IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA

EXEGI PHARMA, LLC, Plaintiff v. ROBERTO PACIFICI, Defendant.	Case No.

COMPLAINT

Plaintiff ExeGi Pharma, LLC ("ExeGi"), by and through its undersigned counsel, as and for its Complaint against Defendant Roberto Pacifici ("Dr. Pacifici"), alleges as follows:

NATURE OF THE ACTION

1. This case arises from a false advertising scheme facilitated by Dr. Pacifici that has damaged and continues to damage not only ExeGi but also thousands of consumers of probiotics.

2. In 2017, Dr. Pacifici, a professor at Emory University who also had been engaged by VSL Pharmaceuticals, Inc. ("VSL Inc.") to be a paid consultant, signed off on a report, along with two other professors, that touted the safety and efficacy of a probiotic product made by VSL Inc. called "VSL#3" (hereinafter,

"GRAS Panel Report" or "Report"). Importantly, for VSL Inc.'s purposes, the Report certified that the VSL#3 product met the criteria to qualify as a "medical food" and could be considered "generally recognized as safe" (GRAS)—a critical standard for this kind of product. The Report, therefore, provided the foundation for VSL Inc.'s (and its distributors') marketing of this product as a "medical food" and GRAS certified, which fact was fully known to Dr. Pacifici at all relevant times. Since 2017, VSL Inc. has extensively and continuously marketed the VSL#3 product as a "medical food" and as GRAS certified, in reliance on Dr. Pacifici's Report and with his knowledge and explicit or implied consent.

3. Dr. Pacifici's Report, however, was based on a thoroughly false premise. Although purporting to certify the safety and efficacy of the probiotic formula then being sold as VSL#3, the Report was, in fact, based upon and supported by a dossier of clinical research performed on and related solely to a ***materially different*** probiotic formulation, which, at the time of the GRAS Panel Report and to this day, no longer was contained in VSL#3. No published safety or efficacy studies have been performed on the version of VSL#3 that was the actual subject of the Report, notwithstanding the Report's false statements to the contrary.

4. The product upon which the studies were ***actually*** performed was the unique, eight-strain, high-potency probiotic formula created by Professor Claudio

De Simone ("De Simone Formulation"). Professor De Simone previously had worked for VSL Inc., and the De Simone Formulation was sold under the brand name VSL#3 until 2016. However, Professor De Simone left VSL Inc. and took his know-how and Formulation with him. The De Simone Formulation now is exclusively licensed to and sold by ExeGi under the brand name "Visbiome."

5. The De Simone Formulation is one of the most extensively studied probiotics now available in the marketplace, having been the subject of more than 70 human clinical trials. Based upon those trials and various studies, the De Simone Formulation is widely considered the gold standard for such products.

6. VSL Inc. and its advisors, including Dr. Pacifici, have capitalized on those trials and studies—albeit falsely—as part of an effort choreographed by VSL Inc. and its licensee distributors, and materially and knowingly assisted by Dr. Pacifici, to palm off the De Simone Formulation and divert product sales from Visbiome to VSL#3.

7. After Professor De Simone left VSL Inc. and VSL Inc.'s license to his De Simone Formulation expired, VSL Inc. and its licensee distributors, Sigma-Tau Pharmaceuticals, Inc. (n/k/a Leadiant Biosciences, Inc. ("Leadiant")) and Alfasigma USA, Inc. ("Alfasigma"), scrambled to manufacture an imitation version of the De Simone Formulation in Italy. The result (hereinafter, "Italian VSL#3" or the

"Imitation Formula") is but a poor imitation of the De Simone Formulation. It has not been the subject of rigorous testing and studies like the De Simone Formulation, and neither its safety nor its efficacy has been proven. But because VSL Inc. gave it the brand name "VSL#3"—the very same brand name under which VSL Inc. had previously sold the De Simone Formulation—VSL Inc. has passed its product off as the same as the De Simone Formulation.

8. VSL Inc. and its distributors bolstered this misleading branding with demonstratively false advertising equating VSL#3 and the De Simone Formulation in their product packaging, the VSL#3 website, social media, and other communication channels, all of which was ultimately reliant on the baseless conclusions in Dr. Pacifici's Report. This false advertising also included false claims that Italian VSL#3 was a "medical food" for the dietary management of various gastrointestinal diseases and disorders, and was GRAS certified, claims made possible by the erroneous Report.

9. In 2017, a company hired by VSL Inc., Intertek, contacted Dr. Pacifici and the two other professors who signed off on the Report to inquire as to whether they would participate in a GRAS panel on Italian VSL#3. Intertek told the professors that the product "has previously been determined to be GRAS twice before," but such was not true. It was the De Simone Formulation that had

previously been determined to be GRAS. Similarly, the dossier that Intertek prepared for the professors included numerous studies that had been performed on the De Simone Formulation (not Italian VSL#3), and the first draft of the report that Intertek prepared for the professors' review glossed over the significant differences between the two products and asserted a false continuity between them. Furthermore, the draft report prepared by Intertek intimated that clinical studies performed on the De Simone Formulation (including those when it was being sold under the brand name VSL#3) were applicable to VSL Inc.'s imitation of the De Simone Formulation. Indeed, Intertek's draft report was based almost entirely upon the false premise that Italian VSL#3 and the De Simone Formulation were, essentially, the same.

10. By the time Dr. Pacifici received the draft report from Intertek, Dr. Pacifici knew that premise was false. Dr. Pacifici was aware that the version of VSL#3 that was the subject of the GRAS panel was composed of a new formula and was being manufactured by a different company, at a different facility, under different conditions. Saliently, this means Dr. Pacifici knew that the clinical studies were inapplicable to Italian VSL#3.

11. Punctuating this, Professor De Simone specifically contacted Dr. Pacifici via email on April 8, 2016, to inform him of all of these relevant facts

concerning the change in VSL#3's formulation and to ensure that Dr. Pacifici knew he could not use the clinical studies about the De Simone Formulation to draw a false equivalence with Italian VSL#3. Dr. Pacifici and Professor De Simone spoke about these matters the week after Professor De Simone sent his email, and they discussed the possibility of scientific collaboration, the ongoing legal dispute about Italian VSL#3, and the ownership of a patent and know-how.

12. On May 10, 2016, Dr. Pacifici sent a letter of introduction to some of his colleagues, in which he indicated that Professor De Simone was the inventor of the original VSL#3 formulation that Dr. Pacifici had used in a recent study, prior to the creation of the imitation Italian VSL#3.

