL-STP License Agreement defines the "Know How" to mean "any relevant information related to [VSL#3] including but not limited to, discoveries, processes, composition, clinical, scientific, technical and marketing data, which are or come into VSL[Inc.]'s possession or control during the Term, and are useful, in order for STPI to have manufactured, promote, distribute, offer for sale and sell" VSL#3 as a "medical food" in the United States.

113. Section 3.1 of the 2010 VSL-STP License Agreement provides that VSL Inc. shall disclose "the Know-How which is available to VSL[Inc.], which is relevant to [VSL#3 as a "medical food" in the United States], which may be developed or acquired by VSL during the Term of this Agreement and which VSL is free to disclose." This was a reference to VSL Inc.'s rights to use and disclose the "Know How" that was defined in the Know How Agreement, which Prof. De Simone and VSL Inc. signed four months earlier.

114. Section 4.1 of the 2010 VSL-STP License Agreement provides that Leadiant "shall have manufactured [VSL#3] at its own cost and expense," that "[a]ny third party manufacturer must be approved in advance by VSL [Inc.]," and that the "manufacture of [VSL#3] shall be conducted strictly in accordance with the following provisions this Article IV and the terms and conditions of this Agreement." Among the limitations on Leadiant's rights to use the Know How set forth in Section 4 are requirements: (a) to comply with applicable laws and regulations relating to "the manufacture, marketing, production, storage and distribution" of VSL#3 as a "medical food" in the United States; and (b) that VSL#3 "shall be manufactured using only materials supplied by a source approved by VSL" and "with the same active

ingredient used in the Clinical Trials and strictly in accordance with (i) all reasonable instructions and recommendations given by VSL from time to time; (ii) current standards of good manufacturing practice; and (iii) all applicable regulatory requirements prescribed by the laws of the [United States]."

115. In accordance with Section 4.1, Leadiant obtained its supplies of VSL#3 from Danisco, which was continuing to manufacture the product under the terms of the 2008 De Simone-Danisco Agreement.

116. Under Article 5 of the 2010 VSL-STP License Agreement, Leadiant was responsible for marketing, distributing, and selling VSL#3 at its own expense.

117. Under Section 5.3 of the 2010 VSL-STP License Agreement, Leadiant was responsible for providing VSL Inc. with monthly reports of its sales of VSL#3 and quarterly reports detailing its marketing activities.

118. Subject to certain exceptions, Section 5.5 of the 2010 VSL-STP License Agreement provides that, "[d]uring the Term of this Agreement and for twelve months from the termination date for any reason," Leadiant or any "Affiliate" (defined as any entity owning 50 percent or more of Leadiant's equity securities or having the right to appoint a majority of its directors) "shall not sell, manufacture, have manufactured, distribute or commercialize any probiotic products other than [VSL#3]."

119. Section 5.5 further provides that, subject to certain exceptions, neither Leadiant nor any "Affiliate" shall "own an interest in an entity that makes, sells, distributes or commercializes an article that competes with [VSL#3] in the [United States]" or shall "in any way participate, directly or indirectly, in manufacturing, selling, distributing or commercializing an article competitive with [VSL#3] in the [United States]."

120. Under Section 6.1 of the 2010 VSL-STP License Agreement, "[a]ny and all information related to [VSL#3] received by [Leadiant] or by its Affiliate ('Confidential Information') shall be maintained in strict confidence" and shall be used "only for the purposes of this Agreement" and disclosed "only to those of [Leadiant's] employees, consultants or other third parties who need to know Confidential Information for the purposes of this Agreement."

121. Section 7.1 of the 2010 VSL-STP License Agreement defines how the required royalty to be paid for the license is to be calculated and when it must be paid.

122. Section 7.2 requires Leadiant to provide VSL Inc. with certain monthly sales reports as well as semi-annual reports detailing total gross sales, relevant "Net Sales," and "other information VSL may reasonably request."

123. Section 9.1 defines the term of the 2010 VSL-STP License Agreement to be through December 31, 2015 and allows the agreement to be renewed automatically for successive two-year periods unless earlier terminated by giving written notice at least 12 months prior to the end of the initial or any renewed term.

F. The Cavazza Family Improperly Pressures Prof. De Simone to Cede Control Over VSL#3

124. In or about mid-2013, Andrea Montevecchi ("Mr. Montevecchi"), Chief Executive Officer of the Sigma-Tau Group (which includes Leadiant) and a director of Leadiant, contacted Prof. De Simone on several occasions to attempt to persuade him to agree to renew the 2010 VSL-STP License Agreement for an additional five-year term beyond 2015 and on terms that were extremely favorable to Leadiant but economically unfeasible for VSL Inc.

125. At around the same time, Paolo Cavazza met with Prof. De Simone and Dr. Park, another director of VSL Inc., to discuss his proposal that Leadiant's licensing rights to VSL#3 be assigned to a new Leadiant subsidiary that would handle Leadiant's nutraceutical business in the

United States. In exchange for such assignment, VSL Inc. and Prof. De Simone would acquire shares in the new company, but Leadiant would have a super majority of such shares. Prof. De Simone rejected this proposal.

126. In or about November 2013, Prof. De Simone met with Enrico Cavazza, who, along with his siblings, had assumed management of his father Claudio's businesses after Claudio Cavazza died in 2011. Enrico Cavazza proposed that Prof. De Simone agree to allow VSL Inc. to purchase the strains of lactic acid bacteria to be used in VSL#3 from Biosint, a company controlled by the Sigma-Tau Group, instead of from Danisco. Prof. De Simone rejected this proposal because, in his view, Biosint's bacterial strains were inferior in quality to the strains used by Danisco and could be detrimental to consumers. In addition, Prof. De Simone also worried about increasing the risk that the Cavazzas could misappropriate his know-how.

127. In or about November 2013, Prof. De Simone and Dr. Park met with Mr. Montevecchi. During this meeting, Mr. Montevecchi complained again about the high cost of VSL#3 and how this was causing Leadiant's profit margins to be too low. Mr. Montevecchi proposed reducing VSL#3's production cost (thus increasing profit) by changing the product's composition and substituting cheaper bacterial strains supplied by Biosint. He argued that since VSL#3 was not being marketed as a drug in the United States, no one would notice the change in composition if everyone remained quiet about it.

128. Prof. De Simone would have none of this. He replied that he would never participate in a scheme to dilute the product secretly, which would violate the trust that consumers had placed in VSL#3 and could lead to adverse health consequences. Mr. Montevecchi, however, was not so easily dismissed this time. Disturbingly, he warned that

unless VSL Inc. offered Leadiant a better profit margin on VSL#3, Prof. De Simone was risking further confrontation with the Cavazza family.

129. On November 21, 2013, Prof. De Simone met with Paolo Cavazza in Rome. Mr. Cavazza explained that Leadiant would be split into two entities, one for "orphan drug" prescription products and the other for nutraceuticals. Mr. Cavazza stated that VSL#3 would be assigned to the nutraceutical division, probably to be called "Sigma Health Sciences," and that the brand VSL#3 would be used to include new formulations, with cheaper bacterial strains and concentrations. Mr. Cavazza also again suggested changing the formulation of VSL#3 in order to obtain higher profitability.

130. By the end of 2013, Prof. De Simone reached the frightening conclusion that profitability was the only objective that Paolo Cavazza and Leadiant had with respect to VSL#3 and their plans for a new nutraceutical division, and they gave no consideration to the health risks to consumers and associated legal and ethical implications. It had become clear that undue threats and pressure from the Cavazzas to cooperate in their plans would only grow.

131. By March 2014, the pressure from the Cavazzas and their surrogates had indeed intensified, as Prof. De Simone had predicted several months earlier. On March 4, 2014, Mr. Montevecchi wrote to Prof. De Simone, demanding that unless the 2010 VSL-STP License Agreement was renewed on the terms he had proposed earlier, Sinaf (Paolo Cavazza's company, which owned one-third of VSL Inc.'s parent, CD International), Taufin (representing the interests of Claudio Cavazza's heirs, which also owned one-third of CD International) or the Cavazzas themselves would bring litigation against Prof. De Simone. At the same time, Mr. Montevecchi admitted in this communication that Prof. De Simone is the "owner of the rights on a brand with significant goodwill in the market."

132. Three days later, on March 7, 2014, Paolo Cavazza telephoned Prof. De Simone, threatening that Sinaf and Taufin would bankrupt VSL Inc. and financially ruin Prof. De Simone and his family if Prof. De Simone did not agree to renew the Know How Agreement (which was set to expire at the end of 2015), thereby allowing VSL Inc. to sub-license to Leadiant the rights to market and sell VSL#3 on the terms Mr. Montevecchi had demanded. Paolo Cavazza made similar threats in a separate telephone call to Dr. Park on the same day.

133. Less than a week later, Prof. De Simone contacted Paolo Cavazza and informed him that VSL Inc. could not accept Leadiant's proposed terms for extending the 2010 VSL-STP License Agreement because to do so would itself bankrupt VSL Inc.

