IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

EXEGI PHARMA, LLC *

Plaintiff, *

v. *

Case No. _____

CAMILLO RICORDI, *

Defendant. *

* * * * * * * * * * * * *

COMPLAINT

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

NATURE OF THE ACTION

1. This lawsuit stems from Defendant's role in a continuing false advertising campaign that has damaged and continues to harm ExeGi, as well as thousands of consumers of probiotics.

2. Defendant is the Editor-in-Chief of *European Review for Medical and Pharmacological Services* ("ERMPS"), a medical journal with a broad reach both inside and outside of the United States. In this role, Defendant is ultimately responsible for what is published in ERMPS – the buck stops with him.

3. Defendant, however, has abdicated his responsibilities to the medical journal and, rather than dedicating it to independent scientific inquiry, has used it as a commercial tool fraudulently to advertise a second-rate medical product. Specifically, by refusing to withdraw, and facilitating the active promotion of, an article published by ERMPS in January of 2020 – *"The*

safety profile of probiotic VSL#3. A meta-analysis of safety data from double-blind, randomized, placebo-controlled clinical trials" (hereinafter, "VSL#3 Article") – Defendant not only has violated editorial and journalistic ethics in his role as editor of a scientific journal, but also has actively contributed to the false advertising of the probiotic VSL#3 by the Actial Group (Actial Srl and its U.S. affiliate, VSL Pharmaceuticals Inc. ("VSL Inc.")) through VSL Inc.'s licensee, Alfasigma USA, Inc. ("Alfasigma").

4. The VSL#3 Article, which was funded by Actial Farmaceutica, an entity that acts on behalf of the Actial Group, falsely concludes that VSL#3 is safe. This improper conclusion is based upon incomplete and unverified data assembled from unrelated clinical studies that were approved to be conducted on humans based upon fraudulent data. The Actial Group, to secure approval of the studies, presented to a group of clinical investigators involved in the studies information and research pertaining to the safety and efficacy of an ***entirely different probiotic***, one created by Professor Claudio De Simone (and sold in the United States exclusively by ExeGi). Once these investigators were informed of this subterfuge, all halted the studies. Yet the authors of the VSL#3 Article went ahead with their analysis anyway, using incomplete data that had been gathered before the studies were halted, and misrepresenting why the studies had been shut down. Upon information and belief, their plowing ahead with these dubious claims was the result of the Actial Group's influence over them and the article.

5. The VSL#3 Article, therefore, is itself a fraud. And the Actial Group, with Defendant's knowing participation, has used it aggressively for commercial purposes, sending it to physicians and other healthcare providers that prescribe the product, and trumpeting it in marketing and advertising to further the entirely unsubstantiated – and literally false – notion that

VSL#3 is clinically proven to be safe, when no published clinical study actually has reached that conclusion.

6. All of the issues with the VSL#3 Article, the studies upon which it was based, and its improper use in commercial advertising have been brought to the attention of Defendant on numerous occasions. Yet Defendant simply ignored multiple emails from Professor De Simone until, when contacted by Plaintiff's counsel, he ran to the Actial Group for guidance instead of seeking to exercise his editorial control over the publication and investigate the issues raised. As a result of Defendant's actions and inaction, ERMPS has not withdrawn or provided any sort of editorial correction to the VSL#3 Article. The article remains widely available in its original form, and, with Defendant's knowledge and active participation, VSL Inc. has made it the centerpiece of its marketing to United States health care professionals and customers.

7. This fraudulent use of pseudo-medical literature is but the latest attempt of the Actial Group to falsely advertise VSL#3. The Actial Group, through VSL Inc. and its distributors, has falsely represented the safety of its product, and promoted, either directly or indirectly, a false equivalence between VSL#3 and the unique, eight-strain, high-potency probiotic formula created by Professor De Simone ("De Simone Formulation") that is sold by ExeGi under the brand name "Visbiome."

8. Professor De Simone previously had worked for VSL Inc., and the De Simone Formulation was sold under the brand name VSL#3 until 2016. Professor De Simone left VSL Inc., however, 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, while VSL#3

now contains a new formula ("Italian VSL#3"). VSL Inc. has used this history to its advantage, however, blurring what should be clear lines between the products.[1]

9. Initially, VSL Inc. simply made blatantly false statements linking Italian VSL#3 to the De Simone Formulation. It baldly stated, for example, that Italian VSL#3 contained: (1) the same formulation as that found in the De Simone Formulation; (2) the "original proprietary blend"; and (3) the "same mix in the same proportions as earlier versions of VSL#3."

10. None of those statements is (or was) true, and VSL Inc. now is forbidden, by order of a federal court, from making any one of them. In 2018, a jury in the United States District Court for the District of Maryland 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. 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.

