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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Drug Cos. Hit With \$18M False Ad Verdict Over Probiotic IP

By **Dani Kass**

Law360 (November 21, 2018, 6:00 PM EST) -- Three drug companies are on the hook for more than \$18 million in damages after a Maryland federal jury found that they wrongfully used their former business partners' proprietary probiotic formula.

U.S. District Judge Theodore D. Chuang signed off on the verdict Wednesday, which found that Alfasigma USA Inc. owed \$15 million for false advertising violations, VSL Pharmaceuticals Inc. owed 2.8 million for breach of contract and unjust enrichment and Leadiant Biosciences Inc. owed \$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.

"We are overjoyed by the results we were able to obtain for our clients, Professor De Simone and ExeGi, during the course of this three-year legal battle," Jeremy Schulman of Schulman Bhattacharya LLC said in a statement. "Establishing that Professor De Simone owns the know-how, winning a large cash judgment, securing a finding of false advertising, and defeating 52 counterclaims aggressively asserted by a team of more than 30 lawyers and staff for the three defendants is very gratifying."

Lead defense counsel at Venable LLP didn't immediately respond to a request for comment Wednesday. Other attorneys for the defendants either deferred to Venable or didn't answer inquiries.

The jury issued its verdict on Tuesday after a 14-day trial.

De Simone first sued in May 2015, accusing VSL and Sigma-Tau Pharmaceuticals Inc. — which has turned into 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.

In response to the suit, VSL and Sigma-Tau filed more than 50 counterclaims, including trademark infringement.

During summary judgment in October, Judge Chuang said the know how was De Simone's and dismissed the infringement claims, among others. The judge also found that VSL was liable for not paying De Simone damages, in breach of their patent licensing agreement.

All that was left was for the jury to determine the amount of damages owed.

The Lanham Act claims that made up the vast majority of the damages were brought by ExeGi, which has exclusive rights to sell the probiotic now. 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.

"They continued to call this knock-off by its original brand name VSL#3, a trademark owned by VSL Pharmaceuticals Inc., and continued to reference the extensive clinical research on the original product showing the original product to be efficacious and safe," Schulman Bhattacharya said in its statement. "During the trial, we proved that the defendants' copy product was not the same as Professor De Simone's original invention and had never been tested in humans to ensure that it performs the same way as the original formula."

The unjust enrichment claims alleged that VSL partnered with supplier Danisco USA Inc. to sell VSL#3 after the licensing agreement ended in Feb. 2015. De Simone had argued that the drugmaker wasn't allowed to buy the products made with his know how, so any money they made off that was unjust.

An attorney who had represented Danisco in the suit last year didn't immediately respond to a request for comment.

De Simone's counsel told Law360 that while this case may be over in the U.S., the inventor is bringing similar suits in South Korea, India, Switzerland, Italy and the U.K., among other countries.

"He's aggressively pursuing all these people all around the world," Schulman said.

De Simone and ExeGi are represented by Jeremy W. Schulman, Jeffrey Gavenman, Koushik Bhattacharya, Sabina Schiller, Jessica Bustamante, Sandra Schiller, Jonathan Barnes and Natalie Moskovchenko of Schulman Bhattacharya LLC.

VSL is represented by Brian L. Schwalb of Venable LLP and Brian Cashmere, Douglas M. Nabhan, Turner A. Broughton and Andrew O. Mathews, of Williams Mullen PC. Leadiant is represented by Charles S. Fax and Liesel J. Schopler of Rifkin Weiner Livingston LLC. Alfasigma is represented by Mark A. Weissman, Lydia Ferrarese and Brian T. Carr of Herzfeld & Rubin PC and Robert S. Brennen of Miles & Stockbridge PC.

Danisco was represented earlier in the litigation by Astor Heaven of Crowell & Moring LLP.

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 Alyssa Miller.