13. Dr. Pacifici, therefore, knew in 2016—well before even being approached about participating in the GRAS panel—about the legal disputes surrounding VSL#3 and the truth about Italian VSL#3. Undeterred, he agreed to participate in the GRAS Panel. Even worse, in 2017, Dr. Pacifici, along with two other professors, signed the final version of the GRAS Panel Report, which was still based almost entirely upon the false premise that Italian VSL#3 and the De Simone Formulation were, essentially, the same. Moreover, subsequent to signing the false GRAS Panel Report, Dr. Pacifici persisted in making public statements (available to U.S. medical professionals involved in recommending probiotics to their patients)

suggesting a false equivalence between Italian VSL#3 and the De Simone Formulation.

14. Even if Dr. Pacifici had been confused about the change from the De Simone Formulation to Italian VSL#3—and he clearly was not—the stark differences between the products were made abundantly clear in the months after he signed the GRAS Panel Report. First, in September of 2017, Dr. Pacifici received a letter from Guido Carpineti, an attorney representing Mendes SA, the Swiss company selling the De Simone Formulation in Europe. As Dr. Pacifici was about to give a presentation at a conference in Rome that referenced VSL#3, Mr. Carpineti requested Dr. Pacifici consider the consequences, which he noted were not trivial, arising from the dissemination of information, even by means of press releases, which led people to believe that the De Simone Formulation and Italian VSL#3 were identical or equivalent in terms of composition, efficacy, and safety.

15. Then, in November of 2017, Dr. Pacifici was deposed in conjunction with litigation in the United States District Court for the District of Maryland (the "Maryland District Court Action"). During that deposition, it was made abundantly clear that the studies upon which the GRAS panel had relied were performed on the De Simone Formulation and not Italian VSL#3.

16. Subsequently, one year later, in perhaps the most significant of a series of legal victories by Professor De Simone and ExeGi related to the De Simone Formulation, a jury in the Maryland District Court Action unanimously found that the distributors of Italian VSL#3 were liable for false advertising by misrepresenting that product to be the same as the De Simone Formulation (now sold as Visbiome). The jury awarded damages of $15 million on ExeGi's false advertising claim, which represented one of the distributors' wrongfully earned profits on the sales of the product.

17. The jury's verdict was then upheld by the federal district court judge, who also entered a permanent injunction to prevent further misrepresentation of Italian VSL#3 as being equivalent to Visbiome. Specifically, the injunction prohibited Alfasigma and Leadiant from citing clinical studies performed on the De Simone Formulation the way they had been citing them or from otherwise implying a false continuity between Italian VSL#3 and the De Simone Formulation. These rulings were upheld by the United States Court of Appeals for the Fourth Circuit.

18. Despite these significant legal victories, which have laid bare the false underpinnings of the GRAS Panel Report and, saliently, have been brought to the attention of Dr. Pacifici multiple times by Professor De Simone, his counsel, and

counsel for the Swiss company Mendes SA, Dr. Pacifici has stubbornly refused to withdraw his authorization and approval of the GRAS Panel Report.

19. Based on Dr. Pacifici's continued authorization of the Report, VSL Inc. and its distributors to this day continue to rely upon the Report to tout that their current version of VSL#3 is a "medical food" and is GRAS. This has continued to cause ExeGi to lose sales to VSL#3. Dr. Pacifici has been specifically and repeatedly informed about these continuing marketing claims based on the Report. Such claims are entirely false and, when relied upon by consumers, harm not only ExeGi but also those consumers. Yet, Dr. Pacifici has repeatedly and continuously refused to back down from his approval of the Report, and indeed he has persisted in making false and misleading public remarks similar to the false information contained in the Report.

20. ExeGi now brings this action to obtain compensatory damages, injunctive relief, and other remedies against Dr. Pacifici for his ongoing role in contributing to VSL Inc.'s false advertising of VSL#3 to the detriment of ExeGi's product, Visbiome.

THE PARTIES

21. Plaintiff ExeGi Pharma, LLC is a limited liability company organized under the laws of New York with its principal place of business at 90 Church Street,

Rockville, Maryland 20850. The members of ExeGi are citizens of Maryland and Switzerland; ExeGi is therefore a citizen of Maryland and Switzerland.

22. Defendant Roberto Pacifici is an individual residing at 730 Brook-Woods Trace, Atlanta, Georgia 30342. He is domiciled in and a citizen of Georgia.

JURISDICTION AND VENUE

23. As the sole plaintiff in this action is a citizen of Maryland and Switzerland, and the sole defendant is a citizen of Georgia, there is complete diversity between the parties.

24. As alleged herein, the amount in controversy between the parties exceeds $75,000.00, exclusive of interest and costs.

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

26. In addition, because this dispute concerns a federal question under Section 43(a) of the Lanham Act, this Court has jurisdiction under 28 U.S.C. § 1331.

27. This Court has personal jurisdiction over Dr. Pacifici as he is domiciled in Georgia.

28. Venue is properly laid in this judicial district under 28 U.S.C. § 1391(b)(1), as Dr. Pacifici is a resident of this judicial district.

FACTUAL ALLEGATIONS

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

29. Professor 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. Professor De Simone has authored hundreds of clinical studies and scholarly papers in the field of probiotics[1], 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"), Ulcerative Colitis ("UC"), Pouchitis, and Irritable Bowel Syndrome ("IBS").

[1] Probiotics are formulations comprised of living 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.

30. During the early 1980s and 1990s, Professor De Simone conducted extensive research into the clinical use of bacterial strains to treat the symptoms associated with various serious diseases, including IBD, IBS, enteral feeding, liver diseases, and many other conditions. Professor 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. Professor De Simone obtained several patents and other intellectual property rights relating to his probiotic formulations in multiple countries, including in the United States. One of Professor De Simone's probiotic formulations was the eight-strain probiotic mix known as the De Simone Formulation.

B. VSL Inc. Commercializes the De Simone Formulation

31. About 20 years ago, Professor De Simone and two brothers, Claudio and Paolo Cavazza, formed VSL Inc. Professor De Simone served for a time as its CEO and as a member of its board. Beginning in 2002, after Professor De Simone decided to license (temporarily) his patent for the De Simone Formulation to VSL Inc., the formulation was launched in the United States under the trademark "VSL#3®."

32. In the ensuing years, VSL Inc. sold VSL#3® with great success. Dozens of human clinical trials of the De Simone Formulation were completed

successfully, and the results of these studies were published in peer-reviewed medical and scientific journals. Such trials demonstrated the safety and effectiveness of the De Simone Formulation in the dietary management of, *inter alia*, IBD, IBS, and Pouchitis, a very serious and rare chronic disorder. With respect to Pouchitis, the De Simone Formulation was ultimately recognized by the world's professional gastroenterology societies as a "standard of care," an achievement that no other probiotic had attained previously.