11. 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 (the jury verdict alone was not enough, apparently, to stop VSL Inc. from making false statements about its product and comparing it to the De Simone Formulation). Specifically, the injunction prohibited VSL Inc.'s licensees, Alfasigma and Sigma-Tau Pharmaceuticals, Inc. (n/k/a Leadiant Biosicenses, Inc. ("Leadiant")), from citing clinical studies performed on the De Simone Formulation or otherwise implying a false continuity between Italian

[1] It is not shocking that VSL Inc. has tried to link Italian VSL#3 with the De Simone Formulation. While Italian VSL#3 is but a poor imitation of the De Simone Formulation and has not been rigorously tested, the De Simone Formulation is one of the most extensively studied probiotics now available, having been the subject of more than 70 human clinical trials. Based upon those trials and studies, the De Simone Formulation is widely considered the gold standard for this type of probiotic.

VSL#3 and the De Simone Formulation. These rulings were upheld by the United States Court of Appeals for the Fourth Circuit.

12. Alfasigma and VSL Inc., however, defiantly continued marketing Italian VSL#3 in a manner that compares it to the De Simone Formulation – stating Italian VSL#3 was "equivalent" to the De Simone Formulation, that clinical studies performed on the De Simone Formulation could be "relied upon to show the efficacy and safety" of Italian VSL#3, and that Italian VSL#3 "ha[d] not changed."

13. On July 30, 2020, the Maryland Federal District Court granted in part ExeGi's contempt motion filed against Alfasigma and VSL Inc. for failing to abide by the injunction. The Court found that Alfasigma and VSL Inc. had committed "blatant" violations.

14. But VSL Inc. is undeterred. Now, in addition to making direct statements, it is attempting, with the help of scientists like Defendant, to establish a connection to the De Simone Formulation and to establish that its product is certified "safe" via corrupt, back-door routes under the guise of science. It is doing so by using studies and research conducted on the De Simone Formulation to establish (fraudulently) Italian VSL#3's bona fides.

15. First, VSL Inc. hired a company called Intertek to put together a report on Italian VSL#3 and assemble a panel of professors who would review the report and then certify Italian VSL#3 as "Generally Recognized as Safe" ("GRAS") – a critical standard for probiotic products. Three professors, including Dr. Roberto Pacifici, a professor at Emory University (who also had been engaged by VSL Inc. to be a paid consultant), signed off on the report, which touted the safety and efficacy of Italian VSL#3 and certified that it met the criteria to qualify as a "medical food" and "GRAS."

16. This report became the foundation for VSL Inc.'s (and its distributors') marketing of Italian VSL#3 as a "medical food" and GRAS certified. But there is a major problem with the report: it was based entirely upon studies and research performed ***on the De Simone Formulation***, not Italian VSL#3. When Dr. Pacifici refused to withdraw his support for the GRAS Panel's report, despite being informed that the studies upon which it was based were conducted on an entirely different probiotic, ExeGi filed a lawsuit against Dr. Pacifici for, *inter alia*, contributory false advertising. Such lawsuit currently is pending in the United States District Court for the Northern District of Georgia (*ExeGi Pharma, LLC v. Pacifici*, Case No. 1:21-CV-02134-TWT).

17. The Actial Group now has exploited the limited and immaterial connections between its imitation product and the De Simone Formulation to fraudulently secure approval for clinical studies that it then can manipulate via commercial advertising masquerading as medical literature. In the VSL#3 Article published by ERMPS, the authors "conclude that VSL#3 is a safe and well-tolerated agent." But, like the GRAS Panel Report, the VSL#3 Article is built on a false premise and fundamentally flawed.

18. Notably, the VSL#3 Article was first published when Professor Antonio Gasbarrini was the editor of ERMPS. Dr. Gasbarrini, in addition to being an employee of Fondazione Policlinico Universitario Gemelli IRCCS, Università del Sacro Cuore (the same institution where one of the authors of the VSL#3 Article holds a position), was a member of the "Scientific Board" for Actial Group and is a scientific advisor for the VSL#3 product. Based upon this (and other) blatant conflicts of interest, it is clear that the VSL#3 Article was the result of a coordinated effort by the Actial Group to promote the false notion that VSL#3 has been proven safe through studies and testing. Indeed, the Actial Group's fingerprints are all over the VSL#3 Article, which has the feel of an infomercial rather than an unbiased piece of journalism.

19. Most significantly, the studies from which the VSL#3 Article's authors draw their conclusions were ***halted*** upon the respective investigators of the studies being informed that the studies were authorized based upon fraudulently represented data. Specifically, because the studies were human clinical trials, they required approval from investigators and ethics committees before they could move forward. Dr. Gasbarrini's associate, Dr. Lucrezia Laterza, put together materials to provide to those charged with approving the various studies. The materials, however, included information based upon, and studies conducted upon, ***the De Simone Formulation*** (not Italian VSL#3), as well as the aforementioned GRAS panel report that also was based entirely upon research, studies and documents related to ***the De Simone Formulation*** (not Italian VSL#3). Thus, the clinical investigators – as well as the participants – were misinformed that the product they would be using was safe based upon safety information relating to an entirely different substance. Not only did this compromise the study itself, but it also put the health of the participants in danger.

