



Litigation Fact Sheet

VSL#3® is one of the most potent probiotics in the world.

VSL#3® is a high potency probiotic that is defined by its very high bacterial concentration (hundreds of billions per gram). It is a combination of eight strains of live lactic acid bacteria that has been cultivated, freeze-dried, and mixed in very high concentrations. Due to its potency, all dosage strengths of the probiotic must be refrigerated to protect the bacteria strains. Introduced in the 2000s, VSL#3® Unflavored Powders (450 billion CFU) was the first probiotic on the market with such a high concentration of bacterial cells.

VSL#3® Product Sales

VSL#3® continues to be sold under the same brand and is distributed by major international pharmaceutical partner groups in more than 30 countries worldwide. In the United States, the probiotic is a “medical food”¹ and is available for sale at select retail pharmacies and directly through the company by calling 1-866 GET-VSL3 (438-8753) and at vsl3.com.

After more than 15 years in production, consumers continue to regard VSL#3® as a vital component in helping to manage their specific gastrointestinal conditions. More than 70 million doses were sold worldwide in 2018.

Company Background

VSL#3® was invented in the early 1990s by scientist Renata Vesely, owner of the company Centro Sperimentale del Latte S.r.l., together with several researchers including Bruna Bianchi Salvadori and Claudio De Simone.

Actial Farmaceutica owns the intellectual property rights related to VSL#3® globally, directly or through its subsidiaries, including VSL Pharmaceuticals Inc. in the United States. Actial develops probiotic bacteria products for use as food supplements, medical foods, and pharmaceutical products for various physiological and pathological conditions. The company has a number of patents that cover many aspects and uses of probiotics and the enzymes derived from probiotic bacteria.

In the United States, the VSL#3® trademark is licensed to Alfasigma USA, Inc., which distributes the probiotic among a portfolio of prescription medical food products to help individuals with conditions such as major depressive disorder, diabetic peripheral neuropathy, and mild cognitive impairment.

United States Litigation

Since VSL#3® was first developed nearly twenty years ago, a number of competitor probiotic products have appeared in several international markets. A competing business interest and former VSL Pharmaceuticals Inc. CEO, Claudio De Simone, has been engaged in an ongoing international business dispute and associated litigation with Actial Farmaceutica and its business partners over VSL#3®.

VSL#3[®]'s associated companies in the United States have been sued by De Simone and his related company, and the resulting litigation is currently being played out in the United States District Court for the District of Maryland. In May 2015, De Simone and his company, ExeGi, brought a lawsuit against VSL Pharmaceuticals, Inc. and its U.S. distributors Lediand and Alfasigma, asserting, among other things, claims of false advertising related to the sales and marketing of the VSL#3[®] product.

On November 20, 2018, the United States District Court for the District of Maryland jury ruled in favor of the plaintiffs, returning a verdict finding the defendants liable for false advertising under the Lanham Act. The verdict was general without any specificity about which of the statements the jury found to be false. There also was no finding that De Simone and ExeGi were entitled to punitive damages.²

This litigation is ongoing as Alfasigma and the other defendants assert that the evidence presented at trial did not support the verdict, and in turn, have submitted post-trial motions to set aside or modify the verdict. These motions are pending review in court.

During the ongoing business dispute and litigation, VSL#3[®] can and will continue to be commercialized under its current brand and name. The November 2018 verdict contained no specific findings concerning the quality, production, efficacy, or safety of VSL#3[®]. There has been no legal action prohibiting the sale, production, or distribution of VSL#3[®], and there is no manufacturer recall of the product.³ The product is available in retail pharmacies and directly through Alfasigma.

How the International Business Dispute Started

In 2014, Claudio De Simone resigned his position as president and CEO of VSL Pharmaceuticals, and shortly after, he engaged in a series of tactics designed to hurt VSL#3[®] sales while developing his alternative product and associated businesses. For example, according to court filings, a court injunction barred De Simone from interfering with the VSL#3[®] product supply when immediately upon his departure from VSL Inc., he attempted to prevent the company's ability to purchase the bacteria from Danisco/Dupont, a prior manufacturer of VSL#3[®].⁴

International Court Rulings

The U.S. litigation is part of a much larger global dispute in multiple jurisdictions around the world, including the United Kingdom, Poland, Switzerland, Germany, Italy, India, and South Korea. There have been adverse rulings against De Simone in several of these cases:

- India: A complaint was filed by CD Pharma India in December 2016 against former business directors Claudio De Simone, Kanwaldeep Singh Chada, Partha Dagupta, and Adiya Sahu.
- Korea: The Seoul Central District Court in South Korea found that companies selling De Simone products (Namu-Mulsan Co. and Bio-Eleven) have violated VSL#3[®] trademark rights by using the trademark in connection to a "De Simone" product.⁵ The decision was finalized on March 6, 2019.

- Italy: Actial filed suit against Claudio De Simone for breach of his fiduciary duties. The court is expected to rule in the coming months.

Marketplace Misinformation

Following the November 2018 verdict, De Simone and ExeGi have disseminated false allegations and promoted misinformation in the marketplace about VSL#3[®], the associated companies, and the litigation, including the jury verdict.

