

PRODUCT LIABILITY

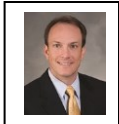
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In ONY, Inc. v. Cornerstone Therapeutics, Inc., the Second Circuit recently held that statements of scientific opinion made about a competitor's product cannot give rise to claims of false advertising under the Lanham Act or state consumer protection laws. This article explores the oftentimes blurry line between protected statements of opinion and misleading commercial speech in false advertising cases and highlights the continued importance of First Amendment principles in cases involving scientific debates.

False Advertising, Scientific Opinion and the First Amendment – The Second Circuit's Opinion in *Ony, Inc. v. Cornerstone Therapeutics, Inc.*

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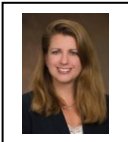


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It is well established that commercial speech enjoys First Amendment protection, but that misleading commercial speech can give rise to liability to both competitors and consumers for false advertising or similar claims. When commercial speech involves a matter of scientific debate, the line between protected speech and an actionable misleading statement can be particularly difficult to identify. The Second Circuit addressed this issue recently in *ONY, Inc. v. Cornerstone Therapeutics, Inc.*,¹ where it held that statements “based on accurate descriptions of the data and methodology underlying those conclusions, on subjects about which there is legitimate ongoing scientific disagreement” cannot give rise to claims of false advertising under the Lanham Act or state consumer protection law. As this article will discuss below, the Second Circuit’s decision is an important reminder that parties involved in false advertising cases that turn on disputed scientific issues should continue to pay close attention to the impact First Amendment principles can have on the outcome.

Fact versus Opinion

The sometimes blurry line between fact and opinion lies at the heart of false advertising law, and identifying that line is a primary issue in false advertising cases involving disputed scientific issues. Statements of opinion have long been protected under First Amendment jurisprudence, stemming from the common law “fair comment” doctrine, which safeguards the right to speak on matters of public affairs and engage in public debate. In its 1964 *Garrison v. Louisiana*² decision, the Supreme Court held that only “calculated falsehoods” could be denied constitutional protection. The federal

Lanham Act similarly prohibits false or misleading descriptions or representations of fact “in commercial advertising or promotion” regarding “the nature, characteristics, qualities, or geographic origin of ... goods, services, or commercial activities.”³ In adjudicating claims based on the Lanham Act, courts have interpreted it to apply to statements only if they are “literally false” or “though literally true, likely to mislead or confuse consumers;” statements of opinion generally did not give rise to Lanham Act liability,⁴ and the same is true for many state consumer protection statutes that govern consumer false advertising claims.

The Second Circuit’s *ONY* Decision

In *ONY*, a pharmaceutical company sued a rival company for false advertising, after the rival company sponsored and published a scientific study which allegedly showed that the rival’s product was superior. Both parties were producers of surfactant, a product which helps improve lung function in premature infants. The defendant hired third parties to conduct a study comparing the effectiveness of each company’s surfactant and then present the findings at different medical conferences and also disseminated the findings via press releases and promotional materials. The plaintiff took issue with defendant’s statements noting that its competitor’s product was associated with a 49.6% greater likelihood of death than its own product, and that even after adjusting for gestational age and birth weight, there was lower mortality among infants who received its surfactant compared with infants who received

³ 15 U.S.C. § 1125(a)(1)(B).

⁴ *Groden v. Random House, Inc.*, 61 F.3d 1045 (2d Cir. 1995) (holding that the statement “guilty of misleading the American public” is “obviously” a statement of opinion that could not be reasonably seen as “implying provable facts” under the Lanham Act).

¹ 720 F.3d 490 (2d Cir. June 26, 2013).

² 379 U.S. 64 (1964).

plaintiff's surfactant. The plaintiff argued that the information in the defendant's article omitted other pertinent scientific information, such data on the infants' length of stay in the hospital, that would inform readers as to why different mortality rates were found in the study. In the plaintiff's view, the scientific statements in the articles were *intentionally* deceptive and misleading because they failed to give an accurate picture of the scientific evidence.

The issue before the Second Circuit was when can statements reporting "research results" lead to false advertising claims. The court concluded as a matter of law that "statements of scientific conclusions about unsettled matters of scientific debate cannot give rise to liability for damages sounding in defamation" and that "secondary distribution of excerpts of such an article cannot give rise to liability, so long as the excerpts do not mislead a reader about the conclusions of the article."