20. Professor De Simone and his counsel contacted the clinical investigators and informed them that the Actial Group had misled physicians and patients into believing that (a) the version of VSL#3 offered for the clinical trials would have the same safety and efficacy as the De Simone Formulation and that (b) prior studies on the De Simone Formulation actually were performed on Italian VSL#3. When these studies' investigators learned the truth about the data and the rulings of the U.S. District Court for the District of Maryland, they immediately stopped their clinical trials. And for good reason: Fragile populations had been convinced to participate in these studies – and to consume Italian VSL#3 – based upon the misrepresentation that the product had been clinically proven safe over a period of 15 years. Because they had been duped, the

organizers of these studies could not in good conscience continue the studies or certify the results thereof.[2]

21. The Actial Group has no such conscience, as not even the halting of the studies put a stop to its ongoing quest to falsely market Italian VSL#3. Indeed, the Actial Group assembled authors who were not a part of the clinical studies, and these authors went ahead and ***used the incomplete results from the clinical trials anyway*** to support their improper conclusion regarding the safety of VSL#3.

22. In sum, the authors combined incongruous, incomplete, and unreliable data for the sole purpose of forcibly extrapolating false or misleading conclusions regarding VSL#3. The VSL#3 Article is thus merely commercial speech. It is to medical journalism what QVC is to Dateline.

23. Defendant was informed of the fraudulent underpinnings of the VSL#3 Article on multiple occasions. After three emails from Professor De Simone (on August 27, September 5, and September 8 of this year) were ignored, Professor De Simone's counsel sent Defendant a letter on September 23, 2021. Notably, just five days later, Defendant sent an email to Giacomo Gori (general manager of Actial Farmaceutica), Dr. Gasbarrini, and several others, including a co-editor of ERMPS. In it, Defendant requested a detailed answer on the validity of the article's underpinnings and suggested there might be a consensus to withdraw the article. He indicated, however, that he would not want to withdraw the article without first hearing the opinions of those on the email, including the Actial Group representative (who was not listed as an author of the article and, thus, should have no role in the editorial process).

[2] Indeed, none of the clinical investigators that performed the studies is listed as an author of the VSL#3 Article.

24. Defendant, the Editor-in-Chief of ERMPS, was, thus, shelving medical and journalistic ethics in favor of seeking permission from the company that paid for the article, which payment redounded to the financial benefit of Defendant and the journal he runs. While stating the article should be withdrawn as false, he left the decision to the company that was falsely marketing the product via that very article. The article has not been withdrawn to date, evidencing that Defendant takes his orders from the Actial Group and remains a knowing and willing participant in their false advertising of VSL#3.

25. Based on Defendant's continued authorization of the VSL#3 Article, VSL Inc. continues, with Defendant's knowledge and participation, to claim in its marketing materials and on its web site that "multiple clinical trials" have demonstrated the safety of this product. Such claims are entirely false and, when relied upon by consumers, harm not only ExeGi but also those consumers. Yet, Defendant has refused to back down from publishing the VSL#3 Article.

26. ExeGi requests this Honorable Court enter judgment against Defendant for his ongoing role in VSL Inc.'s false advertising, order that he withdraw the VSL#3 Article, and award ExeGi damages for the harm caused by Defendant's conduct.

THE PARTIES

27. 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.

28. Defendant Camillo Ricordi is an individual residing at 550 Bay Point Road, Miami, Florida 33137. He is a domiciled in and a citizen of Florida.

JURISDICTION AND VENUE

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

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

31. 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).

32. 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.

33. This Court has personal jurisdiction over Defendant as he is domiciled in Florida.

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

FACTUAL ALLEGATIONS

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

35. 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[3], 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").

36. 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

37. About 20 years ago, Professor De Simone and two brothers, Claudio and Paolo Cavazza, formed VSL Inc., and 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."

[3] 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.

38. 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.

39. 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.

40. 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 authorized to continue to sell VSL#3 containing the De Simone Formulation until January 2016.[4] He eventually licensed his De Simone Formulation to ExeGi, which began to sell it under the name Visbiome in February of 2016.

[4] Leadiant and VSL Inc. failed to pay Professor De Simone for the privilege of selling 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

41. The Cavazzas, meanwhile, hired a team of dairy experts to attempt to reverse engineer the De Simone Formulation. 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 (also, the "Fake Formula"). The Cavazzas went to a new manufacturer in Italy and then began producing the Fake Formula. Beginning in mid-2016, Leadiant began selling this Fake Formula under the trademark "VSL#3" without informing the public of the change in formula.

42. Rather, Leadiant usurped the history of and research into the De Simone Formulation and simply used it for the Fake Formula. Leadiant publicly announced that production of VSL#3 would move from the Danisco facility in the United States to a new manufacturer in Italy, but it 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 was converting from selling the De Simone Formulation as VSL#3 to selling the Fake Formula as VSL#3 and simply pretended there merely had been a change in manufacturing location and nothing more.

43. But the Fake Formula is entirely, materially different from the De Simone Formulation, in numerous ways: the Fake 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.

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liable for unjust enrichment and awarded several million dollars in damages to Professor De Simone.

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

C. Litigation in the District of Maryland

45. Professor De Simone filed suit in the United States District Court for the District of Maryland ("Maryland District Court Action"), bringing various claims against VSL Inc., including a claim for a declaratory judgment that he owned the Know-How. When ExeGi learned that Leadiant and Alfasigma were selling the Fake 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.