134. On March 24, 2014, Mr. Montevecchi and another surrogate of the Cavazzas, Mr. Guido Tugnoli, met with Dr. Park in Munich, Germany to discuss the situation. Here again, Mr. Montevecchi threatened litigation against VSL Inc., and stated his intent to breach the contract with VSL Inc. and also warned that, if necessary, Leadiant would launch a "copy" of VSL#3. Mr. Montevecchi reminded Dr. Park that Sinaf and Taufin, which owned Leadiant and owned two-thirds of VSL Inc.'s ultimate parent, CD International, had the power to do whatever they wanted with VSL#3, even if their plans were not in the best interest of VSL Inc. They further indicated to Dr. Park that their plans did not contemplate any future for VSL Inc.

135. On May 13, 2014, Prof. De Simone received a letter from Maurizio Martinetti, a member of the board of VSL Inc.'s parent company who represented the interests of the Cavazzas. Mr. Martinetti requested copies of VSL Inc. corporate and contractual documents starting from the year 2000. He indicated that he was "landing from Mars," meaning that he was lacking in information even though he had been on the board of the parent company (CD

Investments) for seven years with full access to all documents and contracts and approved all the financial statements of VSL Inc. in the past years.

136. The sudden demand for information by Mr. Martinetti, acting as an agent for Leadiant and the Sigma-Tau Group, amounted to a "fishing expedition" designed to harass and threaten Prof. De Simone and to remind him that VSL Inc. was ultimately the property of the Cavazzas and that they would try to do whatever they wanted with it, even against the best interests of the company. In addition, Mr. Martinetti verbally indicated that the Cavazzas intended to put VSL Inc. under the control of a different CEO and to increase the size of the board of directors so that they could take control of the company's finances and the manufacture of the VSL#3 product. On information and belief, Leadiant and the Sigma-Tau Group planned to sell a different product, never tested before or studied even in animals, under the brand VSL#3 (or a confusingly similar brand) once the Cavazzas took control of VSL Inc.

137. Prof. De Simone became further alarmed when he learned that an attorney in the U.S. with responsibilities for regulatory matters related to the use of VSL#3 as a medical food was contacted by an attorney acting for Leadiant who sought access to confidential information of Prof. De Simone relating to the VSL#3 product.

138. By mid-2014, the evidence supporting Prof. De Simone's suspicion that Leadiant and related companies planned to market a "clone" of VSL#3 was mounting and emanated from multiple independent sources. This reckless conduct gravely concerned Prof. De Simone, who considered these actions to be unethical and in disregard for the safety of consumers who are immunosuppressed and rely on VSL#3 to address their medical conditions. In the absence of appropriate testing for safety and efficacy, no bacterial product should be made available to be

administered to immunosuppressed consumers, since it can be dangerous and even lethal. This fact is well established in the medical community and of major concern for Prof. De Simone.

139. On or about June 4, 2014, a meeting of the shareholders of CD International (VSL Inc.'s ultimate parent company) was held in Luxemburg. At that meeting, Dr. Park made a presentation of the alternative business scenarios then available to VSL Inc., which clearly demonstrated that if the VSL#3 product were licensed to Leadiant on the conditions sought to be imposed by Mr. Montevecchi, VSL Inc. would be financially non-viable within a relatively short period of time. The Cavazzas refused to attach the text submitted by Dr. Park to the minutes of the meeting.

140. Immediately following the shareholders meeting, Sinaf and Taufin changed the majority of the board members of the controlling company (CD Investments) of VSL Inc. Afterwards, through their U.S. attorneys, they falsely accused Prof. De Simone of "wrongdoing including breaching of fiduciary duties." VSL Inc. was significantly increasing its revenues under the management of Prof. De Simone and Dr. Park over the preceding few years. This period of success was preceded by a very distressing period of financial problems, when VSL Inc. was managed by individuals appointed by the Cavazzas who also held positions in STP Italy and Leadiant. The accusations against Prof. De Simone and Dr. Park were an obvious tactic to pressure them to bend to the requests of the Cavazzas for the benefit of Leadiant.

141. Throughout the spring and summer of 2014, surrogates of the Cavazzas, who also were representing CD Investments and Leadiant, actively sought to create a "clone" of the VSL#3 formulation. In fact, Paolo Cavazza himself declared that he was in the advanced process of making a clone of VSL#3.

142. During the summer of 2014, Taufin, Sinaf, and CD Investments began making a series of demands to inspect VSL Inc.'s books and records. VSL Inc. refused these demands because they did not comply with the proper-purpose requirement of Delaware law.

143. On September 4, 2014, CD Investments, in its capacity as the owner of 99.97 percent of the shares of VSL Inc., adopted a written consent changing certain of VSL Inc.'s bylaws. This was unlawful because written consents are not effective actions of the shareholders of Delaware corporations unless they are adopted unanimously. Without such unanimous support, any change in VSL Inc.'s bylaws could only be effected at a duly noticed meeting of VSL Inc.'s shareholders, which included Prof. De Simone (who owned 0.1 percent of VSL Inc.'s shares). Among other things, the illegal change in VSL Inc.'s bylaws purported to: (a) increase the number of VSL Inc.'s permissible directors to three; (b) eliminate indemnification for VSL Inc.'s directors; and (c) amend VSL Inc.'s bylaws to require that future amendments be approved by all directors, not just a majority of directors. This written consent of CD International also contained a resolution electing James Brady ("Mr. Brady") as a new director of VSL Inc. (Prof. De Simone and Dr. Park being the other two).

144. On September 11, 2014, CD Investments and Sinaf filed suit against VSL Inc. in the Delaware Chancery Court to enforce previous demands for the inspection of VSL Inc.'s books and records. Paragraph 8 of their Verified Complaint alleges that VSL Inc.'s "formation derived from a Product Development and Collaboration Agreement (the 'Product Development Agreement') among the following entities: (1) Mendes International SA; (2) Sinaf; (3) Taufin; (4) Mendes Srl ('Mendes'); and (5) De Simone." Paragraph 8 further alleges that "De Simone was the majority stockholder of the Mendes entities" and that the "purpose of the Product

Development Agreement was to optimize the commercial value of certain patents that De Simone owned."

145. Paragraph 9 of CD Investments and Sinaf's Verified Complaint alleges that "[p]ursuant to the Product Development Agreement, and in exchange for financial backing, De Simone and the entities which he controlled were supposed to transfer all of their rights in certain U.S. patents to the Company, including U.S. patents for VSL #3, a probiotic medical food."

146. Several weeks later, on September 29, 2014, Mr. Brady made a demand for inspection of VSL Inc.'s books and records that was virtually identical to demands previously made on behalf of Taufin, Sinaf, and CD Investments.

147. VSL Inc. refused Mr. Brady's demand on two grounds. First, Mr. Brady was demanding that copies of the books and records be sent to the lawyer representing CD Investments and Sinaf in the pending litigation against VSL Inc., which appeared to be a tactic to circumvent that litigation. Second, Mr. Brady had refused to enter into a confidentiality agreement that would prohibit his sharing of information with the Cavazzas and their surrogates —a request born of Prof. De Simone's well-founded suspicion that the Cavazzas were attempting to gather as much information from VSL Inc. as possible to aid their ongoing attempt to clone VSL#3 using inferior and potentially dangerous ingredients.

148. On October 10, 2014, Mr. Brady filed a virtually identical Verified Complaint against VSL Inc. in the Delaware Chancery Court. Mr. Brady's Complaint makes identical allegations to those set forth in paragraphs 8 and 9 of the Verified Complaint filed several weeks earlier by CD Investments and Sinaf.

149. By letter dated October 15, 2014 addressed to the other directors of VSL Inc., and in his capacity as a director of the company, Mr. Brady asserted that VSL Inc. owns or may own

all intellectual property rights in VSL#3 based on: (a) Article VII of VSL Inc.'s bylaws, by which Prof. De Simone purportedly was obligated to transfer to VSL Inc., in the words of Mr. Brady, "all rights owned by [De Simone], directly or through another person, whether patent, trademark, copyright or otherwise, related to any inventions made by [De Simone] in the field of pharmaceutical nutritionals compositions and active principles"; and (b) the purported assignment from Mendes, S.r.l. to VSL Inc., dated September 18, 2000 and signed by Prof. De Simone (the "Mendes Patent Assignment"), of, again in the words of Mr. Brady, "all right title and interest to the intellectual property relating to VSL#3, including know-how and trade secrets related thereto."

150. Article VII of VSL Inc.'s bylaws reads in full as follows:

> Section 7. Transfer of Inventions.
>
> As long as Professor Claudio De Simone owns, directly or indirectly, 4.99% or more of the total voting stock of the Corporation, he shall transfer or offer to transfer, without the payment of further consideration by the Corporation, all rights owned by him, directly or through another person, whether patent, trademark, copyright or otherwise, relating to ***any inventions made by him in the field of pharmaceutical nutritionals compositions and active principles***, whether for animal or human use, ***since the incorporation of the Corporation***, to the Corporation [emphasis added].

151. Although the Delaware litigations ultimately were settled, both Dr. Park and Prof. De Simone resigned from VSL Inc.'s board of directors, and Prof. De Simone also resigned as Chief Executive Officer of the company. Mr. Brady was thus left as the sole remaining director.

