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## ARTICLES

# TRUTH IN ADVERTISING: APPLYING COMMERCIAL SPEECH REGULATIONS TO THE SECONDARY DISSEMINATION OF SCIENTIFIC RESEARCH PUBLICATIONS

CODY CORLISS<sup>†</sup>

### INTRODUCTION

As the biological substance that coats the surface of the lungs, surfactant is critical to human life. Surfactants play a key role in lung function by facilitating the transfer of oxygen from inhaled air into the blood stream. Although the human body naturally produces surfactants, premature babies often cannot produce an adequate surfactant level required for proper lung functioning. As a result, such babies are particularly susceptible to lung collapse and Respiratory Distress Syndrome, a condition that can cause respiratory failure and death.

A number of nonbiological surfactant solutions are available to keep neonatal infants breathing. ONY, a biopharmaceutical company in New York, produces one such product called “Infasurf,” which is derived from bovine lung surfactant. ONY’s chief competitor Chiesi and its American distributor Cornerstone Therapeutics offer a competing surfactant called “Curosurf,” which is derived from porcine lung mince.

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The two products compete in the marketplace and champion the relative superiority of their respective surfactant products. As part of its research program, Chiesi, the manufacturer of Curosurf, hired a number of medical doctors to research the effectiveness of its product. The doctors' study determined that neonatal infants using Chiesi's product are more likely to survive than neonatal infants given ONY's Infasurf. After concluding their research, the doctors published their findings in a medical journal. Once that scientific article was published, Chiesi and Cornerstone issued press releases touting the article's conclusions and distributed its own promotional materials that cited and quoted the scientific publication. ONY offered a vigorous rebuttal: company scientists wrote letters to scientific journals that rebutted the Chiesi study's research methodology. Most interestingly for the purposes of this Article, ONY also filed suit regarding Chiesi and Cornerstone's scientific claims, alleging that use of the scientific article's conclusions in Chiesi's promotional materials violated the Lanham Act.

Is the science in the journal and its resulting promotional use commercial promotion subject to regulation under the Lanham Act, the federal statute regulating false advertising and promotion? The United States Court of Appeals for the Second Circuit held that it was not<sup>1</sup>: "[A]s a matter of law, statements of scientific conclusions about unsettled matters of scientific debate cannot give rise to liability for damages sounding in defamation."<sup>2</sup> The court went even further, concluding that "the 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."<sup>3</sup>

One year later, the Fifth Circuit took up a different false advertising case also stemming from the publication of scientific findings.<sup>4</sup> There, Eastman Chemical Company, the manufacturer of a plastic resin product used in water bottles and food containers, filed suit against two of its competitors, PlastiPure and CertiChem.<sup>5</sup> Eastman alleged that its competitors made false and misleading statements in violation of

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<sup>1</sup> ONY, Inc. v. Cornerstone Therapeutics, Inc., 720 F.3d 490, 492 (2d Cir. 2013).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> Eastman Chem. Co. v. Plastipure, Inc., 775 F.3d 230, 233 (5th Cir. 2014).

<sup>5</sup> *Id.* at 233-34.

the Lanham Act when they claimed that Eastman's products leached chemicals capable of causing human harm.<sup>6</sup> Like in *ONY*, a scientific article was the center of the controversy.<sup>7</sup> Here, CertiChem-backed scientists published an article in a peer-reviewed scientific journal claiming that Eastman Chemicals products had the potential to activate estrogen receptors in the human body and trigger hormone-dependent cancers.<sup>8</sup> After research on the article was completed, but before the article's publication, PlastiPure published a three-page sales brochure that noted the research. The sales brochure contained a chart that depicted Eastman Chemical's products as having significant levels of estrogen-triggering activity ("EA").<sup>9</sup> At trial, the jury found for Eastman, finding that PlastiPure and CertiChem had made false advertising statements about Eastman's product, thereby violating the Lanham Act.<sup>10</sup> The Fifth Circuit agreed that the Lanham Act applied to the use of the scientific findings in PlastiPure's advertising, reasoning that "[a]dvertisements do not become immune from Lanham Act scrutiny simply because their claims are open to scientific or public debate."<sup>11</sup>

