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."

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