152. Nevertheless, the positions taken by CD Investments, Sinaf, and Mr. Brady (on behalf of VSL Inc.) that VSL Inc. owns or has a claim to ownership of the 615 Patent and Prof. De Simone's proprietary formula for the version of VSL#3 produced prior to February 1, 2016 contradict their respective contractual acknowledgments in the Patent License Agreement

(2001), the Confidential Disclosure Agreement (2006), and the Know How Agreement (2010) that Prof. De Simone owns these rights.

153. These positions also are at odds with Mr. Montevecchi's admission in March 2014, on behalf of Leadiant, that Prof. De Simone owns the intellectual property rights in the prior version of VSL#3.

G. Termination of VSL Inc.'s Rights to Sell VSL#3 Utilizing the De Simone Formulation

154. On or about November 14, 2014, Prof. De Simone provided written notice to VSL Inc. that he was terminating the Know How Agreement on the basis of the change-of-control provision and because of VSL Inc.'s breach of the confidentiality provisions of the agreement.

155. The same day, Prof. De Simone provided written notice of the termination of the Know How Agreement to Sinaf, Taufin, and CD Investments, all of whom, directly or indirectly, own shares in VSL Inc. In this letter, Prof. De Simone also proposed entering into a new, restructured business arrangement with VSL Inc., by which he would assume direct responsibility for marketing and selling VSL#3.

156. In identical letters to Prof. De Simone dated November 28, 2014, Taufin and Sinaf (representing the Cavazzas' interests) acknowledged receipt of Prof. De Simone's November 14 letter and the existence of the Know How Agreement. They also requested further information in order to evaluate Prof. De Simone's business proposal, but they did not dispute that the Know How Agreement had been terminated and that VSL Inc. and Leadiant no longer had authority to sell VSL#3 in the United States.

157. On December 5, 2014, Prof. De Simone wrote to Leadiant itself, advising that the Know How Agreement had been terminated and that VSL Inc. had rejected the business proposal set forth in his November 14 letter. Prof. De Simone also pointed out that "VSL does not have

any rights to pass to [Leadiant] [the rights] to purchase the active ingredient from Dupont [Danisco's parent] upon the expiration of its patent license in February 2015." Prof. De Simone also invited Leadiant to discuss a proposed a new business arrangement, which would allow Leadiant to continue selling VSL#3 in the United States after expiration of the Patent License Agreement.

158. On December 24, 2014, Leadiant, by counsel, acknowledged receipt of Prof. De Simone's December 5 letter and expressed interest in exploring his proposed business arrangement.

159. VSL Inc. did not pay royalties due on January 31, 2015, breaching its obligations under the Patent License Agreement. No explanation was given. On February 10, 2015, the Patent License Agreement between VSL Inc. and Prof. De Simone expired.

160. The expiration of the Patent License Agreement and the termination of the Know How Agreement left VSL Inc. and Leadiant without any authority to use, sell, or disclose Prof. De Simone's proprietary methods of growing, the analysis of, and the selection/ratio of the eight strains of bacteria comprising VSL#3, which were (and remain) valuable trade secrets.

161. Despite its demonstrable lack of legal authority to do so, at least through January 2016, VSL Inc. continued to acquire stocks of VSL#3 from Danisco and to allow Leadiant to market and sell the product in the United States throughout 2016. Not only were VSL Inc. and Leadiant failing to pay Prof. De Simone royalties for this sales activity, they both were continuing to use and exploit Prof. De Simone's valuable trade secrets for commercial gain but without his permission.

162. In their Complaints filed in the Delaware books-and-records demand litigation, CD Investments, Sinaf, and Mr. Brady all have taken the position that VSL Inc. either owns or

has a claim of ownership of all rights in certain U.S. patents held by Prof. De Simone, including the U.S. patents for the prior version of VSL #3. This is in stark contradiction to the numerous prior agreements entered among the relevant parties in which it was clearly acknowledged that Prof. De Simone, and only Prof. De Simone, is the sole rightful owner of all intellectual property rights relating to the probiotic formulation underlying VSL#3 (as produced prior to February 1, 2016).

163. More recently, in December 2014, the Cavazzas caused Actial Farmacêutica LDA, a Portuguese company ("Actial") that, along with VSL Inc. and another entity, a subsidiary of CD Investments, to file suit against Prof. De Simone in the High Court of Justice of the United Kingdom (the "UK Litigation"). In this UK litigation, the Cavazzas and their surrogates took the incorrect position that, by virtue of the Collaboration Agreement signed on July 11, 2000 (the same day VSL Inc. was incorporated) by Prof. De Simone, his affiliated companies, and Taufin and Sinaf, Prof. De Simone had agreed to transfer all his rights relating to existing inventions in the pharmaceutical nutritional field to VSL Inc.

164. Despite the Cavazza's new position, the 615 Patent is conspicuously absent from the patents listed in the schedules to the Collaboration Agreement. Furthermore, their position is inconsistent with the 1999 Option Agreement between Prof. De Simone and STP New Jersey, by which STP New Jersey acquired a license, from 2000 to 2006, allowing it to use the 615 Patent and Prof. De Simone's trade secrets to commercialize VSL#3 as a drug in the United States. This new position also is inconsistent with numerous agreements that VSL Inc. and its parent and affiliated companies signed with Prof. De Simone beginning in 2002 by which these companies acquired licensing rights for various territories around the world.

165. In January 2015, a petition was filed with the U.S. Trademark Trial and Appeal Board to cancel the VSL#3 trademark, which is owned by VSL Inc., on the ground that the mark "VSL#3" has become generic.

166. VSL Inc.'s answer to this petition, filed on March 30, 2015, alleges that VSL Inc. owns the "formulation of, and methodology of producing," and "owns all right, title, and interest in and to the trade secrets and know-how relating to," VSL Inc.'s products, including VSL#3.

167. As a result of the events of 2014 and early 2015: (a) VSL Inc. and Leadiant each have repudiated their contractual acknowledgments that Prof. De Simone owns and controls the intellectual property rights in the VSL#3 formula (as produced prior to February 1, 2016) and related trade secrets; (b) VSL Inc. wrongfully has ceased paying Prof. De Simone royalties under the Patent License Agreement for sales of VSL#3 made in 2014 and 2015; (c) VSL Inc. wrongfully continued to permit Leadiant to market and sell VSL#3 based on the De Simone Formulation despite knowing that it no longer had any legal rights to do so; and (d) Leadiant has been unjustly enriched and was misappropriating Prof. De Simone's trade secrets by continuing to profit from the sale of VSL#3, knowing that it lacked any legal rights to do so after November 2014.

H. VSL, Inc.'s and Leadiant's Supply of the De Simone Formulation is Cut Off, Professor De Simone Enters Exclusive Licensing Agreement with ExeGi, and Leadiant Begins Campaign of False Advertising

168. On June 24, 2015, Prof. De Simone sent a letter to Danisco stating that Leadiant could only continue as an Approved Buyer under Schedule A of the DeSimone-Danisco 2008 Agreement until September 15, 2015. On October 1, 2015, this letter was modified such that Leadiant's access to Danisco's supply of VSL#3 was extended to January 31, 2016. Upon

information and belief, Danisco honored Prof. De Simone's instructions and ceased to provide Leadiant with supply of the De Simone Formulation as of January 31, 2016.

169. In May 2015, ExeGi signed an agreement with Prof. De Simone to produce a generic version of the probiotic containing the De Simone Formulation. The license agreement permits ExeGi to have the De Simone Formulation manufactured, as well as to market and sell this formulation, in the United States and elsewhere, based on the trade secrets and know-how owned and possessed by Prof. De Simone. ExeGi launched this product under the name "Visbiome" on February 1, 2016. Since that time, ExeGi has been, and currently is, the only authorized supplier of the De Simone Formulation in the United States and, as of in or about the Summer of 2016 when Leadiant began selling its new version of VSL#3, Visbiome is the only authentic version of the De Simone Formulation in the market.

170. In May 2016, Leadiant publicly announced that production of VSL#3 would be moving from the Danisco facility in the United States to a new manufacturer in Italy (Centro Sperimentale del Latte, or "CSL"). In the months that followed, independent testing (corroborated by anecdotal reports and complaints from consumers) has confirmed that the new version of VSL#3 produced in part at the CSL facility in Italy (the final product is in fact produced by another Italian company, Nutrilinea) is demonstrably different from the original De Simone Formulation being sold by ExeGi, despite being marketed by Alfasigma as identical to the original formulation. Prof. De Simone's fears, which were noted in the initial Complaint two years ago, that the Cavazzas and their surrogates would follow through on their threats to produce a dangerous, cheaper, inferior copy of his formulation, and seek to confuse consumers and the medical community that it is the same as the original formulation, have now become a reality.

171. Leadiant's marketing piece about VSL#3's move to a new manufacturing facility in Italy claimed that the resulting new product will be "the same quality product, containing the same genus and species of bacteria, in the same proportions that you have come to expect." The advertisement goes on to claim, "How will this impact you and your patients? It won't. VSL#3, your first choice probiotic to manage Ulcerative Colitis, IBS and ileal pouch….." Therefore, in this initial notification to the market, Leadiant claimed that the version of VSL#3 produced in the new facility in Italy is clinically equivalent to the Danisco-produced product previously sold as "VSL#3," which contains the De Simone Formulation and now is marketed and sold by ExeGi under the brand name "Visbiome." This claim is entirely false.

