

Second Circuit Holds That Conclusions in Scientific Study Are Not Actionable as False Advertising

Can a company state a claim for relief for false advertising based on its competitor's sponsoring and promoting a scientific study on the ground that the study's conclusions are allegedly incorrect and therefore false? In a recent decision of particular importance to advertisers of pharmaceutical products, the Second Circuit answered in the negative, holding that a study's conclusions were protected speech under the First Amendment.

Background

Ony and Chiesi manufacture competing drugs for the treatment of respiratory distress in neonatal infants. According to Ony's complaint, Chiesi paid to have a database created containing effectiveness data on the parties' drugs. Chiesi then hired doctors to present the data at medical conferences. The doctors ultimately published an article, appearing in a peer-reviewed medical journal, which concluded that Chiesi's drug was associated with a lower rate of infant mortality than Ony's drug. Chiesi distributed the study and used the study's conclusions in its promotional material.

Ony alleged that the study was methodologically unsound because, among other things, the study addressed only mortality rate data and did not include in its analysis the data relating to another key endpoint (length of hospital stay) that would have shown the effectiveness of Ony's drug. Ony asserted a claim against Chiesi for false advertising under the Lanham Act, as well as state law unfair trade practices and common law tort claims. The district court dismissed the complaint in its entirety, and the Second Circuit affirmed.

The Second Circuit's Ruling

The Second Circuit held that the study's publication itself was not actionable. Generally, the First Amendment protects statements of opinion but not false or misleading statements of fact. While scientific conclusions are, in theory, statements of fact, courts are not well-equipped to be arbiters of the truth of scientific facts, particularly in the context of academic or scholarly research directed at educated readers. The Second Circuit concluded that "to the extent a speaker or author draws conclusions from non-fraudulent data, based on accurate descriptions of the data and methodology underlying those conclusions, on subjects about which there is a legitimate ongoing scientific disagreement, those statements are not grounds for a claim of false advertising." The court rejected the argument that Ony could state a claim for false advertising because, according to Ony, "competent scientists" would have included other variables from the database in their analysis. Importantly, Ony did not allege that the data the authors chose to present in the article were fabricated or fraudulently created. The court's conclusions also applied to Ony's claims for unfair trade practices under New York General Business Law § 349 and to Ony's claims under New York common law.

The Court of Appeals also held that Chiesi's use of the study's conclusions in promotional materials was not actionable as tortious interference with prospective business relations, because Ony did not allege that Chiesi misstated the study's conclusions. (The Court of Appeals did not specifically address whether the use of the study's conclusions in promotional materials could constitute false advertising, perhaps because Ony did not raise this argument on appeal.) Finally, the court held that Ony could not claim any injury resulting from the relationship between the study's authors and Chiesi, because the authors disclosed the potential conflict of interest.

Notably, the court did not address the threshold question of whether the publication of the article, or whether Ony's subsequent dissemination of the article, was "commercial advertising or promotion" as required to state a claim under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

Lessons From *Ony, Inc. v. Cornerstone Therapeutics, Inc.*

While the court's opinion signals that the conclusions of a scientific study can be subject to significant First Amendment protection, it does not foreclose false advertising claims based on the use of a study in promotional materials (or based on studies that use fabricated data, for example). A defendant that misstates a study's conclusions or data or omits material data in promotional or advertising materials could still be subject to a false advertising claim. Nor did the court address whether a defendant that promotes the conclusions of one scientific study by expressly or impliedly stating that the conclusions were "proved" by the study, without mentioning contrary results of other, more rigorous or more numerous studies, would be subject to a so-called establishment claim. Similarly, the court did not address the cases that have held that an establishment claim can be based on the accurate reporting of an unreliable study.

The case is *Ony, Inc. v. Cornerstone Therapeutics, Inc.*, No. 12-2414-CV, --- F.3d ----, 2013 WL 3198153, 2013 U.S. App. LEXIS 13067 (2d Cir. June 26, 2013), *aff'g*, No. 11-CV-1027S, 2012 WL 1835671, 2012 U.S. Dist. LEXIS 69956 (W.D.N.Y. May 18, 2012). The Second Circuit's slip opinion can be found [here](#).

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