33. Eventually, some of the other owners of VSL Inc., including members of the Cavazza family, proposed reducing VSL#3's production costs by changing the product's composition and substituting cheaper bacterial strains without informing customers. Professor De Simone rejected this idea, recognizing the potential harm to those who had come to depend upon his formula. This ignited a long conflict between Professor De Simone and the Cavazzas that included years of litigation in federal court. During this time, the Cavazzas also entered into an agreement with Alfa Wassermann, through which they merged their own company, Sigma Tau, with Alfa Wasserman to create a new company, Alfasigma.

34. Professor De Simone resigned from VSL Inc. in November of 2014 and took with him the "Know-How" that was necessary to manufacture his De Simone Formulation. However, Leadiant and VSL were permitted to continue to sell the

version of VSL#3 containing the De Simone Formulation until January 2016.[2] He eventually licensed his De Simone Formulation to ExeGi, which began to sell it under the name Visbiome in February of 2016.

35. The Cavazzas, meanwhile, having lost access to the coveted De Simone Formulation, hired a team of dairy experts to attempt to reverse engineer it. When that task proved impossible, as the dairy experts were unable to ascertain the exact strains used in the product or the correct proportions of the strains they did identify, they instead created a new product—a poor imitation of the De Simone Formulation, Italian VSL#3 (previously defined as the "Imitation Formula"). The Cavazzas went to a new manufacturer in Italy and then began producing the Imitation Formula. Beginning in mid-2016, Leadiant and Alfasigma began selling this Imitation Formula under the trademark "VSL#3®" without informing the public that the formula had changed.

36. Rather, Leadiant and Alfasigma usurped the history of and research into the De Simone Formulation and simply used it for the Imitation Formula. Leadiant and Alfasigma publicly announced that production of VSL#3® would move from

[2] Leadiant and VSL Inc. failed to pay Professor De Simone for the right to sell the De Simone Formulation during this period, however. Based on that failure, the jury in the Maryland District Court Action found VSL Inc. liable for breach of contract and both VSL Inc. and Leadiant liable for unjust enrichment. The jury awarded several million dollars in damages to Professor De Simone for these claims.

the Danisco facility in the United States to a new manufacturer in Italy, but they went to great lengths to assure the public that there would be "no effect" on patients because of that change in manufacturer. In reality, Leadiant and Alfasigma were converting from selling the De Simone Formulation as VSL#3® to selling the Imitation Formula as VSL#3® and simply pretended that there had merely been a change in manufacturing location and nothing more.

37. However, the Imitation Formula is materially different from the De Simone Formulation in numerous ways: the Imitation Formula uses different bacterial strains in a different ratio, has a different biological and immunologic profile, is made with different manufacturing methods, and is not the subject of the extensive studies and research that were performed on the De Simone Formulation.

38. Furthermore, independent testing (corroborated by anecdotal reports and complaints from consumers) confirmed that the Imitation Formula was demonstrably different from the original De Simone Formulation (then being sold by ExeGi as Visbiome). Since the launch of the Imitation Formula (first in Europe, in early 2016, then in the U.S. and Canada, in mid-2016), multiple investigators in Europe have compared the Imitation Formula to the De Simone Formulation and found striking differences between them.

C. Dr. Pacifici's Involvement with VSL Inc.

39. Dr. Pacifici has been involved in medical research for more than 30 years and currently is a professor at Emory University. In 2012, he began doing work on the application of probiotics to medical issues, and it eventually became the main focus of his research.

40. In or around 2015, Dr. Pacifici and collaborators at Emory University designed a study to determine if, in mice, probiotics are capable of preventing the loss of bone mass induced by menopause.

41. One of Dr. Pacifici's collaborators suggested using VSL#3—then still composed of the De Simone Formulation—and the group used the De Simone Formulation as one of two probiotics for the study.

42. The study was completed and published in the Journal of Clinical Investigation in April of 2016.

43. Shortly thereafter, Professor De Simone and Dr. Pacifici spoke by telephone, with Professor De Simone informing Dr. Pacifici about the emergence of Italian VSL#3 and the material differences between that new Imitation Formula and the De Simone Formulation.

44. Later in 2016, VSL Inc. contacted Dr. Pacifici about possibly performing a study to determine if VSL#3—now comprised of the Imitation

Formula—was effective in preventing the loss of bone and the occurrence of osteoporosis in women ages 50 to 65 and whether it was safe. The study was titled "Effect of VSL#3 on Bone Mineral Density in Postmenopausal Women" ("ProBone VSL").

45. VSL Inc. agreed to provide a grant of $465,000 to Emory for the ProBone VSL study.[3]

46. VSL Inc. also inquired if Dr. Pacifici would become a scientific consultant/advisor for them. Dr. Pacifici said he would but that Emory would have to approve such an arrangement.

47. VSL provided Dr. Pacifici with an agreement specifying the terms of the consulting relationship and, after some revisions, Dr. Pacifici and VSL Inc. executed the agreement in early 2017.

48. Sometime thereafter, VSL Inc. asked if Dr. Pacifici would participate in a "GRAS panel" regarding Italian VSL#3. Dr. Pacifici agreed.

49. Dr. Pacifici also participated in a "VSL#3 Meeting" at the Grand Hotel del Gianicola, Roma, Italy in September of 2017. Dr. Pacifici was invited to the

[3] According to Dr. Pacifici's testimony at his deposition in the Maryland District Court Action, approximately three percent of his salary for two years at Emory was funded by the grant.

conference by commercial sponsors of Italian VSL#3, including representatives of their European and Canadian distributor, Ferring. VSL Inc. paid for his trip.

50. On September 11, 2017, Dr. Pacifici gave a presentation titled "Multi-strain bacteria formulation, a new therapeutic opportunity for the treatment of osteoporosis." This presentation took place during a portion of the conference that was called "Benefits of a Multistrain Bacteria Formulation for Health: From Microbiology to Clinical Trials."

51. During his presentation, which took place in a commercial environment, Dr. Pacifici reiterated the same false equivalence between Italian VSL#3 and the De Simone Formulation that had been relied upon and set forth in the GRAS Panel Report. Namely, Dr. Pacifici presented clinical data relating to the De Simone Formulation version of VSL#3 as if it were performed on Italian VSL#3. That presentation perpetuated the false impression that the new, untested formulation that makes up Italian VSL#3 was actually tested to favorable results.

52. Although this conference took place in Italy, it had an audience that included substantial participation from United States doctors and other United States market participants. And the materials for this conference (including video and written materials) were and continue to be readily available to a United States audience.

D. The 2017 GRAS Panel Report

53. In early 2017, a consulting company, Intertek, provided Dr. Pacifici and the other members of the GRAS panel with a draft report, which Intertek (acting as an agent for VSL Inc.) had prepared, and a dossier of reports and studies upon which this initial draft of the GRAS Panel Report purportedly was based. Intertek then asked the three professors to review the draft report and the dossier and then sign a final report. It was made clear to Dr. Pacifici that this was a commercial, rather than scientific, project meant to assist in commercializing Italian VSL#3.

