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$15 Million False Ad Verdict Boosts Damages In Probiotic IP Dispute

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On November 20, 2018, a years-long dispute before Judge Theodore Chuang in the District of Maryland over probiotics culminated in a gut-wrenching $18 million jury verdict against defendant pharmaceutical companies. The case is *De Simone v. VSL Pharmaceuticals, Inc. et al.*, No. 8:15-cv-01356.

The dispute involved numerous claims and counterclaims, including both a claim and a counterclaim for false advertising under the Lanham Act. While the advertising-related issues appeared initially to be only a small part of the case, overshadowed by the 50-plus other claims and counterclaims asserted by the various parties, plaintiff's false advertising claim ultimately proved the most lucrative part of the case, making up a hearty $15 million of the $18 million verdict.

The lawsuit was initiated by Claudio De Simone, the inventor of the probiotic formula at issue, and ExeGi Pharma, the company currently licensed to sell De Simone's probiotics. In 2000, De Simone co-founded VSL Pharmaceuticals, which entered into a joint venture with Alfasigma USA and Leadiant Biosciences to sell De Simone's probiotic formula under the name VSL#3. De Simone later left VSL, ended the joint venture, and began selling his probiotic formula with ExeGi under a new name, Visbiome. De Simone and ExeGi advertised Visbiome as the only probiotic on the market that contains De Simone's original probiotic formula. Meanwhile, defendants Alfasigma and Leadiant continued to sell a probiotic formula under the VSL#3 name, and advertised that product as being exactly the same as De Simone's original probiotic formula. De Simone and ExeGi subsequently filed this lawsuit, asserting a variety of claims, including breach of license agreement, unjust enrichment, and false advertising under the Lanham Act. Defendants responded with over fifty counterclaims, including with their own Lanham Act false advertising claim.

At the heart of both sides' false advertising claims was the question of whether defendants' current formula for VSL#3 was clinically equivalent to Visbiome and to De Simone's original formula of VSL#3 sold during the joint venture. Defendants argued it was. Therefore, they alleged that De Simone and ExeGi engaged in false advertising by marketing Visbiome as the only brand that contains the original De Simone probiotic formula. On the flip side, De Simone and ExeGi argued that defendants' current VSL#3 product was different from Visbiome and from De Simone's original probiotic formula, and that Alfasigma and Leadient therefore engaged in false advertising in marketing their new version of VSL#3 as being exactly the same as De Simone's original probiotic formula. Specifically, De Simone argued that defendants' new version was made with cheaper, untested ingredients, and was therefore less effective.

The jury ultimately sided with De Simone and ExeGi, finding that the defendants' new VSL#3 product differed from De Simone's original probiotic formula, and that Alfasigma and Leadient engaged in false advertising in marketing their new product as identical to De Simone's formula sold during the time of the joint venture. The jury also found defendants liable for breach of contract and unjust enrichment, but it was the $15 million it awarded for the Lanham Act false advertising claim that truly made this judgment a bitter pill for defendants to swallow . Briefing concerning damages calculations under the Lanham Act were filed under seal, so it is not entirely apparent how the jury arrived at this $15 million figure, particularly for a claim that did not initially seem to be a focal point of the case. However, certain trial briefings and jury instructions suggest that Plaintiffs sought to disgorge Defendants' profits that were attributable to Defendants' false advertising of the VSL#3 product. In addition, Defendants' motion for a new trial filed on December 19, 2018 argues that an inflamed jury improperly inflated the

false advertising damages as “quasi-punitive damages” based on Plaintiffs’ counsel’s improper argument on the safety of VSL#3, which was not at issue in the case.

Watch this space for further developments.

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