I. Leadiant Assigns its Rights to A New Entity, Which Continues the False Advertising Campaign

172. Effective June 30, 2016, Leadiant assigned and transferred to STHS its rights for the marketing and sale of VSL#3 under the 2010 VSL-STP License Agreement.

173. On or about August 31, 2016, in a press release ("August 2016 Press Release"), STHS announced that its new Italian-made product was commercially available and that the product was now "Dairy Free" ("Non Dairy VSL#3"). In the August 2016 Press Release, STHS also made numerous false and misleading statements, including that the new Non-Dairy VSL #3 is being manufactured in Italy (by CSL), which is the "…original manufacturing facility." The advertisement goes on to assert that this new facility is "where [VSL#3] was originally developed and produced."

174. The assertion that VSL#3's production was going back to the original manufacturing facility where the product was "developed" attempts to mislead physicians and consumers into believing that this new product is the same as the VSL#3 product made using the De Simone Formulation, and that STHS possesses the requisite technical know-how to make the

same product. This view contradicts VSL Inc.'s position, asserted consistently in all versions of its Counterclaim, that VSL Inc. acquired ownership of the De Simone Formulation's know-how via the Mendes Assignment Agreement of September 2000.

175. Additionally, the assertion that CSL "originally manufactured" the De Simone Formulation was false, as was the claim that CSL "developed" the VSL#3 product made using the De Simone Formulation. CSL has never produced VSL#3 using the De Simone Formulation under the VSL#3 tradename or any other tradename. In fact, CSL could not have produced this product, as it never possessed the De Simone trade secrets or relevant Know How. The CEO of CSL confirmed this fact in a 2016 e-mail exchange with Prof. De Simone, which was presented to the court in the UK Litigation. In addition, the assertion designates CSL as the manufacturer, whereas CSL in fact is only the producer of the single strains, and the real manufacturer of the final product is Nutrilinea.

176. The August 2016 Press Release also made the following false representation: "People who suffer from IBS, ulcerative colitis or an ileal pouch, and who are also among the 30 to 50 million people in the U.S. who have allergies to milk or are lactose intolerant, can now take VSL#3 to manage their IBS, UC or ileal pouch." This statement falsely attempts to equate the new VSL#3 formulation with the prior version of VSL#3 made with the De Simone Formulation. This statement is literally false advertising because the new VSL#3 produced in Italy does not have the same biochemical and immunological features, and does not exhibit the same performance characteristics, as the original VSL #3 that contained the De Simone Formulation.

177. In comparing two biologic agents such as these products, quantitative characteristics, such as cell counts/ratios and species/strain types, are insufficient by themselves to fully characterize the nature of the agent in question. The reason for this is that biologic

products can be qualitatively similar (*i.e.*, same genus/species/strain, same cell counts) yet the functional performance characteristics can be materially different depending on how the strain is produced.

178. While probiotic supplements are not biologic drugs, the FDA's numerous guidance documents with respect to biologic drugs are important to consider. Specifically, the FDA notes that: "In contrast to chemically synthesized small molecular weight drugs, which have a well-defined structure and can be thoroughly characterized, biological products are generally derived from living material- human, animal, or microorganism- are complex in structure, and thus are usually not fully characterized."[2] In the same guidance document, the FDA states: "Because, in many cases, there is limited ability to identify the identity of the clinically active component(s) of a complex biological product, such products are often defined by their manufacturing processes. Changes in the manufacturing process, equipment or facilities could result in changes in the biological product itself and sometimes require additional clinical studies to demonstrate the product's safety, identity, purity and potency."

179. In addition, in 2016, the FDA Center for Food Safety and Applied Nutrition issued a Draft Guidance to Industry regarding Dietary Supplements: New Dietary Ingredient Notifications and Related Issues.[3] In this guidance the FDA takes the positon with respect to live microbial dietary ingredients that are candidate new dietary ingredients (NDIs):

> FDA also considers the manufacturing process, including the fermentation, as an intrinsic part of the identity of an ingredient that is viable at the time of ingestion. We recommend that the fermentation and other parts of the manufacturing process relevant

[2] Food and Drug Administration. *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Guidance for Industry*, 2015.

[3] https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM515733.pdf

> to safety and identity be described in detail in your notification, as recommended in questions VI.A.3 and VI.A.16.
>
> FDA will pay particular attention to the viability of microorganisms in the NDI. The per-serving level of a viable microorganism depends on both the mass (in grams) and the viability (e.g., number of colony-forming units) of the organism in the final product. The composition of the growth medium and the fermentation conditions of the organism are also relevant to the safety of the product, particularly when they alter the form of the organism (e.g., spore vs. vegetative) or the composition of the ingredient (e.g., when the ingredient includes both the organism and the growth medium).

Extensive data, specific to probiotic bacterium, further supports the fact that production and fermentation changes can result in changes to the performance characteristics of a bacterium.

180. There is no dispute that the production characteristics of the new VSL#3 formulation have changed. The Defendants have proactively advertised this fact in numerous ways, citing the now "Non Dairy" production methods used for the Italian-made product. As production characteristics cannot be quantitatively measured in the final product, one must compare the performance of the final product to determine if production changes impact its activity. A proper comparison of the new VSL#3 formulation with the prior version of VSL#3 made with the De Simone Formulation therefore must include both the quantitative and functional performance characteristics of the two products.

181. There are significant qualitative differences between the new VSL#3 formulation and the prior version of VSL#3 made with the De Simone Formulation. For example, the average live-to-dead bacteria ratios of the two products were found to be significantly different. The new VSL#3 has high overall bacterial counts but lower total viable (live) cell counts, meaning that the product has a much higher quantity of dead bacteria (which is not an inert ingredient and therefore detrimental for the host). The number of live *streptococcus*, *bifidobacteium* and *lactobacillus* bacteria species of the two products also is significantly

different, showing different ratios of the various species in each product. Additionally, the critical *streptococcus thermophilus* species was almost 100 times less in the new VSL#3. There also are significant performance differences between the new VSL#3 formulation and the prior version of VSL#3 made with the De Simone Formulation. Thus, when evaluated for impact on cancer cell activity, the prior version of VSL#3 made with the De Simone Formulation was statistically significantly different from the new VSL#3 made in Italy in its capability to arrest proliferation of common cancer cell lines and in inducing apoptotic cell death in those cells.

182. The differences between the new, Italian-made version of VSL#3 and the prior version of VSL#3 made with the De Simone Formulation are further explored in two publications. The January 2017 edition of the *Journal of Cellular Physiology* featured a report entitled "*VSL#3 probiotic differently influence IEC-6 intestinal epithelial cell status and function.*" In this *in vito* study, multiple wound healing assays were used to evaluate performance characteristics of the two products using human, non-transformed, small-intestinal epithelial cell lines (IEC-6). Among the key findings:

- The Italian-made VSL#3 causes clear morphological cell damage on IEC-6 cell lines with reduced cellularity.
- The prior VSL#3 (made using the De Simone Formulation) produced product resulting in an enhanced rate of monolayer healing, while Italian-made VSL#3 did not influence the closure rate.
- The prior VSL#3 product enhanced the formation of elongated and aligned stress fibers, while Italian-made VSL#3 had no effect.
- The prior VSL#3 was able to cause a total inhibition of H_2O_2-induced cytotoxic effects on the cell lines, whereas Italian-made VSL#3 was unable to produce such results.

183. Similarly, the October 2016 edition of the *Journal of International Society of Microbiota* featured a report entitled "*p24 Levels ln vitro are affected positively or negatively depending by the production site of probiotic*." P24 is an antigen that makes up the core of the HIV virus. Blood concentrators of p24 go up in humans very shortly after HIV infection. Donor

peripheral blood cells (PBMCs) were infected with the HIV-1 virus and incubated with the two different VSL#3 probiotics. The Danisco-made VSL#3 and the Italian-made VSL#3 formulations had different effects on the HIV infected cultures. The Danisco-made VSL#3 had an inhibitory activity as measured by p24, while the new Italian-made VSL#3 actually increased the levels of p24 (+8%). This data was presented at the famous Institut Pasteur in Paris and raises serious safety related questions for the HIV community.

184. STHS's false advertising extended to multiple levels of corporate marketing communication, including direct claims of product efficacy and dietary management that are not supported by clinical evaluation. On the *www.VSL3.com* website, STHS repeatedly made claims that new Non-Dairy VSL#3 will provide effective clinical management in IBS, UC, and ileal pouch management. For example, the "About VSL#3" section of the website states:

> VSL#3 is a high potency probiotic medical food designated for the dietary management of ulcerative colitis, irritable bowel syndrome and an ileal pouch. It is a medical food and must not be confused with an over-the-counter dietary supplement. You need to be under medical supervision. VSL#3 is dispensed by a pharmacist.

The "FAQ" section of the *www.VSL3.com* website also states:

> Under which circumstances should VSL#3 or VSL#3 DS be consumed?
>
> VSL#3 should be consumed for the dietary management of medically diagnosed ulcerative colitis (UC), an ileal pouch or irritable bowel syndrome (IBS).