54. At this time, Dr. Pacifici knew, and it was reasonably foreseeable, that his endorsement of the purported GRAS status of the Italian VSL#3 product would be used by VSL Inc. and its distributors as the premise for marketing the product as a safe and effective medical food for the dietary management of specific, serious gastrointestinal diseases and disorders. Indeed, around this time, on March 30, 2017, Dr. Pacifici received an email from Tomas Jonaitis at Intertek. In the email, Dr. Pacifici was specifically informed that his signing onto the GRAS Panel Report "allows VSL to market the product as described in the document."

55. Despite the serious consequences and public health implications of his endorsement, and despite his scientific and ethical duties, Dr. Pacifici (and the other two professors who worked on the GRAS Panel) failed to engage in scientific

inquiry or perform their own research in order to verify the information in the Report or to materially revise the Report. In fact, there were several published studies that showed the new version of VSL#3 was quite different from the De Simone Formulation. Upon information and belief, Dr. Pacifici was aware of, and simply ignored, those studies. At a minimum, Dr. Pacifici was obligated to check the correctness of the data and the Report provided to him. And, as detailed above, he had specific knowledge of the differences between Italian VSL#3 and the De Simone Formulation. Without regard for any of this information or his duties, Dr. Pacifici endorsed the GRAS Panel Report and its false claims of equivalence. Upon information and belief, Dr. Pacifici's failures were motivated by his desire to please VSL Inc. for his own personal benefit. VSL Inc. had, in this regard, provided Emory $465,000 to support his research, paid for his travel to Italy, and signed a private consulting agreement with him.

56. Dr. Pacifici and the other professors on the GRAS Panel merely suggested minor revisions to Intertek's draft. On May 3, 2017, Dr. Pacifici signed the GRAS Panel Report, which touted Italian VSL#3's safety and efficacy and labeled it a "medical food." All three professors, including Dr. Pacifici, were required to sign the GRAS Panel Report for it to become effective; thus, without Dr. Pacifici's assent, the Report of this panel could not have been issued, and upon

information and belief no other GRAS Panel had been assembled as of 2017 or since that time.

57. The GRAS Panel Report, however, is fatally flawed, as it is based upon the false premises that (i) Italian VSL#3 was the subject of the studies performed on the De Simone Formulation and (ii) the Italian VSL#3 contains the same formulation as the De Simone Formulation. Notably, the Court in the Maryland District Court Action has prohibited such claims via a permanent injunction.

58. The problems with the GRAS Panel Report are legion. Most notably, the Report relies upon and repeatedly cites to the extensive clinical history ***of the De Simone Formulation*** for its conclusion that Italian VSL#3 is safe and effective. Specifically, the Report claims that the use of Italian VSL#3

> under the intended conditions of use as a medical food is supported by a number of clinical studies conducted in adult patients and children, with [ulcerative colitis] or [irritable bowel syndrome], and in adult patients with pouchitis or hepatic encephalopathy. In addition to endpoints of efficacy in these patient groups, these studies support the safety of [Italian VSL#3 and] indicate no evidence of adverse effects associated with intended use.

Report, p. 10. Such claims are totally false as applied to Italian VSL#3.

59. Furthermore, the Report indicates heavy reliance on the studies of the De Simone Formulation to justify its "finding" of safety and efficacy of the Italian VSL#3 product. For example, the Report states:

a. "Six published studies have been conducted on VSL#3® administration in subjects with [Ulcerative Colitis]." Report, p. 8. These studies were performed on the De Simone Formulation, not Italian VSL#3.

b. "Six clinical trials have been published on VSL#3® administration in subjects with an ileoanal pouch with or without cases of pouchitis." *Id.*, p. 9. These studies were, again, done on the De Simone Formulation.

c. "A total of 8 clinical trials have been published on use of VSL#3® as a medical food for subjects with IBS." *Id.* Again, these clinical trials were performed on the De Simone Formulation, not Italian VSL#3.

d. "Dietary management with VSL#3® formulations was examined in a range of subjects from as early as 1.7 years old to 18 years of age with mild-to-moderate acute UC …, newly diagnosed UC …, or IBS," and these "randomized, double-blind, placebo-controlled studies in young patients" support the conclusion that VSL#3® is safe "for use in this target population." *Id.* The cited studies were on the De Simone Formulation rather than Italian VSL#3.

e. "Ten clinical trials have been published on the use of VSL#3® as a medical food for subjects with cirrhosis and with and without a history of [Hepatic Encephalopathy]." *Id.*, p. 10. Not only were these trials

performed on the De Simone Formulation rather than Italian VSL#3, the Report exacerbates this error by stating that intake of Italian VSL#3 "was well tolerated in all studies with no serious adverse effects reported."

60. Each of the above-referenced studies and trials was performed on or using the De Simone Formulation. Yet the Report portrays the findings of these studies and trials as though they were done with Italian VSL#3.

61. Of the 137 total citations and references in the GRAS Panel Report that purport to support the conclusion that Italian VSL#3 is safe and effective, Dr. Pacifici and his team reference at least 69 clinical studies on the De Simone Formulation. Thus, the GRAS designation falsely states or implies the continued applicability of these clinical studies to Italian VSL#3.

62. The differences between the version of Italian VSL#3 and the De Simone Formulation tested in the cited studies is obvious from the studies themselves. The GRAS Panel Report indicated that the Italian VSL#3 contained seven probiotic strains, while the studies in the dossier refer to the De Simone Formulation as being an eight-strain product. In addition, the GRAS Panel Report states that the product it is certifying is non-dairy, while the studies in the dossier indicate they were performed on a product (the De Simone Formulation) with dairy.

Yet, the Report falsely concluded that Italian VSL#3—the seven-strain, non-dairy product—was the product studied in the previous clinical studies and was therefore safe and effective.

63. Furthermore, the Report ignored other significant differences between the manufacturing processes of the two formulations and the fact that the De Simone Formulation has a completely different proteomic, enzymatic, and immunological profile than Italian VSL#3.

64. The GRAS Panel Report also claimed "that the change in toll manufacturer for VSL#3® and VSL#3® DS does not result in meaningful changes in the quality or safety of these medical foods products." *Id.*, p. 11. This assertion was not supported by any visits to the production sites, and the Report signatories were not in a position to compare the different procedures in place in the United States and Italy.

65. The GRAS designation for Italian VSL#3 is false and misleading for a related reason: it is unsupported by scientific evidence. A GRAS determination requires two elements: "technical evidence of safety" and "common knowledge." (US FDA, 1997). The "common knowledge" element requires that (1) the pivotal data and information supporting safety be generally available to the scientific community and (2) there exists evidence of a consensus among qualified experts that

such data and information establish the safety of the intended use. Italian VSL#3 has no such supporting data. Further, Italian VSL#3 does not have technical evidence of safety for its "intended use": the dietary management of the symptoms of UC, IBS, or pouchitis.