The First Amendment protects academic freedom, scientific inquiry, and scientific publication, but what protection applies when scientific findings are distributed as commercial speech outside their initial academic realm? Commercial speech is subject to the Lanham Act prohibition against false or misleading statements of fact used in advertising or promotion. At what point does protected scientific inquiry transform into commercial speech that is subject to the stricter Lanham Act scrutiny? These two recent circuit court decisions have only blurred the distinction; the two decisions differed on whether commercial speech standards apply when false or misleading scientific results are distributed beyond their initial academic spheres. The result is an uneven judicial landscape on the evaluation of false advertising claims involving scientific research. This Article examines the peculiarities of the Lanham Act and the use of scientific findings in advertising or promotion. This Article

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<sup>6</sup> *Id.* at 234.

<sup>7</sup> *ONY, Inc.*, 720 F.3d at 492.

<sup>8</sup> *Eastman Chem. Co.*, 775 F.3d at 233–34.

<sup>9</sup> *Id.*

<sup>10</sup> *Id.* at 234.

<sup>11</sup> *Id.* at 236.

also argues that the Fifth Circuit's *Eastman* decision is the better model than what is used in the Second Circuit. If the distribution of noncommercial speech serves any commercial purpose, the speech becomes commercial and is regulated by the Lanham Act. Although the Second Circuit noted that "it is the essence of the scientific method that the conclusions of empirical research are tentative and subject to revision,"<sup>12</sup> the Lanham Act holds distributors to a higher standard.<sup>13</sup> A distributor of academic statements in advertising or promotion must guarantee that the statements and findings it distributes are true so as not to mislead the public. Sophisticated scientists may understand that academic research articles are subject to later revision, but the general population is less likely to understand such a distinction. The *ONY* holding will immunize advertisers who rely on science, to the ultimate detriment of consumers who are likely to believe that scientific findings constitute "facts."

Part I of this Article examines the Lanham Act generally and the Act's regulation of commercial speech. Part II reviews the interplay between the Lanham Act and the First Amendment protections afforded to scientific inquiry and scientific publication. It then examines the secondary dissemination of scientific findings, arguing that a third party's dissemination of the scientific findings or a press release quoting those findings constitutes commercial speech that should be regulated by the Lanham Act. This Article explores how the recent *ONY* decision has the potential to chill Lanham Act litigation, and it argues that future decisions following *ONY*'s logic could foreclose Lanham Act litigation where the truth of scientific findings may be at issue. Lastly, this Article contends that future Lanham Act decisions should instead follow the logic of the Fifth Circuit's *Eastman* decision, which properly keeps the secondary dissemination of scientific publications under the ambit of the Lanham Act.

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<sup>12</sup> *ONY, Inc.*, 720 F.3d at 496.

<sup>13</sup> See *Eastman Chem. Co.*, 775 F.3d at 236.

I. HISTORY OF THE LANHAM ACT & KEY ELEMENTS TO  
CONSIDER FOR SCIENTIFIC SPEECH USED IN COMMERCIAL  
ADVERTISING

A. *General Background of the Lanham Act Regulating  
Commercial Speech*

An understanding of the Lanham Act and its effect on commercial speech can best be understood through an examination of the history and elements of the Act. As an initial matter, § 43(a) of the Lanham Act proscribes false statements or false representations made in commercial advertising or promotion.<sup>14</sup> The Lanham Act provides a private right of action for unfair competition claims based on false advertising.<sup>15</sup> In recent years, the Lanham Act has become a powerful tool in the battle for market supremacy. A Lanham Act suit from a competitor can stall a new or rising entrant in the marketplace and increase a rival's cost of doing business.<sup>16</sup> Given its power as a business weapon, an examination of Lanham Act suits suggests that many are unlikely to have much impact on consumer welfare.<sup>17</sup> Moreover, as one scholar argued, the threat of Lanham

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<sup>14</sup> Trademark Act of 1946 § 43(a), 15 U.S.C. § 1125(a)(1)(B) (2012).

<sup>15</sup> § 1125(a)(1).

<sup>16</sup> Jean Wegman Burns, *Confused Jurisprudence: False Advertising Under the Lanham Act*, 79 B.U. L. REV. 807, 809 (1999).