However, upon information and belief, there is no published data supporting these claims of product efficacy and dietary management. STHS does not provide any citations or notifications about published data on the Non-Dairy VSL#3 in its own materials and there is no known trial notification about Non-Dairy VSL#3 on the *www.clinicaltrials.gov* database. Non-Dairy Because VSL#3 is not the same product as the original VSL#3 made using the De Simone

Formulation, clinical data regarding the latter cannot support the claims about the efficacy of Non-Dairy VSL#3.

185. STHS committed additional acts of false advertising by citing studies performed using the "VSL#3" product produced by Danisco with the De Simone Formulation in discussing Non-Dairy VSL#3 on the *www.VSL3.com* website and in the package insert for the product. For example, under the website section "Evidence Based Science," STHS states the following:

> VSL#3 is one of the few probiotic preparations supported by Level One (double-blind, placebo-controlled) scientific data. VSL#3 has a 15-year track record of demonstrated clinical benefits as well as commercial use. Over 170 published studies and reviews have been released. The following studies have provided us with the educational content on this website

The site then goes on to provide links to numerous clinical studies in the field of IBS, UC and pouchitis. For example: Tursi et al. 2010 - Tursi A., et al. Am J Gastroenterol 105:2218-27 (2010); Ng et al. 2010 - Ng S.C., et al. Inflamm Bowel Dis. 16:1286-98 (2010); and Sood et al. 2009 - Sood A., et al. Clin Gastroenterol Hepatol 11:1202-9 (2009). In each case, the link to the study in question is a study performed using the "VSL#3" product produced by Danisco with the De Simone Formulation, and not the Non-Dairy VSL#3 produced in Italy by CSL. As noted above, the De Simone Formulation probiotic and the Non-Dairy VSL#3 probiotic are simply materially different products, making these clinical citations literally false and misleading.

186. STHS's false advertising extended to numerous false representations on its Facebook platform as well. As just one example, on March 19, 2017, a Facebook user asked STHS, "When did you reformulate VSL#3 Thanks!" on the VSL#3 Facebook page. In response, STHS publically replied with the following statement:

> VSL#3 Hi Timmy- VSL#3 contains the same 8 diverse strains and high potency that have effectively managed the symptoms of IBS, UC and an ileal pouch for 15 years. By upgrading the manufacturing process, we are also happy to share that that VSL#3 is dairy-free,

> making it one of the few dairy-free probiotics available to patients. Now 30-50 million people who have allergies to milk or are lactose intolerant and who suffer with IBS, ulcerative colitis or an ileal pouch will be able to take VSL#3 to help manage their symptoms. To further improve VSL#3, a small amount of cornstarch, an inactive ingredient that reduces moisture and preserves bacterial potency and stability, was added. VSL#3 unflavored packets have always contained cornstarch. Now we have added it to the capsules and DS. The inclusion of cornstarch does not affect the efficacy, potency, composition and strain components of the product. Hope this info helps!

The statement that "VSL#3 contains the same strains" is literally false. The product produced by Danisco with the De Simone Formulation and previously sold under the "VSL#3" trademark contains strains that are not present in the new, Non-Dairy VSL#3. VSL's affiliate recently admitted this in the UK Litigation. Specifically, the court in the UK Litigation was told that the Non-Dairy VSL#3, produced in Italy, is made using "naturally sourced" strains, not strains sourced from Danisco or Professor De Simone, which are used for the De Simone Formulation.

187. Leadiant and STHS committed further acts of false advertising by omitting important information about their product ingredients to create a false impression that Non-Dairy VSL#3 is linked to the product produced by Danisco with the De Simone Formulation. As is common practice in the probiotic industry, Leadiant previously labeled its products with the genus, species and strain designation numbers for each of the eight bacterial strains contained in the product. Respected organizations such as the Council for Responsible Nutrition and the International Probiotics Association specifically recommend this practice in its Best Practices Guidelines for Probiotics[4], as individual strains of the same genus and species can have different functional properties. Prior to Leadiant's change to the Non-Dairy VSL#3, marketing materials

[4] https://www.crnusa.org/sites/default/files/pdfs/CRN-IPA-Best-Practices-Guidelines-for-Probiotics.pdf

such as the VSL#3 Patient Brochure" *did include* the specific strain designation numbers, along with the genus and species. In contrast, the current U.S. marketing statements for Non-Dairy VSL#3, such as found in the product package insert and on the website, do not include the strain designation numbers along with the genus and species. This is no surprise because if STHS were to include the strain designation numbers, it would be an admission to consumers that new VSL#3 no longer contains the strains of the De Simone Formulation.

188. STHS's false advertising also extends to written representations to the medical community. In or around November 2016, in a memorandum circulated to medical professionals, STHS responded to a recently published paper in the medical journal Plos One ("STHS November 2016 Memo"). The study evaluated "old" VSL#3 made with the De Simone Formulation versus the "new" VSL#3 that is commercially available in the UK. The analysis was conducted in Europe by scientists at the University of L'Aquila. The Journal, Plos One, is a peer-reviewed, non-profit medical publication. Notably, the STHS November 2016 Memo did not claim that the new VSL#3 formulation being sold in the UK (the subject of the analysis) is different from the new VSL#3 formulation that was contemporaneously being sold in the United States. As a result, it is reasonable to infer that all VSL#3 branded products for sale anywhere in the world now are manufactured in Italy. The analysis of the Plos One investigators therefore is applicable to "VSL#3" branded products sold in the United States and in the UK.

189. The STHS November 2016 Memo makes numerous false and misleading representations, starting with the assertion that ExeGi "sponsored" the study. ExeGi did no such thing.

190. The STHS November 2016 Memo goes on to state:

> VSL#3 was originally produced in Italy until 2006 when it relocated to the U.S. When manufacturing moved to the U.S., VSL#3 was not

> considered "newfound" and was not any different to the VSL#3 produced in Italy. Our Italian manufacturing facility is not only a GMP facility but, unlike many other medical foods, is also a pharmaceutical grade facility that must follow FDA guidelines. As you know many companies relocate their manufacturing facilities from time to time. This does not mean the products are "newfound" and are different in what they do. The same applies to VSL#3.

191. In contrast with STHS's statements, "VSL#3"-branded probiotics containing the De Simone Formulation were manufactured only at Danisco's plant in Madison, Wisconsin, from the time they were launched in the U.S. in 2002. The production remained at this facility until January 31, 2016, when the 2010 Know-How Agreement expired by its own terms. Even before the commercial launch of VSL#3, however, the clinical supply for studies conducted in the early 2000s was produced exclusively at Danisco's Madison facility. The assertion that an "original" Italian producer was making "VSL#3" branded products as late as 2006 is literally false and is intended to confuse physicians and patients.

192. The Chief Executive Officer of CSL has confirmed that his company never produced VSL#3-branded products. STHS's false statement to the contrary is a transparent attempt to sweep up research that is not applicable to the product it currently sells and to link its new formulation to the "historical" probiotic formulation formerly associated with the VSL#3 trademark. Furthermore, these statements are intended to confuse physicians and patients into believing that CSL possesses the proprietary formulation and know-how required to make the De Simone Formulation, which CSL's chief executive demonstrated is not true.

193. Effective April 1, 2017, STHS merged into a different entity, Alfasigma, and STHS ceased operation. Alfasigma therefore is liable for all previous wrongdoing by STHS under the doctrine of successor liability. In addition, the same false advertising described above has continued since the merger. The *www.VSL3.com* website continues to display the false

statements described above, but the website footer now shows that the website is run by Alfasigma. The false representations in the product inserts also persist under Alfasigma.

COUNT I
(Declaratory Judgment Pursuant to 28 U.S.C. § 2201—
Prof. De Simone Against All Defendants)

194. Prof. De Simone adopts by reference each and every one of the foregoing factual allegations as if alleged in full in Count I, except as they may be inconsistent with the specific allegations contained in Count I.

195. By virtue of the lawsuits filed against VSL Inc. in Delaware in the fall of 2014 by CD Investments, Sinaf, and Mr. Brady, and by virtue of Mr. Brady's other communications to Prof. De Simone and Dr. Park, VSL Inc. and Leadiant are contesting and denying Prof. De Simone's rightful claims to ownership of the intellectual property rights underlying the VSL#3 product.

196. VSL Inc. was incorporated on July 11, 2000.

197. The 615 Patent was issued on February 10, 1998 and reissued as Patent No. RE40,023 E on January 22, 2008 to list Prof. De Simone as the sole inventor and owner.

198. Prof. De Simone created the invention described in the 615 Patent (which became known as VSL#3) and developed all associated trade secrets long before the incorporation of VSL Inc. on July 11, 2000.

199. As a result, the 615 Patent and the associated know how and trade secrets are not among the intellectual property that Prof. De Simone was obligated to transfer to VSL Inc. according to the Collaboration Agreement.

200. By its terms, the Mendes Patent Assignment of September 18, 2000 assigned to VSL Inc. Mendes, S.r.l.'s "entire right, title and interest . . . in and to the said inventions as

described in said patents and patent applications" that are set forth on Schedule I to the Mendes Patent Assignment.

201. VSL#3, the invention described in the 615 Patent, and the associated trade secrets are nowhere mentioned on Schedule I to the Mendes Patent Assignment.