66. In addition to its improper claim that Italian VSL#3 is GRAS for the intended uses indicated in the GRAS Panel Report, the Report falsely relies upon the studies and trials done with the De Simone Formulation to make the claim that Italian VSL#3 is a "medical food."

67. The term "medical food" has a statutory definition, however, and assigning such term necessarily implies that the associated product has met certain criteria.

68. The definition is set out at 21 U.S.C. 360ee(b)(3) as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

69. Italian VSL#3 does not meet that definition and simply is not a "medical food." It has never been the subject of a medical evaluation under recognized scientific principles required to establish that it is effective and safe for

the specific dietary management of *any* disease or condition.[4] The De Simone Formulation, on the other hand, has undergone the requisite medical evaluation, *i.e.*, the studies that were provided to Dr. Pacifici and the GRAS panel, among others. Accordingly, the use of the term "medical food" with respect to Italian VSL#3 is not only unsupported, but it also falsely implies that the studies provided to Dr. Pacifici and the GRAS panel pertaining to the De Simone Formulation are applicable to Italian VSL#3 and suggests a "false continuity" between Italian VSL#3 and the De Simone Formulation.

70. According to its Frequently Asked Questions About Medical Foods; Second Edition Guidance for Industry ("Medical Foods FAQ"), the Food and Drug Administration ("FDA") "considers the statutory definition of medical foods to narrowly constrain the types of products that fit within this category of food." Medical Foods FAQ, p. 4. And the FDA has established criteria to clarify this statutory definition. Found at 21 CFR 101.9(j)(8), the criteria are as follows:

> (i) It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or

[4] Stating that a product is a "medical food" necessarily means that medical evaluations have determined it provides specifically modified nutritional support to manage the unique nutritional needs that result from certain conditions. Here, no medical evaluations have determined Italian VSL#3 provides specifically modified nutritional support to manage the unique nutrient needs resulting from IBS or Ulcerative Colitis.

> exclusive feeding of a patient by means of oral intake or enteral feeding by tube;
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> (ii) It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;
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> (iii) It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
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> (iv) It is intended to be used under medical supervision; and
>
> (v) It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

71. Italian VSL#3 has never been tested clinically in humans to determine whether it is effective for dietary management of patients with UC, IBS, or hepatic encephalopathy. There is no human data to suggest that it provides specifically modified nutritional support to manage the unique nutritional needs that result from certain conditions.

72. In fact, since the launch of Italian VSL#3 (first in Europe, then in the U.S. and Canada), multiple investigators in Europe have compared Italian VSL#3 to the De Simone Formulation and found striking differences between them.

73. Additional articles appeared in various peer-reviewed scientific journals, comparing the functional and performance characteristics of the De Simone Formulation and Italian VSL#3, as well as in abstracts at international conferences. All of the articles and abstracts concluded that there are significant differences between the two products.[5]

E. Litigation in the District of Maryland

74. De Simone filed suit in the United States District Court for the District of Maryland (the previously defined "Maryland District Court Action"), bringing various claims against VSL Inc., including a claim for a declaratory judgment that he owned the Know-How to make the De Simone Formulation. When ExeGi learned that Leadiant and Alfasigma were selling the Imitation Formula and marketing it as "the same" as, and equally efficacious to, the De Simone Formulation, ExeGi joined the Maryland District Court Action and brought claims against Leadiant and Alfasigma for false advertising under the Lanham Act. In response, Alfasigma filed a series of counterclaims against both ExeGi and Professor De Simone. In total, VSL Inc., Alfasigma, and Leadiant brought 52 counterclaims.

[5] For good reason: the Italian VSL#3 reviewed had seven strains of bacteria (rather than eight) and contained different ratios of bacteria, too. Italian VSL#3 also is manufactured in a different facility according to a different proprietary process than the De Simone Formulation.

75. The District Court granted summary judgment for Professor De Simone on the issue of Know-How, ruling that Professor De Simone owned it. Then, in November of 2018, after a three-week trial, the jury reached a unanimous verdict in favor of Professor De Simone and ExeGi and against VSL Inc., Alfasigma, and Leadiant. The jury awarded Professor De Simone and ExeGi $18,014,041 in damages, including $15 million to ExeGi on its false advertising claim.

76. The jury's verdict and award of $15 million in damages on the false advertising claim was necessarily premised on the finding that the two probiotic products are materially different. As a basic matter, as the evidence showed at trial, the De Simone Formulation contains eight strains of bacteria, while Italian VSL#3 contains seven. In addition, the De Simone Formulation contains lactose, while Italian VSL#3 does not, and they are made by different manufacturers, using different processes. The evidence at trial, including expert testimony, further showed that Italian VSL#3 and the De Simone Formulation have materially different biological, proteomic, enzymatic, and immunological profiles. And, per expert testimony, those differences would have a material effect on how the two products would perform in the body, including the conclusion that the differences were substantial enough that there was no expectation that Italian VSL#3 would have any

of the beneficial effects that were studied and documented to belong to the De Simone Formulation in the clinical studies and clinical history.

77. When Leadiant and Alfasigma challenged the sufficiency of the evidence to support this jury conclusion in post-trial motions, the Court pointedly disagreed and rejected the motions. Indeed, the Court adopted the jury's conclusion as its own. The Court stated in its Opinion that "the scientific evidence established that the products are not the same," and "the harm to ExeGi was the promoting of a false continuity between Italian VSL#3 and the De Simone Formulation." *De Simone v. VSL Pharm. Inc.*, No. CV TDC-15-1356, 2019 WL 2569574, *3-*4 (D. Md. June 20, 2019).

78. Based on those findings, the Court entered a permanent injunction that forbids the VSL#3 distributors from claiming that Italian VSL#3 (1) contains the same formulation found in the De Simone Formulation; (2) contains the "original proprietary blend"; or (3) contains the "same mix in the same proportions as earlier versions of VSL#3." The injunction further forbids the distributors from citing or referring to any clinical studies performed on the De Simone Formulation or earlier versions of VSL#3 as if they were performed on Italian VSL#3.

79. After the decisions in the Maryland District Court Action, ExeGi reached out to Emory, which was embarking on the human clinical study of VSL#3,

headed by Dr. Pacifici. Upon hearing of the decisions, Emory halted the study. Several other major educational institutions in the United States and Europe also ceased clinical trials on "VSL#3" when it became public that the version of VSL#3 being used in the trials was the untested Imitation Formula and not the De Simone Formulation. Those institutions, which ceased their studies out of concern for patient safety and on the basis that VSL Inc.'s claim to a robust clinical history was disproven, included Stanford University, University of Wisconsin (Madison), University of Louisville, Policlinico Casilino Roma, and Università Cattolica Roma.