46. The District Court granted summary judgment for Professor De Simone on the issue of the Know-How, ruling 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 $15,000,000 to ExeGi for its false advertising claim.

47. 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 (Italian VSL#3 does not), and the products 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, 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.

48. When Leadiant and Alfasigma challenged the sufficiency of the evidence to support this jury conclusion in post-trial motions, the Court heartily disagreed. 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 (D. Md. June 20, 2019), *3-4.

49. Based on those findings, the Court entered a permanent injunction that forbid distributors from claiming that Italian VSL#3 (1) continues to contain 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 forbid distributors from citing or referring to any clinical studies performed on the De Simone Formulation or earlier versions of VSL#3 as relevant or applicable to Italian VSL#3.

50. Despite the entry of this injunction, VSL Inc. continued to promote a false equivalency with its product. VSL Inc. also has attempted to link its product to the De Simone

Formulation and falsely market its Fake Formula as safe through more subtle, but just as improper, methods.

D. The GRAS Report

51. In early 2017, a consulting company called Intertek provided Dr. Pacifici, Professor I. Glenn Sipes of the University of Arizona, and Dr. Gary Williams of New York Medical College with a draft report on Italian VSL#3. Intertek had prepared the draft report and put together the dossier of reports and studies upon which this initial draft purportedly was based. Intertek then asked the three professors to serve as a "GRAS Panel" that would review the draft Report and information in the dossier and then sign a revised report. It was made clear that this was a commercial, rather than scientific, project meant to commercialize Italian VSL#3.

52. 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. 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."

53. Despite the serious consequences 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. 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 minimum, Dr. Pacifici was obligated to check

the correctness of the data and the Report provided to him. And, based upon conversations Dr. Pacifici had with Professor De Simone, Dr. Pacifici 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, however, Dr. Pacifici endorsed the GRAS Panel Report and its false claims of equivalence. Upon information and belief, Dr. Pacifici's failures were based upon his motivation to keep VSL Inc., his benefactor, happy.

54. Dr. Pacifici and the other professors on the GRAS Panel merely suggested meager revisions to Intertek's draft and, 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."

55. The GRAS Panel Report, however, is fatally flawed. 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 – as if it were Italian VSL#3 that was the subject of the studies (or that Italian VSL#3 and the De Simone Formulation contain the same formulation). Notably, the Court in the Maryland District Court Action has prohibited such claims via a permanent injunction.

56. When Dr. Pacifici refused to withdraw his endorsement of the GRAS Panel Report despite the issues outlined above, ExeGi had no choice but to file a lawsuit against him.

E. <u>The Approval of the Studies and Publication of the VSL#3 Article</u>

57. The VSL#3 Article, published in the second issue of the 24th volume of ERMPS, opens with the acknowledgment that the product "has been so far scarcely investigated on the aspect of safety."

58. Clearly, the Actial Group wanted to fix that. As noted above, certification as "GRAS" is significant for probiotic products. With the aforementioned GRAS Panel Report under

attack, the Actial Group now is seeking to prove the safety of its product through fabricated medical literature.

59. The Actial Group's influence on the VSL#3 Article is obvious and troubling. First, Actial Farmaceutica funded the writing of the VSL#3 paper (as noted in the "Acknowledgments" section of the paper), and, upon information and belief, receipt of such funding and desire for further funding has motivated Defendant's actions described in this Complaint. In addition, two of the authors of the paper, Antonella Bacchieri and Pierluigi Navarra, served as consultants for Actial Farmaceutica (as noted in the "Conflicts of Interests" section of the article). Third, and most egregious, the Editor-in-Chief of ERMPS at the time of publication, Dr. Gasbarrini, was a member of the Actial Group's "Scientific Board" and is a scientific advisor for the VSL#3 product. In addition, he is an employee of the same institution where one of the authors of the article, Dr. Navarra, is a professor of pharmacology.

60. If all that were not enough, the information gathered by Dr. Laterza (Dr. Gasbarrini's assistant) and presented to the various investigators and Ethics Committees that act as gatekeepers for authorization of human clinical trials, contained false attribution to Italian VSL#3 of information that related to the De Simone Formulation. Thus, the investigators and Ethics Committees – not to mention the patients who agreed to participate in the studies – were convinced by inapplicable information.

61. The VSL#3 Article based its analysis upon three "double-blind, randomized, placebo-controlled trials" conducted on VSL#3, and also "considered" "[d]ata from a large open-label observational trial." The trials exploring the effect of VSL#3 included: the ESDO trial (on obese pregnant women); the PROREM UC trial (on patients with ulcerative colitis); the PROBONE trial (on women with osteoporosis), and the POST trial (on patients with irritable

bowel syndrome). The VSL#3 Article indicated the authors "pooled and analyzed data from the ESDO, PROREM UC and PROBONE trials, because of the close similarities in study design," and that "[d]ata from the POST trial were also considered but were analyzed in a separate setting, because of differences in study design that did not allow pooling of the data."

62. There are multiple problems, however, with the studies and the authors' use of them in formulating their conclusions about Italian VSL#3.