202. Mendes has never assigned to VSL Inc. the invention described in, or any other intellectual property rights arising from, the 615 Patent.

203. Since Prof. De Simone and Dr. Park resigned from VSL Inc.'s board of directors, the company has adopted the position advanced by Director Brady, namely, that, by virtue of Article VII of VSL Inc.'s bylaws and the Mendes Patent Assignment, VSL Inc. owns or has a claim to ownership of the intellectual property rights arising from the invention described in the 615 Patent.

204. Prof. De Simone strongly disputes that either he or Mendes, S.r.l. assigned or agreed to assign any rights in the invention described in the 615 Patent, or its associated trade secrets, to VSL Inc. in September 2000 or at any other time.

205. By virtue of the foregoing facts, there is an actual and justiciable controversy, of sufficient immediacy and reality, between the parties over who owns the intellectual property rights arising from or related to the invention described in the 615 Patent, including the aforementioned trade secrets.

206. As alleged herein, this Court possesses an independent basis for subject-matter jurisdiction over the parties: diversity of citizenship.

207. Issuance of the declaratory judgment prayed for herein will serve a useful purpose in clarifying and settling Prof. De Simone's ownership of the intellectual property rights in the 615 Patent and will terminate and afford relief from the uncertainty, insecurity, and controversy

giving rise to this proceeding. Such uncertainty, insecurity, and controversy has already arisen because of the positions taken in the Delaware litigation and because VSL Inc. has now adopted those positions, which Prof. De Simone vigorously contests.

COUNT II
(Breach of Contract—Patent License Agreement— Prof. De Simone Against VSL Inc.)

208. Prof. De Simone adopts by reference each and every one of the foregoing factual allegations as if alleged in full in Count II, except as they may be inconsistent with the specific allegations contained in Count II.

209. The Patent License Agreement is a valid, binding, and enforceable contract between Prof. De Simone and VSL Inc., supported by the consideration of the mutual promises and undertakings expressed therein.

210. Prof. De Simone has substantially performed all of his duties under the Patent License Agreement.

211. Under Section 4.1 of the Patent License Agreement, in exchange for the license granted to VSL Inc. of the rights in the 615 Patent, VSL Inc. promised to pay Prof. De Simone "a royalty of 3 % on Net Sales of the Products sold by VSL for Net Sales up to and including US$ 50,000,000.00"; and "a royalty of 5 % on Net Sales of the Products sold by VSL for Net Sales in excess of US$ 50,000,000.00."

212. Since the beginning of 2014, VSL Inc. has failed to pay Prof. De Simone any royalties on its Net Sales of VSL#3, thereby materially breaching its obligations under Section 4.1.

213. As a direct and proximate result of VSL Inc.'s breach of the Patent License Agreement, Prof. De Simone has suffered compensatory damages in an amount to be proven at trial but in no event less than $5,000,000.00.

COUNT III
(Unjust Enrichment— Prof. De Simone Against All Defendants)

214. Prof. De Simone adopts by reference each and every one of the foregoing factual allegations as if alleged in full in Count III, except as they may be inconsistent with the specific allegations contained in Count III.

215. On or about November 14, 2014, Prof. De Simone validly terminated The Know How Agreement on the grounds that there had been a change of control of VSL Inc. and because of VSL Inc.'s breach of its duty of confidentiality under the agreement.

216. As a result, VSL Inc. had no rights to continue marketing and selling VSL#3 in the United States after the Patent License Agreement expired on February 10, 2015. VSL Inc. rights were also cut off by virtue of its failure to pay royalties due under the Patent License Agreement.

217. By virtue of the termination of the Know How Agreement and the expiration and material breach of the Patent License Agreement, VSL Inc. no longer could validly sub-license any rights to market and sell VSL#3 to Leadiant or its successors.

218. By virtue of VSL Inc.'s, Leadiant's, STHS's, and (either directly or under the doctrine of successor liability for STHS's wrongdoing) Alfasigma's continuing and unauthorized marketing and sale in the United States of the former version of VSL#3 containing the De Simone Formulation, they realized profits to which they were not entitled.

219. On information and belief, VSL Inc. acquired, or allowed Leadiant and STHS to acquire, a substantial inventory of the VSL#3 product for distribution and sale in the United States after all three companies knew that their legal rights to engage in such activity had lapsed. In addition, Leadiant made significant money by transferring its rights regarding VSL#3 to STHS after its legal rights to sell the De Simone Formulation had lapsed.

220. By virtue of Danisco's ability to manufacture VSL#3 using Prof. De Simone's proprietary and secret formula, Prof. De Simone has conferred a valuable benefit on VSL Inc., Leadiant, STHS, and Alfasigma, consisting of the value of the inventory of the former version of VSL#3 that the companies recently possessed and the amount paid by STHS to Leadiant for the transfer of Leadiant's rights.

221. VSL Inc., Leadiant, STHS, and Alfasigma knowingly accepted this valuable benefit under circumstances giving them reason to know that their continued use and enjoyment of it creates an obligation to pay for its value.

222. As a matter of equity and good conscience, VSL Inc., Leadiant, STHS, and Alfasigma should be ordered to make restitution to Prof. De Simone of all profits the companies have gained as a result of their continuing, unauthorized marketing and sale of the former version of VSL#3 produced using the De Simone Formulation, including the profit from the transfer of rights from Leadiant to STHS. In addition, they should be required to return to Danisco any amount of the product that they currently hold in inventory.

COUNT IV
(Misappropriation of Trade Secrets—Prof. De Simone Against All Defendants)

223. Prof. De Simone adopts by reference each and every one of the foregoing factual allegations as if alleged in full in Count IV, except as they may be inconsistent with the specific allegations contained in Count IV.

224. Since at least 2002, and continuing through some point in 2016, the formula and method of growing and mixing the eight strains of lactic acid bacteria in VSL#3 had been used in a business and afforded a demonstrable competitive advantage to Prof. De Simone and VSL Inc.

225. VSL#3's formula and selection criteria for the bacterial strains were in fact secret and not a matter of public knowledge. They were not generally known to, and not readily

ascertainable by proper means by, other persons who can obtain economic value from their disclosure or use.

226. The formula and selection criteria for the bacterial strains were, and currently are, known only to Prof. De Simone and to Danisco. Prof. De Simone has made efforts reasonable under the circumstances to maintain the secrecy of the formula and selection criteria for the bacterial strains, including by entering into: (a) the Confidential Disclosure Agreement with Danisco, VSL Inc., and VSL Inc.'s parent companies, which obligates all parties to maintain the secrecy of the formula; (b) the 2008 De Simone-Danisco Agreement, which obligates Danisco to maintain the secrecy of the formula; and (c) the Know How Agreement with VSL in 2010, which obligates VSL Inc. to hold in strict confidence, and limit VSL Inc.'s ability to use or disclose "relevant information related to [VSL#3] including but not limited to discoveries, processes, composition, technical and scientific data" that are in Prof. De Simone's possession or in control and are necessary for VSL Inc. to perform its duties under the Know How Agreement.

227. In addition, the 2010 VSL-STP Agreement obligates Leadiant to keep strictly confidential, and not use for purposes other than performing its obligations under the agreement, "all information related to" VSL#3 "received by [Leadiant] or by its Affiliate."

228. The De Simone Formulation and selection criteria for the bacterial strains have value to Prof. De Simone and anyone who would compete with him or his affiliated companies because there is no competitive product that replicates the formulation's precise mix of bacteria strains and the health benefits it offers.

229. Prof. De Simone has expended great sums of money and considerable efforts over many years in developing his formula and selection criteria for the bacterial strains.

230. It would be extremely difficult, if not impossible, for anyone to produce or duplicate the De Simone Formulation without access to the formula and selection criteria for the bacterial strains.

231. By virtue of the foregoing facts, the De Simone Formulation's formula and selection criteria for the bacterial strains are trade secrets within the meaning of 11-1201 of the Commercial Law Article of the Annotated Code of Maryland.

232. VSL Inc., Leadiant, and STHS acquired a considerable inventory of VSL#3 from Danisco, which allowed them and Alfasigma (either directly or under the doctrine of successor liability for STHS's wrongdoing) to continue to market and sell the version of VSL#3 produced using the De Simone Formulation through at least some point in 2016, despite the expiration or termination of their contractual rights to do. The inventory of VSL#3 possessed by VSL Inc., Leadiant, and STHS was manufactured using Prof. De Simone's proprietary formula and selection criteria for the bacterial strains, which are trade secrets. This inventory could not exist but for the trade secrets used in manufacturing it. As a result, all three Defendants acquired and used Prof. De Simone's trade secrets without his express or implied consent.

233. Given their knowledge of the termination of their contractual rights to market and sell VSL#3, VSL Inc.'s, Leadiant's, STHS's, and Alfasigma's continued accumulation of an inventory of the product after such rights terminated amounted to an acquisition of Prof. De Simone's trade secrets with knowledge or reason to know that such trade secrets were acquired by improper means.

234. Since no later than February 10, 2015, VSL Inc. and Leadiant also have been using and profiting from Prof. De Simone's trade secrets—by marketing and selling VSL#3 and by Leadiant transferring its rights to STHS—knowing or having reason to know that they were

acquired under circumstances giving rise to a duty to maintain their secrecy or limit their use. Such circumstances include the Defendants' entry into or knowledge of the Patent License Agreement, the Know How Agreement, the 2010 VSL-STP License Agreement, and the agreements with Danisco, all of which do not permit VSL Inc. and Leadiant to market and sell VSL#3 after the applicable licensing rights expired or were terminated.