80. Notably, in March 2020, the following comment was posted on ClinicalTrials.gov regarding the halted Emory study: "The investigational product became the subject of a court judgment upholding false advertising claims concerning the product's similarity to earlier products sold under the same name. Because of questions raised by this ruling, no participants are considered as being assigned to a protocol-defined study arm."

81. Since 2007, the U.S. government has required companies, universities, federal agencies, and nonprofits that sponsor clinical trials to report their results, whether positive, negative, or inconclusive, so that doctors, patients, and researchers

can learn about the safety and efficacy of new drugs or devices.[6] The comment on ClinicalTrials.gov, and Emory's decision to discontinue the study, acknowledged reality: that Italian VSL#3 and the DeSimone Formulation are different and cannot be used interchangeably.

82. While Emory backed away from Dr. Pacifici's intended study, Dr. Pacifici has not rescinded his approval of the GRAS Panel Report, despite ExeGi's requests.

83. Dr. Pacifici's continuing support for the GRAS Panel Report runs directly contrary to the Maryland Federal District Court's statement that "there is a public interest in ensuring that the public not be misled into believing that a particular product offered to address health needs will have the same efficacy as a trusted product when that has not been established." *De Simone*, 2019 WL 2569574, at *1.

84. Notably, ExeGi filed a contempt motion against Alfasigma and VSL Inc. for failing to abide by the Maryland Federal District Court's injunction. The

[6] Charles Piller, *In a first, FDA cites violation of clinical trials reporting law*, SCIENCE (April 28, 2021), https://www.sciencemag.org/news/2021/04/first-fda-cites-violation-clinical-trials-reporting-law.

Court granted the motion, in significant part, on July 30, 2020, finding Alfasigma and VSL Inc. had committed "blatant" violations.

85. Although the Court found that the characterization of Italian VSL#3 as a medical food and GRAS did not, on their face, violate the precise language of the permanent injunction, the Court was careful to point out that Alfasigma and VSL Inc. could not cite to the clinical studies of the De Simone Formulation to support their "medical food" or GRAS claims (which is what the GRAS Panel Report repeatedly does). Further, without clinical studies of their own on the intended medical applications of Italian VSL#3, or a GRAS report untethered to the clinical studies about the De Simone Formulation, as the Court aptly observed, the "VSL Parties run the risk that they may not be able to adequately respond to any consumer inquiries into the GRAS or medical food designations without violating" the permanent injunction that had been issued by the Maryland Federal District Court. As the scope of this motion was only whether Alfasigma and VSL Inc. violated the injunction, the Court did not determine, nor was it asked to determine, whether the "GRAS" or "medical food" indications were violations of the Lanham Act.

86. Despite this limited scope, the Court made clear that VSL Inc. and its related parties were "on notice of the identified violations and of potential violations that could arise from the use of the clinical studies in support of the GRAS and

medical food claims, any such violations occurring in the future will likely result in more serious sanctions."

87. Remedial measures are warranted for Dr. Pacifici, who has long been aware of the differences between the products and yet signed the GRAS Panel Report, refused to rescind that Report, and made public remarks about Italian VSL#3, all premised on a false conclusion that the product is the same as the De Simone Formulation. In so doing, he has materially contributed to the false advertising of the VSL#3 product, engaged in unfair competition, and tortiously interfered with ExeGi's business relations.

COUNT I
(Contributory False Advertising Under 15 U.S.C. § 1125(a)(1)(B) of the Lanham Act)

88. 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.

89. Alfasigma, a third party, engaged in false advertising that has injured ExeGi, as found by the jury and by the Court in the Maryland District Court Action. This false advertising is ongoing and has proximately caused injury to ExeGi's commercial interest in sales of Visbiome, and such injury is continuing.

90. Dozens of false and/or misleading statements made by Alfasigma and VSL Inc., which have been consistently repeated in commercial advertising from 2016 through the present, were based on Dr. Pacifici's Report. Those statements lack any valid evidentiary or scientific support and create a false continuity between Italian VSL#3 and the De Simone Formulation. Specifically, they are based upon an entirely different probiotic product and on studies conducted on that different product.

91. Specifically, the Report was, and continues to be, used by Alfasigma to falsely advertise its product as a "medical food" for the dietary management of various diseases, as GRAS certified, and the same as or equivalent to Visbiome. These advertising statements deceived, continue to deceive, and/or had the capacity to deceive wholesalers, suppliers, doctors, and ultimate consumers, who because of their deception purchased (and recommended the purchase of) Italian VSL#3 rather than Visbiome, the lone product that contained the De Simone Formulation from mid-2016 to the present.

92. The false statements in the Report, and in Alfasigma's advertising based on the Report, are statements of fact.

93. Even if framed as opinions, the statements in the Report, and in Alfasigma's advertising based on the Report, should be treated as statements of (incorrect) fact because they fairly imply a factual basis that justify the statements.

94. Whether or not a probiotic is "GRAS" and is a "medical food" are key considerations for wholesalers, suppliers, doctors, and probiotics consumers when making purchasing decisions. This is particularly true for products that are marketed based on their ability—such as Visbiome—or their purported ability—such as Italian VSL#3—to manage serious gastrointestinal disorders. Thus, the deception had a material effect on the purchasing decisions of wholesalers, suppliers, doctors, and probiotics consumers.

95. The misrepresented attributes of Italian VSL#3 materially affect interstate commerce.

96. ExeGi has been and continues to be injured by the false statements in the Report and in Alfasigma's advertising based on the Report, as a direct and proximate result of Dr. Pacifici's 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 sold by ExeGi under the brand name Visbiome.

97. The underpinning of much of the false advertising engaged in by Alfasigma has been the Report. And, despite the ruling in the Maryland District Court Action, Alfasigma continues to rely upon the flawed conclusions of the Report to claim that Italian VSL#3 is a medical food and GRAS and that there is an equivalence between Italian VSL#3 and Visbiome. Such false claims permit Alfasigma to sell its product to the detriment of ExeGi.

98. Dr. Pacifici has contributed to the false advertising by knowingly inducing and helping cause it, and he materially participated in it by signing off on the GRAS Panel Report, by refusing to rescind the Report, and by making the public remarks detailed herein, despite being informed, numerous times and in numerous ways both before and after the Report was signed, that the studies upon which the Report was based were performed on the De Simone Formulation and not on Italian VSL#3. Dr. Pacifici, thus, intended to participate in and actually knew about the false advertising being committed by Alfasigma. He materially furthered such false advertising, and without Dr. Pacifici's contributions, the false advertising would have been reduced or eliminated.

