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Probiotic Drug Cos. In Contempt For Violating Ad Injunction

By **Craig Clough**

Law360 (July 31, 2020, 9:58 PM EDT) -- A Maryland federal judge on Thursday ruled that two drug companies are in contempt for violating an injunction that followed an \$18 million jury verdict that they wrongfully used their former business partners' proprietary probiotic formula, saying the companies committed "blatant violations" of the injunction in their promotional materials.

U.S. District Judge Theodore D. Chuang found that VSL Pharmaceuticals, Inc. and Alfasigma USA, Inc. – referred to as the "VSL parties" – violated his permanent injunction following their trial loss to Claudio De Simone and drug company ExeGi Pharma LLC.

The judge said the VSL defendants violated the injunction through statements made in a press release Facebook posts about the value of their products, but stopped short of granting the plaintiffs any share of the profits the VSL defendants may have made as a result of their violations.

Judge Chuang instead opted for an award of attorneys fees and an order to remove any offending materials from public view and a stern warning about any future violations.

"These limited sanctions, including the attorney's fees, are warranted because certain violations, such as the September 2019 Facebook statements, were blatant violations of the permanent injunction, and other violations, such as the claims that VSL#3 is 'clinically proven' persisted over an extended period of time," the judge wrote. "Moreover, the number of different violations demonstrates that the VSL parties' efforts to avoid violations of the permanent injunction were notably deficient."

A jury in November 2018 found that three drug companies were on the hook for more than **\$18 million in damages** for wrongfully using their former business partners' proprietary probiotic formula.

The jury found that Alfasigma USA Inc. owed \$15 million for false advertising violations, VSL Pharmaceuticals Inc. 2.8 million for breach of contract and unjust enrichment and Leadiant Biosciences Inc. \$172,000 for unjust enrichment. The plaintiffs were Italian inventor Claudio De Simone and drug company ExeGi Pharma LLC, which now has the license to sell the probiotic.

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

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

During summary judgment in October 2018, Judge Chuang said that the know-how was De Simone's and that VSL was liable for not paying De Simone royalties, in breach of their patent licensing agreement. All that was left was for the jury to determine damages.

The Lanham Act claims that made up the vast majority of the damage claims were brought by ExeGi,

which now has exclusive rights to sell the probiotic. That drugmaker argued that Alfasigma advertised that the "counterfeit" formulation it was selling after De Simone ended their agreement was the same as what was sold during the partnership.

The court in June 2019 issued a permanent injunction barring the defendants from making certain representations about VSL#3, and the De Simone parties later filed a motion claiming VSL Pharmaceuticals and Alfasigma had violated the injunction.

The VSL parties argued that any violations were "inadvertent and swiftly corrected," the judge said.

The judge ruled that statements the VSL parties made on Facebook that its Italian VSL#3 is "clinically proven" violate the permanent injunction, as did a September 2019 press release in which the De Simone parties' product Visbiome was described as the "generic" version of VSL#3.

"The court finds that the identified violations, which were designed to create a false continuity between Italian VSL#3 and the De Simone Formulation so that VSL#3 could keep its prior customers and potentially poach new ones, caused harm to the De Simone Parties for the reasons set forth" in the court's memorandum opinions, the judge said.

The judge rejected a third accusation that some product information sheets circulated by the VSL parties violated the injunction

The judge also rejected the De Simone parties' request for all or a share of the VSL parties products sales during the relevant time period of the violations.

"The court declines to impose such a sanction," the judge said. "First, although harm can be inferred from these violations, the De Simone Parties have not put forth evidence of quantifiable damages of such a magnitude as would warrant such a remedy."

The judge instead ordered the VSL parties to remove any offending materials from public view and to pay reasonable attorneys fees to the plaintiffs for bringing the motion. He also gave the VSL parties a warning that "any such violations occurring in the future will likely result in more severe sanctions."

Counsel for the defendants did not immediately respond to a request for comment.

"We're pleased that the court has vindicated our position and he agreed with our perspective on that," Jeremy W. Schulman of Schulman Bhattacharya LLC, who represents the plaintiffs, told Law360. "We hope that the defendants will finally heed the court's ruling and abide by it and correct their false statements which have been prejudicing our clients."

De Simone and ExeGi are represented by Jeremy W. Schulman and Jeffrey Gavenman of Schulman Bhattacharya LLC.

VSL Pharmaceuticals is represented by Brian L. Schwalb and Calvin R. Nelson of Venable LLP.

Alfasigma is represented by Mark A. Weissman and Lydia Ferrarese of Herzfeld & Rubin PC; and Robert S. Brennen, Erinn M. Maguire and Annie M. McGuire of Miles & Stockbridge PC.

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

--Editing by Peter Rozovsky.

Correction: A previous version of this article misspelled the name of attorney Jeffrey Gavenman and mislabeled which firms represent the defendants. The errors have been corrected.