235. By virtue of the foregoing facts, VSL Inc., Leadiant, STHS, and Alfasigma have misappropriated Prof. De Simone's trade secrets.

236. VSL Inc.'s, Leadiant's, STHS's, and Alfasigma's continuing marketing and sale of VSL#3 has proximately caused Prof. De Simone to suffer damages, or has unjustly enriched the Defendants, as measured by the value of the VSL#3 inventory that they sold or that remains in their possession or control, which is worth at least $3,000,000.00, plus the value of the transfer of rights from Leadiant to STHS.

237. Given that the Defendants were well aware that their legal rights to continue marketing and selling VSL#3 terminated, their persistence in this conduct amounts to a willful and malicious misappropriation of Prof. De Simone's trade secrets. As a result, Prof. De Simone is entitled to an award of exemplary damages, not exceeding twice the damages he has suffered as a direct and proximate result of such conduct, as well as reasonable attorneys' fees under sections 11-1203 and 11-1204 of the Commercial Law Article of the Annotated Code of Maryland.

COUNT V
(Civil Conspiracy— Prof. De Simone Against All Defendants)

238. Prof. De Simone adopts by reference each and every one of the foregoing factual allegations as if alleged in full in Count V, except as they may be inconsistent with the specific allegations contained in Count V.

239. As reflected in their acts and omissions in 2014, as alleged herein (if not before then), VSL Inc. and Leadiant entered into a tacit agreement to misappropriate and wrongfully claim ownership of Prof. De Simone's trade secrets after February 10, 2015, when their legal rights to market and sell VSL#3 terminated.

240. Since February 10, 2015, VSL Inc., Leadiant, STHS, and Alfasigma (either directly or under the doctrine of successor liability for STHS's wrongdoing) have continued to market and sell VSL#3, despite knowing of their lack of any legal right to do so, and this conduct has been in furtherance of Defendants' conspiracy to misappropriate Prof. De Simone's trade secrets.

241. As a direct and proximate result of this conspiracy, and the acts taken in furtherance of it, Prof. De Simone has suffered damages in the amount of at least $3,000,000.00, which is the value of the VSL#3 inventory that the Defendants sold or otherwise still possess and from which they are illegally profiting.

242. Given that the Defendants were well aware that their legal rights to continue marketing and selling VSL#3 terminated, their persistence in this conduct amounts to a knowing, conscious, and reckless disregard for Prof. De Simone's legal rights and the risk of harm Defendants' conduct was likely to cause, and is causing, him. Defendants therefore have acted with actual malice.

243. Under the circumstances, the assessment of punitive damages in the amount of $1,500,000.00 is necessary to punish VSL Inc.'s, Leadiant's, STHS's and (either directly or under the doctrine of successor liability for STHS's wrongdoing) Alfasigma's misconduct and deter such behavior by them and others.

COUNT VI
(False Advertising Under 15 U.S.C. § 1125(a) — ExeGi Against Leadiant, STHS, and Alfasigma)

244. ExeGi adopts by reference each and every one of the foregoing factual allegations as if alleged in full in Count VI, except as they may be inconsistent with the specific allegations contained in Count VI.

245. As alleged herein, Leadiant, STHS, and Alfasigma have made, and Alfasigma continues to make, material false representations about-Non Dairy VSL#3 in commercial advertisements in violation of 15 U.S.C. § 1125(a).

246. As described above, Leadiant, in its initial notification to the market about moving production to Italy, claimed that the version of VSL#3 produced in the new facility in Italy is clinically equivalent to the Danisco-produced product previously sold as "VSL#3," which was produced using the De Simone Formulation. This statement is literally false, for the reasons describe above. Leadiant also made false representations by omitting important information about its product ingredients to create a false impression of linkage to the product produced by Danisco with the De Simone Formulation. Upon information and belief, Leadiant or its attorneys drafted, reviewed and/or approved of the false statements made by Leadiant.

247. As described above, STHS made numerous false representations, including but not limited to:

(a) the false representations contained in the August 2016 Press Release;

(b) the false representations about product efficacy and dietary management contained on the *www.VSL3.com* website;

(c) citing studies performed using the "VSL#3" product produced by Danisco with the De Simone Formulation in discussing Non Dairy VSL#3 on the *www.VSL3.com* website and in its package insert;

(d) the false representations made by STHS on Facebook;

(e) omitting important information about new VSL#3's product ingredients to create a false impression of linkage to the product produced by Danisco with the De Simone Formulation; and

(f) the false representations contained in the STHS November 2016 Memo.

Upon information and belief, STHS or its attorneys drafted, reviewed and/or approved of these false statements made by STHS.

248. As described above, Alfasigma has made, and continues to make, numerous false representations, including but not limited to.

(a) the false representations about product efficacy and dietary management contained on the *www.VSL3.com* website;

(b) citing studies performed using the "VSL#3" product produced by Danisco with the De Simone Formulation in discussing Non Dairy VSL#3 on the *www.VSL3.com* website and in its package insert; and

(c) omitting important information about new VSL#3's product ingredients to create a false impression of linkage to the product produced by Danisco with the De Simone Formulation.

Upon information and belief, Alfasigma or its attorneys drafted, reviewed and/or approved of these false statements made by Alfasigma.

249. The false representations by Leadiant, STHS, and Alfasigma are material, as consumers, practitioners, and other healthcare providers will believe that they are purchasing, recommending, or prescribing a product containing the De Simone Formulation, which has been the subject of many clinical trials and a lengthy patient history when, in reality, the product they are purchasing is fundamentally different, with a different source and different effects, with little or no testing history, and little or no patient history.

250. These false representations by Leadiant, STHS, and Alfasigma are intended to, and will, deceive a substantial segment of consumers, practitioners, and other healthcare providers into mistakenly believing that Non-Dairy VSL#3 has the same biochemical and immunological features, the same performance characteristics, and the supporting clinical data as the original VSL#3 made by Danisco using the De Simone Formulation.

251. Leadiant, STHS, and Alfasigma placed these false representations in interstate commerce by publishing them, *inter alia*, in press releases, on the *www.VSL3.com* website, in package inserts, and on Facebook.

252. ExeGi is likely to be injured by the false advertising described herein through both a direct diversion of its sales and by a lessening of goodwill associated with the original De Simone Formulation made by Danisco, which ExeGi currently sells under the brand name Visbiome. Leadiant's, STHS's and Alfasigma's false representations are intended to divert sales from Visbiome to Non-Dairy VSL#3. Furthermore, the goodwill associated with Visbiome, which is made by Danisco using the De Simone Formulation, will be diminished because consumers that falsely believe that Non-Dairy VSL#3 is the equivalent of the Visbiome product will think less of ExeGi and Visbiome, given that the Non-Dairy VSL#3 fails to meet the performance standards of Visbiome. As Non-Dairy VSL#3 has not undergone a single clinical

trial, and independent testing and consumer reaction has revealed material differences with the De Simone Formulation and serious efficacy deficiencies in Non-Dairy VSL#3, it is likely that Non-Dairy VSL#3 will indeed fail to meet the performance standards of the De Simone Formulation, which was heavily tested by clinical trials and has a long user history.

WHEREFORE, Plaintiffs demand judgment against Defendants:

A. On Count I (Declaratory Judgment), declaring that Prof. De Simone is the lawful and rightful owner of all intellectual property rights arising from or related to the invention described in the 615 Patent and all associated trade secrets, including, but not limited to, the proprietary formula, selection criteria for the bacterial strains, and all related know-how underlying the De Simone Formulation;

B. On Count II (Breach of Contract), awarding Prof. De Simone compensatory damages in an amount to be proven at trial but in no event less than $5,000,000.00 and enjoining Defendants from taking any actions to commercialize any products utilizing the proprietary formula or any related know how and intellectual property rights underlying the De Simone Formulation;

C. On Count III (Unjust Enrichment), ordering VSL Inc., Leadiant, STHS, and Alfasigma, jointly and severally, to make restitution to Prof. De Simone for the value of the VSL#3 inventory they have held since February 10, 2015, the value of which is at least $3,000,000.00, and for the aggregate profits the companies have received for their sale of VSL#3 since February 10, 2015; ordering Leadiant to make restitution to Prof. De Simone for the value of the transfer of its rights to STHS; and enjoining Defendants from taking any actions to commercialize any products utilizing the proprietary formula or any related know how and intellectual property rights underlying the De Simone Formulation;

D. On Count IV (Misappropriation of Trade Secrets), awarding Prof. De Simone: (1) compensatory damages in an amount to be proven at trial but in no event less than $3,000,000.00; (2) exemplary damages of twice the amount of Prof. De Simone's actual damages; and (3) the reasonable attorneys' fees he has incurred and will incur in protecting his trade secrets; and enjoining Defendants from taking any actions to produce, have produced, or commercialize any products utilizing the proprietary formula or any related know how and intellectual property rights underlying the De Simone Formulation;

E. On Count V (Civil Conspiracy), awarding Prof. De Simone: (1) compensatory damages in an amount to be proven at trial but in no event less than $3,000,000.00; (2) punitive damages in the amount of $1,500,000.00; and (3) an injunction prohibiting Defendants from taking any actions to commercialize any products utilizing the proprietary formula or any related know how and intellectual property rights underlying the De Simone Formulation;

F. On Count VI (False Advertising), awarding ExeGi: (1) compensatory damages in an amount to be proven at trial but in no event less than $3,000,000.00; (2) punitive damages in the amount of $1,500,000.00; and (3) an injunction prohibiting Leadiant, STHS, and Alfasigma from making false statements regarding Non-Dairy VSL#3 or Visbiome.