99. As alleged herein, Dr. Pacifici knew or should have known that the GRAS Panel Report contains numerous materially false representations, including but not limited to the false representations enumerated in Paragraphs 58-70 above.

100. As described above, Dr. Pacifici knew or should have known that those false representations would be relied upon by Alfasigma to falsely advertise Italian VSL#3, which was likely to confuse consumers about Italian VSL#3® and cause consumers to buy it rather than Visbiome.

101. Despite this knowledge, Dr. Pacifici signed off on the GRAS Panel Report and, further, has continuously refused to rescind his support for the GRAS Panel Report, allowing VSL Inc. and its distributors to falsely state and falsely imply that Italian VSL#3 has the safety and efficacy data that was, in actuality, generated from studying the De Simone Formulation alone. Such false statements include, but are not limited to, the perpetual marketing that Italian VSL#3 is a "medical food" and "GRAS" when neither status has been properly established.

102. Dr. Pacifici's perpetuation of the false representations in the Report is intended to divert sales from Visbiome to Italian VSL#3, and it has successfully, directly, and proximately caused that diversion. Furthermore, the goodwill associated with Visbiome, which is made by Danisco USA, Inc. using the De Simone Formulation, has been and will be diminished because consumers falsely believe that Italian VSL#3 is the equivalent of Visbiome and has the clinical studies and clinical history supporting the safety and efficacy of Visbiome when it does not. Therefore,

consumers have thought and will think less of ExeGi and Visbiome based on such false representations.

103. As Italian VSL#3 has not undergone a single human clinical trial, and independent testing and consumer reaction has revealed material differences with the De Simone Formulation and serious efficacy deficiencies in Italian VSL#3, it is likely Italian VSL#3 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.

104. Dr. Pacifici's contributory false advertising has caused ExeGi to suffer damages totaling more than $10 million.

105. There is a substantial likelihood that ExeGi will succeed on the merits of this claim, especially given the findings in the Maryland District Court Action.

106. ExeGi has suffered and will continue to suffer irreparable harm unless an injunction is issued.

107. The potential continuing injury to ExeGi far outweighs any possible harm to Dr. Pacifici. In fact, Dr. Pacifici would help and improve his own standing by backing away from the demonstrably false claims in the GRAS Panel Report.

108. The requested injunction is in the public interest as consumer deception, by its very nature, is against the public interest.

COUNT II
(Unfair Competition under
15 U.S.C. § 1125(a)(1)(A) of the Lanham Act)

109. 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.

110. Under 15 U.S.C. § 1125(a)(1)(A), a person commits unfair competition if he "uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact which is likely to cause confusion . . . or to deceive as to the affiliation, connection, association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person."

111. Here, Dr. Pacifici has engaged in unfair competition in violation of the Lanham Act in several ways.

112. First, by signing off on and by continuing to authorize the GRAS Panel Report, he has caused a likelihood of confusion or misunderstanding as to the approval and certification of Italian VSL#3 as a medical food and GRAS because the Report relies upon studies and research performed on Visbiome rather than Italian VSL#3.

113. Second, by signing off on and by continuing to authorize the GRAS Panel Report, Dr. Pacifici represented and has caused Alfasigma to represent that Italian VSL#3 has approval of scientists and that there is a consensus among qualified experts that data and information relating to Italian VSL#3 establish the safety of its intended use. There is no such approval or consensus regarding Italian VSL#3.

114. Third, by signing off on and by continuing to authorize the GRAS Panel Report, Dr. Pacifici falsely represented and has caused Alfasigma to represent that Italian VSL#3 is of a particular standard and quality—*i.e.*, that it is a medical food and GRAS. Both of those conclusions are false, based upon the lack of clinical trials or other research to support them.

115. Dr. Pacifici has been specifically and repeatedly informed of the falsity of those communications, both before and after he endorsed the GRAS Panel Report. Dr. Pacifici's GRAS Panel Report, and his continuous and repeated refusal to withdraw that Report, even after being advised that the studies and research upon which it was based were performed on the De Simone Formulation (then being sold as Visbiome) rather than Italian VSL#3 (then being sold as VSL#3®) continues to foster a confusion and misunderstanding about the efficacy and safety of Italian VSL#3.

116. In the GRAS Panel Report, Dr. Pacifici misrepresents facts, and has caused Alfasigma to misrepresent facts. As such, ExeGi is entitled not only to damages but also to injunctive relief that requires recission of Dr. Pacifici's endorsement of the GRAS Panel Report.

117. The representations made by Dr. Pacifici in endorsing the GRAS Panel Report, including that Italian VSL#3 is a medical food, GRAS, and effective, are false.

118. Dr. Pacifici was at all times fully aware that his work in relation to the GRAS Panel Report was commercial in nature and conducted in the course of his and Alfasigma's business.

119. There is a substantial likelihood that ExeGi will succeed on the merits of this claim, especially given the findings in the Maryland District Court Action.

120. ExeGi has suffered and will continue to suffer irreparable harm unless an injunction is issued.

121. The potential continuing injury to ExeGi far outweighs any possible harm to Dr. Pacifici. In fact, Dr. Pacifici would help and improve his own standing by backing away from the demonstrably false claims in the GRAS Panel Report.

122. The requested injunction is in the public interest as consumer deception, by its very nature, is against the public interest.

123. Given that Dr. Pacifici has been made aware of the misrepresentations in the GRAS Panel Report and the flaws undergirding it, Dr. Pacifici has willfully engaged in such misrepresentations, knowing them to be deceptive.

COUNT III
(Violation of Georgia Unfair Competition Statute, O.C.G.A. § 10-1-370, *et seq.*)

124. 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.

125. According to O.C.G.A. § 10-1-372(a):

> A person engages in a deceptive trade practice when, in the course of his business, vocation, or occupation, he: … (2) Causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services; … (5) Represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he does not have; … (7) Represents that goods or services are of a particular standard, quality, or grade or that goods are of a particular style or model, if they are of another; … or (12) Engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.

126. Here, Dr. Pacifici has engaged in deceptive trade practice pursuant to Ga. Code Ann. § 10-1-372(a) in a number of ways.

127. First, by signing off on and by continuing to authorize the GRAS Panel Report, he has caused a likelihood of confusion or misunderstanding as to the

approval and certification of Italian VSL#3 as a medical food and GRAS because the Report relies upon studies and research performed on Visbiome rather than Italian VSL#3.

128. Second, by signing off on and by continuing to authorize the GRAS Panel Report, Dr. Pacifici represented and has caused Alfasigma to represent that Italian VSL#3 has approval of scientists and that there is a consensus among qualified experts that data and information relating to Italian VSL#3 establish the safety of its intended use. There is no such approval or consensus regarding Italian VSL#3.