<sup>17</sup> See, e.g., *Abdallah v. Pileggi*, No. 97-1581, 1998 WL 180491, at \*1 (Fed. Cir. Apr. 17, 1998) (alleging that a company falsely represented that its necktie was patented); *United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1178 (8th Cir. 1998) (claiming that an advertisement's wording and images misrepresented that it killed roaches within twenty-four hours); *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 941 (3d Cir. 1993) (claiming that a motor oil company deceptively claimed its product "outperforms any leading motor oil against viscosity breakdown"); *Twentieth Century Fox Film Corp. v. Suarez Corp. Indus.*, No. 98 Civ. 1711(WK), 1998 WL 126065, at \*1 (S.D.N.Y. Mar. 19, 1998) (claiming a necklace was not an authorized copy of a piece of jewelry in a movie); *Avon Prods., Inc. v. S.C. Johnson & Son, Inc.*, 984 F. Supp. 768, 796 (S.D.N.Y. 1997) (claiming that a lotion did not actually act as a bug repellent); *Playtex Prods., Inc. v. Gerber Prods. Co.*, 981 F. Supp. 827, 828 (S.D.N.Y. 1997) (alleging falsity where competitor falsely represented that its cup was fifty percent easier to drink from than a competitor's cup); *Heublein, Inc. v. E & J Gallo Winery, Inc.*, No. 94CIV.9155 (JFK)(AJP), 1995 WL 168846, at \*3 (S.D.N.Y. Apr. 7, 1995) (claiming that an alcoholic drink was mislabeled "Margarita" when it only contained margarita flavoring and no tequila); *Kraft Gen. Foods, Inc. v. Del Monte Corp.*, No. 93 CV. 4413, 1993 WL 557864, at \*42 (S.D.N.Y. Sept. 22, 1993) (claiming that "gelatin" was used on a product that was not actually vegetable based); *Complaint at ¶ 3, Sony Comput. Entm't Am. LLC v. Bridgestone Ams., Inc.*, No. C 12 4753 LB, 2012 WL 4339671 (N.D. Cal. Sept. 11, 2012) (claiming that a tire

Act litigation leads companies to avoid “hard-edged, but truthful, advertising” in favor of safe, less-informative ads that are less likely to provide grounds for a Lanham Act suit.<sup>18</sup>

*B. The History of the Lanham Act and Its 1988 Amendments*

In its sixty years of existence, the Lanham Act, the chief U.S. law regulating commercial speech, has provided a flexible legal framework to regulate competition in the marketplace.<sup>19</sup> An understanding of the Act and its history is important to understand the legal interpretations regarding the Lanham Act and the regulation of commercial speech.<sup>20</sup>

In 1946, Congress passed the Lanham Act, formally codifying the federal trademark law,<sup>21</sup> to “place all matters relating to trade-marks in one statute and to eliminate judicial obscurity, to simplify registration and to make it stronger and more liberal, to dispense with mere technical prohibitions and arbitrary provisions, to make procedure simple, and relief against infringement prompt and effective.”<sup>22</sup> Although, in the words of one court, the Lanham Act brought the “creation of a ‘new statutory tort’ intended to secure a market-place free from deceitful marketing practices,”<sup>23</sup> the Act was rarely invoked for

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company’s commercials misled the public when it hired an actor who had previously appeared in a series of video game commercials).

<sup>18</sup> Burns, *supra* note 16, at 809.

<sup>19</sup> See Joseph D. Garon, *The Lanham Act: A Living Thing*, 7 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 55, 56 (1996) (writing that the Lanham Act has proven to be a flexibility to adapt to vast and unpredictable changes in the business world); *id.* at 56 n.6 (“Like our U.S. Constitution which was drafted by the framers to be applicable and adaptable in any age, so too can the Lanham Act be interpreted to apply to current legal problems and to deal with changing political, economic and moral issues.” (quoting Randy Lipsitz, *Judging by Appearance: How the Lanham Act Protects Product Shapes; Issue Continues To Confound Lawyers*, N.Y.L.J., Dec. 2, 1996, at S4)).

<sup>20</sup> See, e.g., Mark A. Lemley, *The Modern Lanham Act and the Death of Common Sense*, 108 YALE L.J. 1687, 1710–15 (1999) (arguing that courts should not construe the Lanham Act as a broad anticopying statute partly because some commercial uses of a trademark are important in societal discourse); Rebecca Tushnet, Trademark Law as Commercial Speech Regulation, 58 S.C. L. REV. 737, 737–39 (2007) (noting the difficulties of establishing clear boundaries between commercial speech regulated by the Lanham Act and the First Amendment).