The facts on existing misinformation:

- The “De Simone Formulation,” is a marketing term that De Simone coined in 2015 in connection with his lawsuit against VSL Pharmaceuticals Inc. and Alfasigma.
- There has been no finding that VSL#3[®] is a “fake” or “counterfeit” product. VSL Inc. is the owner of all rights, title, and interest to the VSL#3[®] registered trademarks. Alfasigma USA is the exclusive licensee of the VSL#3[®] trademark in the United States.
- Ferring Pharmaceuticals’ decision to remove VSL#3[®] from the Canadian market in 2018 was strictly a business decision and not related to the U.S. or any other international litigation. Ferring also is not a defendant in the U.S. litigation.
- There was no specific finding by the court that the VSL companies made any false statements under the Lanham Act about the composition and clinical history of VSL#3[®].⁶
- The court has not made any specific finding concerning the extensive clinical studies from VSL#3[®]’s over 15-year history. This rich clinical history, particularly for specific gastrointestinal conditions, is supportive of the VSL#3[®] product sold by Alfasigma.

¹ The term medical food is "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."

² Claudio De Simone, et al. v. VSL Pharmaceuticals, Inc., et al. United States District Court For the District of Maryland (Southern Division). (2018).

³ Claudio De Simone, et al. v. VSL Pharmaceuticals, Inc., et al. United States District Court For the District of Maryland (Southern Division). (2018).

⁴ Actial Farmaceutica LDA v. Claudio De Simone, et al. The United Kingdom, In the High Court of Justice, Chancery Division, Before Mr. Justice Norris. (2014, December 18).

⁵ Actial Farmaceutica S.R.L. v. Namu-Mulsan Inc., et al. Seoul Central District Court. Civil Division 62. Conciliation Order.

⁶ Claudio De Simone, et al. v. VSL Pharmaceuticals, Inc., et al. United States District Court For the District of Maryland (Southern Division). (2018).

VSL#3® Fact Check

VSL#3® is a high potency probiotic that is defined by its very high bacterial concentration (hundreds of billions per gram). It is a combination of eight strains of live lactic acid bacteria that has been cultivated, freeze-dried, and mixed in very high concentrations. Due to its potency, all dosage strengths of the probiotic must be refrigerated to protect the bacteria strains. Introduced in the 2000s, VSL#3® Unflavored Powders (450 billion CFU) was the first probiotic on the market with such a high concentration of bacterial cells.

After more than 15 years in production, consumers continue to regard VSL#3® as a vital component in helping to manage their specific gastrointestinal conditions. In 2018 alone, more than 70 million doses of VSL#3® were sold worldwide. VSL#3® is available at select retail pharmacies and directly through the company by calling 1-866 GET-VSL3 (438-8753) and at vsl3.com.

A competing business interest and former VSL Pharmaceuticals Inc. CEO, Claudio De Simone, has engaged in an ongoing international business dispute and associated litigation over VSL#3®. In 2014, shortly after De Simone resigned from the company, he engaged in a series of tactics designed to hurt VSL#3® sales.¹

Litigation between De Simone and VSL Inc. is currently being played out in the U.S. court. In response to circulated misinformation about VSL#3®, the associated companies, and the litigation, here are the facts:

Distortion of the Facts	Fact Check
A November 2018 jury verdict ruled that VSL#3® is a fake or counterfeit product, not the original version.	For over 15 years, VSL#3® has been consistently branded, produced, and commercialized around the world. VSL Pharmaceuticals has always retained its U.S. trademark of the product, currently seen in competitors' use of the trademark symbol when mentioning it. The jury verdict did not make any specific finding that regarding the VSL#3® trademark. ²
Claudio De Simone, invented VSL#3®, called the "De Simone Formulation."	VSL#3® was invented in the 1990s by Renata Vesely, owner of the company Centro Sperimentale del Latte S.r.l, together with several researchers including Bruna Bianchi Salvadori and Claudio De Simone. The "De Simone Formulation," is a marketing term that De Simone coined in 2015 in connection with his lawsuit against VSL Pharmaceuticals Inc. and Alfasigma.
VSL#3®'s rich history of clinical studies can no longer be connected to the probiotic and instead should be connected to a competitor product.	The court has not made any specific finding concerning the extensive clinical studies from VSL#3®'s over 15-year history. This rich clinical history, particularly for specific gastrointestinal

	conditions, is supportive of the VSL#3 [®] product sold by Alfasigma.
Following the November verdict, VSL#3 [®] was removed from market in Canada.	Ferring Pharmaceuticals' decision to remove VSL#3 [®] from the Canadian market was strictly a business decision and not related to the U.S., or any other litigation. Also, Ferring is not a defendant in the U.S. litigation. ³
Serious public health concerns have been raised.	<p>Patient health is at the center of VSL#3[®]. Alfasigma USA follows strict pharmacovigilance practices, tracking any "adverse events," and this tracking has not revealed any safety issues.</p> <p>The November verdict contained no specific findings concerning the quality, production, efficacy, or safety of VSL#3[®].⁴ There has been no legal action prohibiting the sale, production, or distribution of VSL#3[®], and there is no manufacturer recall of the product.</p>

¹ Actial Farmaceutica LDA v. Claudio De Simone, et al. The United Kingdom, In the High Court of Justice, Chancery Division, Before Mr. Justice Norris. (2014, December 18).

² Claudio De Simone, et al. v. VSL Pharmaceuticals, Inc., et al. United States District Court For the District of Maryland (Southern Division). (2018).

³ Claudio De Simone, et al. v. VSL Pharmaceuticals, Inc., et al. United States District Court For the District of Maryland (Southern Division). (2018).

⁴ Claudio De Simone, et al. v. VSL Pharmaceuticals, Inc., et al. United States District Court For the District of Maryland (Southern Division). (2018).