129. Third, by signing off on and by continuing to authorize the GRAS Panel Report, Dr. Pacifici falsely represented and has caused Alfasigma to represent that Italian VSL#3 is of a particular standard and quality—*i.e.*, that it is a medical food and GRAS. Both of those conclusions are false, based upon the lack of clinical trials or other research to support them.

130. Dr. Pacifici has been specifically and repeatedly informed of the falsity of those communications, both before and after he endorsed the GRAS Panel Report. Dr. Pacifici's GRAS Panel Report, and his continuous and repeated refusal to withdraw that Report, even after being advised that the studies and research upon which it was based were performed on the De Simone Formulation (then being sold

as Visbiome) rather than Italian VSL#3 (then being sold as VSL#3®) continues to foster a confusion and misunderstanding about the efficacy and safety of Italian VSL#3.

131. In the GRAS Panel Report, Dr. Pacifici misrepresents facts, and has caused Alfasigma to misrepresent facts. As such, ExeGi is entitled to injunctive relief, per O.C.G.A. § 10-1-373, that requires recission of Dr. Pacifici's endorsement of the GRAS Panel Report.

132. The representations made by Dr. Pacifici in endorsing the GRAS Panel Report, including that Italian VSL#3 is a medical food, GRAS, and effective, are false.

133. Dr. Pacifici was at all times fully aware that his work in relation to the GRAS Panel Report was commercial in nature and conducted in the course of his and Alfasigma's business.

134. There is a substantial likelihood that ExeGi will succeed on the merits of this claim, especially given the findings in the Maryland District Court Action.

135. ExeGi has suffered and will continue to suffer irreparable harm unless an injunction is issued.

136. The potential continuing injury to ExeGi far outweighs any possible harm to Dr. Pacifici. In fact, Dr. Pacifici would help and improve his own standing by backing away from the demonstrably false claims in the GRAS Panel Report.

137. The requested injunction is in the public interest as consumer deception, by its very nature, is against the public interest.

138. Given that Dr. Pacifici has been made aware of the misrepresentations in the GRAS Panel Report and the flaws undergirding it, Dr. Pacifici has willfully engaged in such misrepresentations, knowing them to be deceptive.

COUNT IV
(Tortious Interference with Business Relations)

139. 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.

140. At all relevant times, ExeGi has had valid, ongoing business relationships with wholesalers and distributors of Visbiome, as well as doctors and end users of Visbiome, and had the expectancy of business with other potential wholesalers, distributors, and end users.

141. These relationships are for ExeGi's benefit, as the wholesalers and distributors purchase and sell Visbiome, and the end users also purchase Visbiome often under the direction of their doctors.

142. At all relevant times, Dr. Pacifici has been aware of ExeGi's valid, ongoing business relationships described above, as well as its expectation of additional such business relationships.

143. Dr. Pacifici is a stranger to the ongoing business relationships described above, as well as to ExeGi's expected business relationships.

144. Dr. Pacifici purposely, and with malice with the intent to injure ExeGi and with reckless disregard for public health, interfered with these relationships by endorsing the GRAS Panel Report and then refusing to rescind that endorsement (and, thus, the Report itself) after it was made clear that the Report was based upon studies and research performed on the De Simone Formulation and not Italian VSL#3.

145. Such actions were improper, as they were based on false information, materially perpetrated a fraud on consumers, endangered public health, and were intended to advantage VSL Inc. and its distributors and cause harm to ExeGi, and taken without privilege, right, or justifiable cause. Furthermore, such actions proximately caused Alfasigma to engage in false advertising that induced wholesalers, distributors, doctors and end users of Visbiome to purchase (or recommend the purchase of) Italian VSL#3 rather than Visbiome and, therefore, not to enter into or continue business relationships with ExeGi.

146. Dr. Pacifici's conduct was intentional, willful, and calculated to cause harm to ExeGi's lawful business of selling Visbiome.

147. As a direct and proximate result of Dr. Pacifici's endorsement of the GRAS Panel Report and his refusal to rescind such endorsement, wholesalers, distributors, doctors, and end users of Visbiome have purchased (or have recommended the purchase of) Italian VSL#3 rather than Visbiome.

148. Dr. Pacifici's tortious interference with ExeGi's business relations and prospective business relations has caused ExeGi to suffer damages totaling more than $10 million.

COUNT V
(Attorneys' Fees and Expenses under O.C.G.A. § 13-6-11)

149. 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.

150. Dr. Pacifici has acted in bad faith, been stubbornly litigious, and caused ExeGi unnecessary trouble and expense.

151. ExeGi is therefore entitled to recover its expenses of litigation, including reasonable attorneys' fees, from Dr. Pacifici in accordance with O.C.G.A. § 13-6-11.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that the Court enter judgment in its favor, and against Dr. Pacifici, and award the following relief:

A. On Count I (Contributory False Advertising Under 15 U.S.C. § 1125(a)(1)(B) of the Lanham Act), awarding ExeGi: (1) compensatory damages in an amount to be proven at trial but in no event less than $10 million; (2) injunctive relief requiring Dr. Pacifici to rescind formally his approval and endorsement of the GRAS Panel Report and to state affirmatively that such rescission is based upon the false premises upon which the Report was based; (3) litigation costs, expenses and attorneys' fees; and (4) any further relief as the Court may deem just and proper.

B. On Count II (Unfair Competition under 15 U.S.C. § 1125(a)(1)(A) of the Lanham Act), awarding ExeGi: (1) compensatory damages in an amount to be proven at trial but in no event less than $10 million; (2) injunctive relief requiring Dr. Pacifici to rescind formally his approval and endorsement of the GRAS Panel Report and to state affirmatively that such rescission is based upon the false premises upon which the Report was based; (3) litigation costs, expenses and attorneys' fees; and (4) any further relief as the Court may deem just and proper.

C. On Count III (Violation of Georgia Unfair Competition Statute – O.C.G.A. § 10-1-370, *et seq.*): (1) injunctive relief, per § 10-1-373(a), requiring Dr.

Pacifici to rescind formally his approval and endorsement of the GRAS Panel Report and to state affirmatively that such rescission is based upon the false premises upon which the Report was based; (2) costs and attorneys' fees per § 10-1-373(b); and (3) any further relief as the Court may deem just and proper.

D. On Count IV (Tortious Interference), awarding ExeGi: (1) compensatory damages in an amount to be proven at trial but in no event less than $10 million; (2) injunctive relief requiring Dr. Pacifici to rescind formally his approval and endorsement of the GRAS Panel Report and to state affirmatively that such rescission is based upon the false premises upon which the Report was based; and (3) any further relief as the Court may deem just and proper.

E. On Count V (Attorneys' Fees and Expenses), awarding ExeGi its reasonable attorneys' fees, costs, and expenses.

F. On all counts, pre-judgment and post-judgment interest.

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

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

Respectfully submitted, this 20th day of May, 2021.

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