<sup>21</sup> Lanham Act, Pub. L. No. 79-489, § 46(a), 60 Stat. 427 (1946) (codified as amended in scattered sections of 15 U.S.C.).

<sup>22</sup> S. REP. NO. 79-1333, at 3 (1946), as reprinted in 1946 U.S.C.C.A.N. 1274, 1274.

<sup>23</sup> Johnson & Johnson v. Carter-Wallace, Inc., 631 F.2d 186, 189 (2d Cir. 1980).

the first thirty years following its enactment.<sup>24</sup> In the 1970s and 1980s, however, a significant increase in Lanham Act related litigation greatly expanded the scope of the Act beyond mere trademark infringement and into the realm of alleged deceitful statements about products or services.<sup>25</sup>

Prior to 1988, nearly all Lanham Act cases involved traditional advertising.<sup>26</sup> A revision of the Act by Congress in 1988 set the stage for the further regulation of commercial speech.<sup>27</sup> As part of these revisions, Congress rewrote § 43(a). The two parts of § 43(a) concern (1) false designations of origins and (2) false advertising or promotion.<sup>28</sup> The pertinent section reads:

(1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—

(A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or

(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.<sup>29</sup>

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<sup>24</sup> Burns, *supra* note 16, at 816 (describing the Lanham Act as being “largely dormant for almost thirty-five years”).

<sup>25</sup> See *id.* at 816–17; Ashley N. Calhoun, Comment, *Winking in the Dark: An Analysis of Corrective-Advertising Damages Under the Lanham Act and the Effect on the American Economy*, 32 STETSON L. REV. 821, 825 (2003).

<sup>26</sup> Burns, *supra* note 16, at 819.

<sup>27</sup> See Trademark Law Revision Act of 1988, Pub. L. No. 100-667, § 132, 102 Stat. 3935, 3946 (codified as amended in 15 U.S.C. § 1125(a) (2012)). The amendments took effect in 1989.

<sup>28</sup> 15 U.S.C. § 1125(a)(1).

<sup>29</sup> *Id.*

The legislative history regarding the revisions has increased confusion, rather than clarified matters.<sup>30</sup> The Senate Report noted that the modifications to § 43(a) were designed “to codify the interpretation [that § 43(a)] has been given by the courts.”<sup>31</sup> Still, as one scholar noted, the 1988 Congressional revisions overruled some aspects of prior case law.<sup>32</sup> For example, where Congress made the new § 43(a)(1)(B) applicable to the misrepresentations about a plaintiff's product, Congress overruled prior lower court decisions interpreting the original § 43(a) to apply only to statements about a defendant's own product.<sup>33</sup> Legal decisions in the intervening years have largely established the Lanham Act principles that the 1988 congressional reforms failed to clarify.<sup>34</sup>

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<sup>30</sup> See, e.g., Burns, *supra* note 16, at 820 (writing that the scant legislative history and the actual text of that history “creates as much confusion as clarity”); Frank Z. Hellwig, *The Trademark Law Revision Act of 1988: The 100th Congress Leaves Its Mark*, 79 TRADEMARK REP. 287, 311 (1989) (noting that “due to a lack of a unifying legislative history, the drawback is that [§ 43(a)] will continue to be a source of much controversy and litigation necessary to clarify it”).

<sup>31</sup> S. REP. NO. 100-515, at 2 (1988), as reprinted in 1988 U.S.C.C.A.N. 5577, 5603.

<sup>32</sup> Burns, *supra* note 16, at 821 (writing that Congress intentionally overruled prior case law).

<sup>33</sup> See, e.g., *U.S. Healthcare, Inc. v. Blue Cross*, 898 F.2d 914, 921 (3d Cir. 1990); *Bernard Food Indus., Inc. v. Dietene Co.*, 415 F.2d 1279, 1283 (7th Cir. 1969); *Skil Corp. v. Rockwell Int'l Corp.*, 375 F. Supp. 777, 782–83 (N.D. Ill. 1974) (allowing an action based on false statements in comparative advertising where a defendant allegedly misrepresented both its product and the plaintiff's product).