63. First, the meta-analysis published in the VSL#3 Article entirely lacks the characteristics of scientific quality and correctness. The four studies from which the article's authors processed data are macroscopically heterogeneous, with different numbers of subjects, different treatment days, and different treatment doses. The authors, thus, combined incongruous, incomplete, and unreliable data for the sole purpose of forcibly extrapolating false or misleading conclusions on the use of VSL#3.

64. More egregious is the fact that the authors used data from studies that had been halted before completion and then, in their article, white-washed the reasons why the studies had been stopped. According to the introduction of the paper: "The randomized, placebo-controlled, clinical trials were prematurely interrupted due to slow recruitment rate (ESDO study) or to administrative issues (PRO BONE and PROREM UC studies). No study has been interrupted due to safety or clinical issues." Such is blatantly false.

65. The actual reason these three studies were halted is because the clinical investigators of the respective studies were made aware of the non-correspondence between Italian VSL#3 (used in the research) and the De Simone Formulation. Counsel for Professor De Simone advised the investigators that the Actial Group had implemented initiatives to mislead physicians and patients into believing that the probiotic being tested (Italian VSL#3) would have the same

efficacy as the De Simone Formulation probiotic, and that prior studies on the De Simone Formulation showing its safety and efficacy actually were performed on Italian VSL#3. Of course, the U.S. District Court for the District of Maryland had prohibited such reliance in commercial advertising directed at or readily accessible to United States consumers because it constitutes false advertising of Italian VSL#3.

66. Yet this is exactly what the Actial Group did. It provided documents to those charged with approving the studies of VSL#3 – including the faulty GRAS panel report – that were solely attributable to the De Simone Formulation ***but passed them off as approving the safety of Italian VSL#3***.

67. In essence, the Actial Group initiated the ESDO, PRO BONE, and PROREM UC studies by intentionally deceiving investigators and ethics committees. As soon as those investigators and ethics committees learned the facts and applicable court rulings, however, they immediately stopped the clinical trials (but could not stop the authors' use of the incomplete and fraudulently obtained data).

68. The statement of the VSL#3 Article's authors that the interruption of the studies was not imposed by clinical and safety reasons is, therefore, untethered from reality. And, as a consequence of the material falsity of the documents provided by the Actial Group, the approval of the various investigators and Ethics committees – as well as the informed consent of patients – is entirely invalidated.

69. The PROREM UC study was interrupted on April 24, 2019, without any complete results being obtained. This interruption was justified by the fact that the probiotic being used was not the De Simone Formulation and, thus, lacked any prior clinical study for efficacy and safety in the studied population.

70. Professor Alessandro Armuzzi of Policlinico Gemelli, the Principal Investigator in the PROREM UC study, has neither closed nor validated the clinical records of the patients involved with the project and, therefore, no real and complete results suitable for publication are available.

71. Professor Armuzzi stated, in a letter: "Considering the new information about VSL#3 … the scientific assumptions, on which the clinical trial 'PRObiotic VSL#3® for Maintenance of Clinical and Endoscopic REMission in Ulcerative Colitis – PROREM UC' (ClinicalTrials.gov Identifier NCT03415711) was initially based, are probably incorrect." Professor Armuzzi added that he had "asked the Ethics Committee of my Hospital the precautionary and immediate interruption of the study to safeguard the patients' right to receive complete and updated information, before deciding to participate to a clinical trial."

72. The PRO BONE study conducted at Emory University, in which Dr. Pacifici was involved, determined, based upon the ruling in the Maryland District Court Action, that none of the 35 individuals who consented to participate in the study "are considered as being assigned to a protocol-defined study arm." The position of the study was further explained by Emory's Associate General Counsel, Christopher J. Kellner, who explained:

> (1) Dr. Pacifici did provide VSL with the data that had been collected in the clinical trial prior to its termination, as he was obligated to do; (2) Dr. Pacifici and his collaborators did not comment on or interpret the data and ***did not draw any conclusions based on the incomplete data***; (3) ***Dr. Pacifici and his collaborators were not asked for permission to publish the incomplete data***; (4) Dr. Pacifici and his collaborators did not participate in drafting, review, or publication of the article; and (5) Dr. Pacifici and his collaborators were not even aware that the data was going to be included in a published article.

(Emphasis added.)

73. While the VSL#3 Article's authors claim that the ESDO study was halted early because of delays in enrollment of patients – "slow recruitment" – the truth is that the trial was

stopped as soon as Professor DeSimone informed the study's lead investigator that Actial's version of VSL#3 did not correspond to the original De Simone Formulation. Professor Herbert Valensise, the principal investigator of the ESDO study, confirmed this and further indicated that: (1) the data in the study was neither verified nor returned to Actial; (2) he disregarded all data reported arbitrarily by other scientific reports and the results were neither analyzed nor peer-reviewed; (3) he would take legal action if information from the initial phase of the study was used arbitrarily by a third party; and (4) the ERMPS authors have published a meta-analysis based on data not validated by the underlying investigators.

74. Consistent with their stopping the studies, none of the three clinicians who performed the studies (Dr. Armuzzi, Dr. Pacifici, and Dr. Valensise) or their collaborators is listed as an author of the VSL#3 Article. Such is highly unusual and violates the standards of scientific integrity relating to data and validity.