G. Awarding such costs against all Defendants as may seem equitable and just under section 3-410 of the Courts and Judicial Proceedings Article of the Maryland Code; and

H. Awarding such other, further, and general relief as to the Court seems just and proper.

Dated: May 8, 2017

SHULMAN, ROGERS, GANDAL, PORDY & ECKER, P.A.

By: /s/ Jeremy W. Schulman

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JURY DEMAND

In accordance with Rule 38(b) of the Federal Rules of Civil Procedure, Professor De Simone and ExeGi hereby demand a trial by jury on all issues raised by the claims asserted in the foregoing Amended Complaint that are triable as of right by a jury.

Dated: May 8, 2017

SHULMAN, ROGERS, GANDAL, PORDY & ECKER, P.A.

By: /s/ Jeremy W. Schulman
Jeremy W. Schulman, Esq.

EXHIBIT 3

Maryland Federal Jury Unanimously Finds Probiotic Sellers Liable for False Advertising and Awards Product Inventor More than $18 Million in Damages

November 26, 2018

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GREENBELT, Md.--(BUSINESS WIRE)--Nov 26, 2018--A federal jury on Tuesday, Nov. 20, unanimously ruled in favor of a probiotic inventor who sued his former business partners after an international dispute concerning false advertising, ownership of a propriety formulation and unpaid royalties. The inventor accused his former partners of attempting to make a copy of his invention and selling it to unsuspecting patients under the same brand name, even though the copy product had never been clinically tested.

The three-week trial in the U.S. District Court for the District of Maryland in Greenbelt included plaintiffs Professor Claudio De Simone and ExeGi Pharma LLC, of Rockville, Md., against defendants VSL Pharmaceuticals Inc., Leadiant Biosciences Inc. and Alfasigma USA Inc. The jury unanimously ruled that the pharmaceutical companies collectively owe the probiotic inventor, De Simone, more than $18 million in damages, including $15 million for defendant Alfasigma USA's violation of the Lanham Act by deceiving patients, physicians and other stakeholders concerning the probiotic product they have been marketing since 2016.

De Simone successfully argued in court that VSL Pharmaceuticals had attempted to create a "knock-off" of De Simone's product, even though they never had access to the propriety formula. They continued to call this knock-off by its original brand name, "VSL#3 ® ", a trademark owned by VSL Pharmaceuticals Inc., and continued to reference the extensive clinical research on the product proving the product was efficacious and safe, even though they never fully tested the copy product. During the trial, De Simone was able to prove that the defendants' copy product was not the same as De Simone's original invention and had never been tested in humans to ensure that it performs the same way as the original formula. De Simone is currently partnered with co-plaintiff ExeGi Pharma to sell the formulation under the brand name Visbiome®.

Prof. De Simone and ExeGi were represented in the case by Jeremy W. Schulman of the law firm Schulman Bhattacharya, LLC.

"We are proud that we're protecting the life's work of a brilliant scientist, Prof. Claudio De Simone, who is responsible for helping thousands of patients worldwide to live better lives by managing their serious medical conditions through the invention of a superior, high-potency probiotic product," Schulman said.

De Simone commented: "I am grateful that the jury saw through the falsehoods of the defendants and ruled in our favor. I created the probiotic product to help patients who had suffered for years with gastrointestinal illnesses and diseases. I never imagined that a multi-national pharmaceutical company and the other defendants would attempt to steal my invention and then pass off an inferior and fake product as mine. Now I will turn my attention to supporting patients in Europe, Asia and other parts of the world who are at risk of being similarly misled."

View source version on businesswire.com:https://www.businesswire.com/news/home/20181126005445/en/

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Drug Cos. Hit With $18M False Ad Verdict Over Probiotic IP

By **Dani Kass**

Law360 (November 21, 2018, 6:00 PM EST) -- Three drug companies are on the hook for more than $18 million in damages after a Maryland federal jury found that they wrongfully used their former business partners' proprietary probiotic formula.

U.S. District Judge Theodore D. Chuang signed off on the verdict Wednesday, which found that Alfasigma USA Inc. owed $15 million for false advertising violations, VSL Pharmaceuticals Inc. owed 2.8 million for breach of contract and unjust enrichment and Leadiant Biosciences Inc. owed $172,000 for unjust enrichment. The plaintiffs were Italian inventor Claudio De Simone and drug company ExeGi Pharma LLC, which now has the license to sell the probiotic.

"We are overjoyed by the results we were able to obtain for our clients, Professor De Simone and ExeGi, during the course of this three-year legal battle," Jeremy Schulman of Schulman Bhattacharya LLC said in a statement. "Establishing that Professor De Simone owns the know-how, winning a large cash judgment, securing a finding of false advertising, and defeating 52 counterclaims aggressively asserted by a team of more than 30 lawyers and staff for the three defendants is very gratifying."

Lead defense counsel at Venable LLP didn't immediately respond to a request for comment Wednesday. Other attorneys for the defendants either deferred to Venable or didn't answer inquiries.

The jury issued its verdict on Tuesday after a 14-day trial.

De Simone first sued in May 2015, accusing VSL and Sigma-Tau Pharmaceuticals Inc. — which has turned into Alfasigma and Leadiant — of misusing his intellectual property. The formulation was "a unique probiotic medical food that he invented to manage rare and persistent gastrointestinal disorders," the complaint said.

De Simone had entered into a joint venture with Sigma-Tau about 15 years before the suit was filed, during which they started to sell a product, VSL#3, using the licensed IP. The relationship ended in 2014, and there was a fight over who had the rights to the "know how" behind VSL#3.

In response to the suit, VSL and Sigma-Tau filed more than 50 counterclaims, including trademark infringement.

During summary judgment in October, Judge Chuang said the know how was De Simone's and dismissed the infringement claims, among others. The judge also found that VSL was liable for not paying De Simone damages, in breach of their patent licensing agreement.

All that was left was for the jury to determine the amount of damages owed.

The Lanham Act claims that made up the vast majority of the damages were brought by ExeGi, which has exclusive rights to sell the probiotic now. That drugmaker argued that Alfasigma advertised that the "counterfeit" formulation it was selling after De Simone ended their agreement was the same as what was sold during the partnership.

"They continued to call this knock-off by its original brand name VSL#3, a trademark owned by VSL Pharmaceuticals Inc., and continued to reference the extensive clinical research on the original product showing the original product to be efficacious and safe," Schulman Bhattacharya said in its statement. "During the trial, we proved that the defendants' copy product was not the same as Professor De Simone's original invention and had never been tested in humans to ensure that it performs the same way as the original formula."

The unjust enrichment claims alleged that VSL partnered with supplier Danisco USA Inc. to sell VSL#3 after the licensing agreement ended in Feb. 2015. De Simone had argued that the drugmaker wasn't allowed to buy the products made with his know how, so any money they made off that was unjust.

An attorney who had represented Danisco in the suit last year didn't immediately respond to a request for comment.

De Simone's counsel told Law360 that while this case may be over in the U.S., the inventor is bringing similar suits in South Korea, India, Switzerland, Italy and the U.K., among other countries.

"He's aggressively pursuing all these people all around the world," Schulman said.

De Simone and ExeGi are represented by Jeremy W. Schulman, Jeffrey Gavenman, Koushik Bhattacharya, Sabina Schiller, Jessica Bustamante, Sandra Schiller, Jonathan Barnes and Natalie Moskovchenko of Schulman Bhattacharya LLC.

VSL is represented by Brian L. Schwalb of Venable LLP and Brian Cashmere, Douglas M. Nabhan, Turner A. Broughton and Andrew O. Mathews, of Williams Mullen PC. Leadiant is represented by Charles S. Fax and Liesel J. Schopler of Rifkin Weiner Livingston LLC. Alfasigma is represented by Mark A. Weissman, Lydia Ferrarese and Brian T. Carr of Herzfeld & Rubin PC and Robert S. Brennen of Miles & Stockbridge PC.

Danisco was represented earlier in the litigation by Astor Heaven of Crowell & Moring LLP.

The case is De Simone v. VSL Pharmaceuticals Inc. et al., case number 8:15-cv-01356, in the U.S. District Court for the District of Maryland.

--Editing by Alyssa Miller.

EXHIBIT 4

VSL#3®

The Living Shield®

Please note that as of November 15th 2018, VSL#3 will no be longer available in the Canadian market. For alternatives, please contact your healthcare provider.

In case of any questions, please contact:
Tel: 1-866-384-1314

Natural Product Number NPN 80042116

This website is intended only for Canadian residents only.

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