<sup>34</sup> For example, although the Lanham Act is often regarded as a consumer welfare statute and the language of the congressional direction suggested that consumers were intended to have standing, a recent United States Supreme Court decision affirmed the widespread federal court decisions that held that Lanham Act standing is not available to the actual consumers who are injured by false advertising. *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1388 (2014) (“Read literally, that broad language [of § 43(a)] might suggest that an action is available to anyone who can satisfy the minimum requirements of Article III. No party makes that argument, however, and the ‘unlikelihood that Congress meant to allow all factually injured plaintiffs to recover persuades us that [§ 1125(a)] should not get such an expansive reading.’” (second alteration in original) (quoting *Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 266 (1992))); see also *Conte Bros. Auto., Inc. v. Quaker State-Slick 50, Inc.*, 165 F.3d 221, 229 (3d Cir. 1998) (“Conferring standing to the full extent implied by the text of § 43(a) would give standing to parties, such as consumers, having no competitive or commercial interests affected by the conduct at issue.”), *abrogated by Lexmark Int'l, Inc.*, 134 S. Ct. at 1391–93. Federal courts have unanimously rejected the right of consumers to bring a suit under the Lanham Act. *Lexmark Int'l, Inc.* 134 S. Ct. at 1390 (“A consumer who is hoodwinked into purchasing a disappointing product may well have an injury-in-fact cognizable under Article III, but he cannot invoke the protection of

### C. *The Lanham Act's Key Elements*

To prevail on a false advertising claim, the traditional analysis is that a plaintiff must prove five elements: (1) the existence of a defendant's false statement of fact about its own or another product in a commercial advertisement; (2) that the statement actually deceived or had the tendency to deceive a substantial segment of the audience; (3) materiality—that is, likelihood that a purchasing decision was influenced—of the deception; (4) that the statement entered interstate commerce due to the defendant; and (5) injury or likelihood of injury to the plaintiff, whether by loss of sales to defendant or loss of goodwill associated with plaintiff's products, as a result of the defendant's false statement.<sup>35</sup> Interstate commerce is an element of the Lanham Act that is nearly always met.<sup>36</sup> In addition, the injury

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the Lanham Act—a conclusion reached by every Circuit to consider the question.”). Instead, standing confers to competitors or others active in the marketplace that might be harmed by false representations in commercial speech. *Id.* (“[A] plaintiff must allege an injury to a commercial interest in reputation or sales.”); *Harold H. Huggins Realty, Inc. v. FNC, Inc.*, 634 F.3d 787, 798 (5th Cir. 2011) (“Deterioration of competitive position is precisely the kind of injury the Lanham Act was intended to redress.”). Industry competitors or another company active in the marketplace must bring suit against the company allegedly engaging in false or misleading advertising or promotion. *Id.* at 797.

<sup>35</sup> *Wells Fargo & Co. v. ABD Ins. & Fin. Servs., Inc.*, 758 F.3d 1069, 1071 (9th Cir. 2014); *Newcal Indus., Inc. v. Ikon Office Sol.*, 513 F.3d 1038, 1052 (9th Cir. 2008); *Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 272 (4th Cir. 2002); *Warner-Lambert Co. v. Breathasure, Inc.*, 204 F.3d 87, 91–92 (3d Cir. 2000); *United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1180 (8th Cir. 1998); *Skil Corp.*, 375 F. Supp at 782–83.

<sup>36</sup> Given the nature of advertising and promotion, the interstate commerce requirement is rarely invoked in a Lanham Act defense and is even less likely to succeed. It has long been acknowledged that the Lanham Act “confers broad jurisdictional powers upon the courts of the United States.” *Steele v. Bulova Watch Co.*, 344 U.S. 280, 283 (1952); *see also U.S. Healthcare, Inc.*, 898 F.2d at 922 (“The commerce requirement has been broadly interpreted.”). There are, however, certain instances where the interstate commerce requirement is not met, such as where the advertising or promotion is solely of a local variety. *See, e.g., Goldberg v. Bell Atl.*, No. 99 Civ. 2889 (DC), 2000 WL 1459834, at \*4 (S.D.N.Y. Sept. 29, 2000) (“[A]ll of the factual allegations suggest the statements were made exclusively in Rockland County—that they were ‘purely local.’ The complaint alleges that the wrongful acts occurred within the Southern District of New York, that the yellow pages in question were compiled and published for Rockland County, that the directories were distributed ‘county wide’ in Rockland County, and that Donnelley was the ‘exclusive’ agent for soliciting advertisements in Rockland County. There is nothing to suggest, and plaintiffs do not allege, that the purported wrongful statements were made anywhere other than in Rockland County (and within New York State).” (citation omitted)); *Licata & Co., Inc. v. Goldberg*, 812 F. Supp. 403, 409 (S.D.N.Y. 1993) (“The