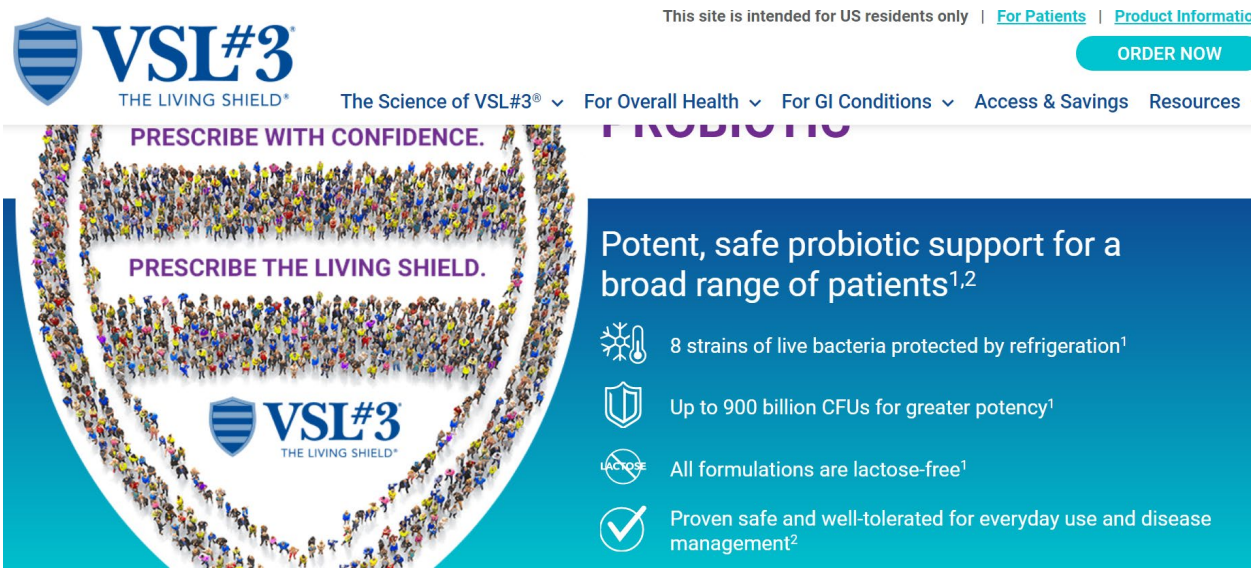
75. Based upon the above, it is clear that the authors of the VSL#3 Article made material misrepresentations about the reasons for the interruption of the three human clinical trials. Such demonstrates the irregularity of the studies themselves and the lack of any previous studies suitable to support the efficacy and safety of Italian VSL#3 in the respective study populations. Furthermore, the three human clinical trials all were halted before any reliable data could be generated. Yet the authors of the VSL#3 Article pressed forward regardless and used such information to draw their ill-founded conclusion that Italian VSL#3 is safe.

F. <u>Use of the VSL#3 Article in Marketing</u>

76. With the publication of the VSL#3 Article and Defendant's continued endorsement of such article for his own benefit and the benefit of its paid sponsor, the Actial Group has a piece of fraudulent commercial advertising in the public sphere (which is then sent directly to physicians

and other healthcare providers) that is masquerading as pseudo-medical literature. Furthermore, with Defendant's publication and continued endorsement of the VSL#3 Article, Actial Group and its affiliates have the (false) basis upon which they can claim that VSL#3 is clinically proven to be safe. They have not hesitated to make this dubious claim.

77. On the first page of the web site https://hcp.vsl3.com ("hcp.vsl.com") that is intended for health care professionals in the United States is the claim that Italian VSL#3 is "[p]roven safe and well-tolerated for everyday use and disease management." The citation for such claim is the VSL#3 Article. *See* https://hcp.vsl3.com (photo captures below).



References: 1. VSL#3® Product Information. Alfasigma USA, Inc.; 2019. **2.** Panetta V, Bacchieri A, Papetti S, De Stefani E, Navarra P. The safety profile of probiotic VSL#3®. A meta-analysis of safety data from double-blind, randomized, placebo-controlled clinical trials. *Eur Rev Med Pharmacol Sci.* 2020;24(2):963-973. **3.** Data on file, ProVoice Survey February 2019 – January 2020. Alfasigma USA, Inc.

78. In addition, on the "Formulation" section of the hcp.vsl.com web site is the claim that "VSL#3® has been studied in double-blind, randomized, placebo-controlled clinical trials and was proven to be safe and well-tolerated." This claim also cites to the VSL#3 Article. *See* https://hcp.vsl3.com/formulation/ (photo captures below).

79. The VSL#3 Article is also cited on the hcp.vsl.com web site for the claim that: "The safety of VSL#3® was similar to the safety profile of a placebo in 3 separate medical studies." *See* https://hcp.vsl3.com/for-ibs/ (photo captures below).

80. In addition, the web site www.vsl3.com states that "VSL#3 has been shown to be safe in multiple clinical trials." *See* https://www.vsl3.com/ibs/safety (photo capture below).