In reaching its decision, the court noted that when a statement is made within the context of an ongoing scientific debate "about which there is considerable disagreement," then the "dividing line between fact and opinion" often employed in First Amendment analysis "is not entirely helpful." Thus, even though the plaintiff alleged that the published study contained "false statements of fact," the Second Circuit found that the scientific statements were opinions which could not give rise to claims of false advertising. As the court explained, it is "the essence of the scientific method that the conclusions of empirical research are tentative and subject to revision." Statements concerning "contested and contestable scientific hypotheses" are more "closely akin to matters of opinion" rather than fact, meant to be understood "by the relevant scientific communities." The Second Circuit added that courts are "ill-equipped to undertake to referee such

controversies" and that the "trial of ideas" will instead play out "in the pages of peer-reviewed journals" where the "scientific public sits as the jury."

The court highlighted the fact that the plaintiff did not allege that the data in the article was "fabricated" or "fraudulently created," as opposed to claiming that the "inferences" drawn from the data were incorrect and misleading. The court also relied on the fact that the scientific study published the relevant data and discussed both the study's limitations and potential conflicts of interest. The court would have found the case more difficult had the plaintiff alleged "that the data presented in the article were fabricated or fraudulently created" versus a disagreement with the ultimate conclusions of the study. Here, "when the conclusions reached by experiments are presented alongside an accurate description of the data taken into account and the methods used, the validity of the authors' conclusions may be assessed on their face by other members of the relevant discipline or specialty."

The Western District of Texas's *Eastman Chemical* Decision

Applying the Second Circuit's holding beyond the facts in *ONY* may not be straightforward, and the safe harbor for statements of scientific opinion identified in *ONY* is likely a narrow one, as evidenced by the Western District of Texas's treatment of *ONY* in the first decision applying its holding, *Eastman Chem. Co. v. PlastiPure, Inc.*⁵

In *Eastman Chemical*, a plastic resin producer brought a false advertising claim against a competitor, claiming the defendant made false and misleading statements about plaintiff's product in press releases, an advertising

⁵ 2013 WL 4677702 (W.D. Tex. Aug. 30, 2013).

brochure, and on its website. Specifically, plaintiff argued that the defendant improperly claimed that plaintiff's resin product posed a health hazard to humans by leaching chemicals "capable of causing estrogenic activity when subject to various stressors." The plaintiff presented evidence that its resin product did not "exhibit estrogenic activity" or leach chemicals capable of causing this activity "after being subjected to common-use stressors." Importantly, no evidence was presented by either side supporting the claim that plaintiff's product was "actually harmful to humans." Therefore, the plaintiff argued that defendant's claims were an alleged mischaracterization and distortion of the science on which the statements were based.

In response, the defendant cited *ONY* and argued that its statements were "matters of scientific debate protected by the First Amendment." In declining to apply the holding in *ONY*, the *Eastman* court characterized the dispute in that case as involving statements in an article in a published, peer-review scientific journal. Conversely, in *Eastman*, the plaintiff challenged statements in "non-scientific materials" such as press releases, "none of which included the full context of the [underlying] scientific paper." The plaintiff also challenged statements which "pre-dated" the publication of the relevant article. According to the court, the "scientific debate" in *Eastman* did not take place within the "pages of academic journals," but rather in "commercial advertisements targeted at consumers." Therefore, the *Eastman* court viewed the scientific debate as a standard "battle of the experts," which was proper for the jury to resolve.

Conclusion

The contours of these two decisions and others applying First Amendment principles to issues of scientific debate are important for any advertiser addressing an issue of scientific opinion, and the extent of First Amendment protection for such statements will continue to be difficult to identify. For example, the *Eastman* court distinguished statements made to consumers in "commercial advertisements or promotions" from those made to other scientists within the context of a peer-reviewed journal, but the court did not address the fact that *ONY* also involved statements about the study made in promotional materials as opposed to scientific journals. According to the *Eastman* court, the statements made in that case were "without the necessary context presented by a full scientific study, such as a description of the data, the experimental methodology, the potential conflicts of interest, and the differences between raw data and the conclusions drawn by the researcher," but this description perhaps raises more questions than it answers. For example, what if promotional material links to the full publication of a study on a website but does not include it in the material itself? And what does it mean to properly disclose the underlying data and methodology? And what if the advertiser is describing an entire body of studies on a particular topic all of which cannot be included in the publication? The individual factual situations are no doubt endless, and advertisers intending to address a matter of scientific debate would be well advised to evaluate their statements against the principles outlined in these decisions in an effort to maximize the chances of First Amendment protection.

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