81. For all the reasons explained above, the claims that VSL#3 has been "proven to be safe" and "shown to be safe in multiple clinical trials" are literally false, and the references to "3 separate medical studies" are misleading at best. The referenced studies were authorized upon false pretenses and then shut down prior to generating results that could be verified and relied upon. The VSL#3 Article's authors made an entirely unwarranted conclusion based upon incomplete data from a study that never should have been authorized in the first place. Defendant, despite knowledge of all the issues with the VSL#3 Article, has not withdrawn the article or even provided any sort of editorial correction. Defendant's actions and inactions have contributed directly to the false advertising that has harmed ExeGi and consumers of probiotics who place great weight on the status of a probiotic as being clinically proven safe.

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

82. ExeGi incorporates and adopts by reference each and every one of the foregoing factual allegations in paragraphs 1-81 as if alleged in full in Count I, except as they may be inconsistent with the specific allegations contained in Count I.

83. Alfasigma, a third party, has engaged in false advertising that has injured ExeGi, as found by the jury and by the Court in the Maryland District Court Action. Such false advertising, done in coordination with the Actial Group, proximately caused injury to ExeGi's commercial interest in sales.

84. Alfasigma and VSL Inc. have made a number of false and/or misleading statements in commercial advertising, both in the VSL#3 Article published in ERMPS itself and in statements that were based upon the VSL#3 Article.

85. As to statements based upon the VSL#3 Article, specifically, on the very first page of the web site https://hcp.vsl3.com ("hcp.vsl.com") that is intended for health care professionals in the United States is the claim that Italian VSL#3 is "[p]roven safe and well-tolerated for everyday use and disease management." The citation for such claim is the VSL#3 Article.

86. In addition, on the "Formulation" section of the hcp.vsl.com web site is the claim that "VSL#3® has been studied in double-blind, randomized, placebo-controlled clinical trials and was proven to be safe and well-tolerated." This claim also cites to the VSL#3 Article.

87. The VSL#3 Article is also cited on the hcp.vsl.com web site for the claim that: "The safety of VSL#3® was similar to the safety profile of a placebo in 3 separate medical studies."

88. In addition, the web site www.vsl3.com states that "VSL#3 has been shown to be safe in multiple clinical trials."

89. Such statements regarding safety are false, or at the very least misleading, as the VSL#3 Article is based upon incomplete results of clinical trials that were approved through a fraudulent process. The information and research that was presented to ethics boards and others in charge of approving the clinical trials on Italian VSL#3 related to an entirely different probiotic, the De Simone Formulation. And when such deception was brought to the attention of those in

charge of the clinical trials, the clinical trials were shut down before any reliable data could be generated.

90. The statements and conclusions in the VSL#3 Article used by Alfasigma and VSL Inc. deceived, and/or had the capacity to deceive, wholesalers, suppliers, and consumers, who purchased Italian VSL#3 rather than Visbiome, the lone product that contained the De Simone Formulation from mid-2016 to present.

91. The statements are statements of fact.

92. Even if framed as opinions, the statements in the VSL#3 Article should be treated as statements of (incorrect) fact because they fairly imply a factual basis that justifies the statements.

93. The safety of a probiotic is a key consideration for wholesalers, suppliers, 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 (and is having) a material effect on the purchasing decisions of wholesalers, suppliers, and probiotics consumers.

94. The misrepresented product affects interstate commerce.

95. ExeGi has been and continues to be injured by these misrepresentations, as a direct and proximate result of Defendant'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.

96. Key claims made in marketing and advertising of Italian VSL#3 have been made in and been supported by the VSL#3 Article. Such claims materially help Alfasigma sell VSL#3 to the detriment of ExeGi.

97. Defendant has contributed to the false advertising by knowingly inducing and helping cause it, and he materially participated in it by continuing to publish and refusing to withdraw the VSL#3 Article or provide any sort of editorial correction when he learned: that the clinical studies upon which it was based were fraudulently approved; that studies were incomplete, having been halted when the clinical investigators in charge of the studies learned of the fraudulent approval; that the authors of the article had made misstatements about why the studies had been halted; and that some of the authors and the editor-in-chief of ERMPS at the time of the article's publication had significant conflicts of interest. Defendant was aware that VSL Inc. and Alfasigma were using, and were relying on, the VSL#3 Article in commercial advertising. Defendant, thus, intended to participate in and actually knew about the false advertising of VSL Inc. and Alfasigma and materially furthered the unlawful conduct.

98. As alleged herein, Defendant knew that the VSL#3 Article was based upon analysis of incomplete studies that were fraudulently sanctioned, and he knew or should have known that the VSL#3 Article's analysis of such incomplete and fraudulently sanctioned studies would be likely to confuse customers about Italian VSL#3 and cause them to purchase it rather than Visbiome.

99. Despite this knowledge, Defendant has stood by and not withdrawn – or, at a bare minimum, provided any editorial correction to – the VSL#3 Article, which allows VSL Inc. and its distributors to cite the article and falsely imply that Italian VSL#3 has been through numerous clinical trials and has been determined to be safe. Defendant, therefore, has actively and materially

furthered the unlawful conduct of VSL Inc. and its distributors by working to bring about their false advertising.

100. Defendant's refusal to withdraw the article or provide editorial correction thereto, and his endorsement of such article, is intended to divert sales from Visbiome to Italian VSL#3, and it has successfully caused that diversion.

101. Defendant's actions have directly and proximately caused ExeGi to suffer damages totaling more than $7 million.

COUNT II

Violation of Florida Deceptive and Unfair Trade Practices Act – Fla. Stat., § 501.201, *et seq.*

102. ExeGi incorporates and adopts by reference each and every one of the foregoing factual allegations in paragraphs 1-81 as if alleged in full in Count II, except as they may be inconsistent with the specific allegations contained in Count II.

103. Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA") declares unlawful "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." Fla. Stat. § 501.204(1).

104. Here, Defendant has engaged and is engaging in a deceptive act and unfair practice in the conduct of trade or commerce – specifically, he has refused to withdraw or provide any correction to a fatally flawed VSL#3 Article that was published in the *European Review for Medial and Pharmacological Services* for which he is Editor-in-Chief. Defendant knows that the article is based upon incomplete and improper data from studies that were approved based upon fraudulent information provided to those in charge of the studies. Yet he stands by it.

105. The actions of Defendant are unethical, unscrupulous and are substantially injurious to consumers. Additionally, the actions of Defendant are likely to mislead consumers acting reasonably under the circumstances to the consumers' detriment.

106. As a direct and proximate result of Defendant's actions and inactions with respect to the VSL#3 Article, ExeGi has suffered actual damages totaling more than $7 million.

107. 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.

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

109. The potential continuing injury to ExeGi far outweighs any possible harm to Defendant. In fact, Defendant would help and improve his own standing by withdrawing from publication or correcting the VSL#3 Article.

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

111. Given that Defendant has been made aware of the issues with the studies upon which the VSL#3 Article is based, as well as the fraudulent means by which such studies were approved, Defendant has willfully engaged in such misrepresentations, knowing them to be deceptive and unfair.

COUNT III
(Tortious Interference with Business Relationships)

112. ExeGi incorporates and adopts by reference each and every one of the foregoing factual allegations in paragraphs 1-81 as if alleged in full in Count III, except as they may be inconsistent with the specific allegations contained in Count III.

113. At all relevant times, ExeGi has had valid, ongoing business relationships with wholesalers and distributors of Visbiome, as well as end users of Visbiome, that afford ExeGi legal rights. In addition, ExeGi has had the expectancy of business with other potential wholesalers, distributors, and end users that afford ExeGi prospective legal rights.

114. These relationships are for ExeGi's benefit, as the wholesalers and distributors purchase and sell Visbiome, and the end users also purchase Visbiome.

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

116. Defendant intentionally and without justification has interfered with these relationships by refusing to withdraw from publication, or issue any sort of correction to, the VSL#3 Article, even after becoming aware of the fact that the article is based upon invalid and incomplete data from studies that were shut down because they were approved on fraudulent bases.

117. Such actions were improper and taken without privilege, right, or justifiable cause. Furthermore, such actions induced wholesalers, distributors, and end users of Visbiome to purchase Italian VSL#3 rather than Visbiome and, therefore, not to enter into or continue business relationships with ExeGi.

118. As a direct and proximate result of Defendant's actions and inaction with respect to the VSL#3 Article, wholesalers, distributors, and end users of Visbiome have purchased Italian VSL#3 rather than Visbiome.

119. Defendant's tortious interference with ExeGi's business relationships and prospective business relationships has caused ExeGi to suffer damages totaling more than $7 million.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that the Court enter judgment in its favor, and against Defendant, 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 $7 million; (2) prejudgment and post-judgment interest; (3) injunctive relief requiring Defendant to withdraw, formally, the article published in the *European Review for Medical and Pharmacological Services* titled: "*The safety profile of probiotic VSL#3. A meta-analysis of safety data from double-blind, randomized, placebo-controlled clinical trials*"; and (4) any further relief as the Court may deem just and proper.

B. On Count II (Violation of the Florida Deceptive and Unfair Trade Practices Act – Fla. Stat., § 501.201, *et seq.*): (1) actual damages in an amount to be proven at trial but in no event less than $7 million; (2) prejudgment and post-judgment interest; (3) injunctive relief, requiring Defendant to withdraw, formally, the article published in the *European Review for Medical and Pharmacological Services* titled: "*The safety profile of probiotic VSL#3. A meta-analysis of safety data from double-blind, randomized, placebo-controlled clinical trials*"; and (4) any further relief as the Court may deem just and proper.

C. On Count III (Tortious Interference with Business Relationships), awarding ExeGi: (1) compensatory damages in an amount to be proven at trial but in no event less than $7 million; (2) prejudgment and post-judgment interest; (3) injunctive relief requiring Defendant to withdraw, formally, the article published in the *European Review for Medical and Pharmacological Services* titled: "*The safety profile of probiotic VSL#3. A meta-analysis of safety data from double-blind, randomized, placebo-controlled clinical trials*"; and (4) any further relief as the Court may deem just and proper.

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

DEMAND FOR JURY TRIAL

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

Dated: October 19, 2021

Respectfully submitted,

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