requirement, which requires the plaintiff to show economic or reputational harm directly flowing from the false advertising or promotion event, is likely to be met if the false advertising comes in the context of marketplace competition.<sup>37</sup> As a result, this Article will not address these two elements in the discussion below.

The elements themselves appear to have little more than a historical accident, originating in a 1974 district court decision.<sup>38</sup> That decision, which did not conduct a formal analysis of the named false advertising elements, cited as its only authority a 1956 law review article that had formulated the elements based solely on pre-Lanham Act case law.<sup>39</sup>

### 1. False or Misleading Statement of Fact

As an initial matter, it is unquestionable that a literally false statement made in commercial speech is grounds for a Lanham Act claim. If a statement is actually false, relief can be granted on the court's own findings without reference to the reaction of the buyer or consumer of the product.<sup>40</sup> Establishing the truth of a scientific question can be a difficult analysis. Section 43(a)

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Lanham Act's reach, while long, does not extend to the full outer limits of the commerce power.”).

<sup>37</sup> The plaintiff must show economic or reputational injury flowing directly from the deception wrought by the defendant's advertising, “and that occurs when deception of consumers causes them to withhold trade from the plaintiff.” *Lexmark Int'l, Inc.*, 134 S. Ct. at 1391. Moreover, courts have been cognizant that reputational harm resulting from the sale of falsely labeled products is difficult to prove, and an erosion of consumer confidence in a product can take time to fully develop. See *Camel Hair & Cashmere Inst. of Am., Inc. v. Associated Dry Goods Corp.*, 799 F.2d 6, 13 (1st Cir. 1986). Still, there are some limits to the ability to prove injury, such as where a court rejected a Lanham Act claim where the plaintiff presented “nothing beyond mere conjecture with regard to the anticipated harm to [its] reputation. And, significantly, [Plaintiff] has experienced an increase in sales since the industry became aware of Defendants' mistake.” *Riverdale Mills Corp. v. Cavatorta N. Am., Inc.*, 146 F. Supp. 3d 356, 362 (D. Mass. 2015) (rejecting a Lanham Act claim regarding the composition of lobster fishing nets where alleged false statements occurred for an isolated period of time, Defendant ceased selling of the alleged mislabeled product, Defendant took steps to inform customers of labeling product, Defendant took steps to inform customers of labeling issue, and where Plaintiff's sale actually increased in the period in question).

<sup>38</sup> See *Skil Corp.*, 375 F. Supp. at 782–83.

<sup>39</sup> See *id.* at 783 (citing Gilbert H. Weil, *Protectability of Trademark Values Against False Competitive Advertising*, 44 CALIF. L. REV. 527, 537 (1956)).

<sup>40</sup> *Am. Brands, Inc. v. R. J. Reynolds Tobacco Co.*, 413 F. Supp. 1352, 1357 (S.D.N.Y. 1976).

cases often require judges and juries to make factual determinations on technical, scientific, or medical issues in which they have little background or expertise.<sup>41</sup>

Misleading statements are equally actionable. The vast majority of false advertising cases have recognized that even statements that are “literally” true can similarly mislead consumers and are therefore actionable under § 43(a).<sup>42</sup> As one court explained, if false advertising law merely prohibited literal falsehoods, “clever use of innuendo, indirect intimations, and ambiguous suggestions could shield the advertisement from scrutiny precisely when protection against such sophisticated deception is most needed.”<sup>43</sup>

As the Lanham Act makes actionable any false or misleading statement of fact, a statement of opinion is not actionable.<sup>44</sup> Congress added the words “of fact” to the original version of the section in the 1988 amendments to avoid a First Amendment constitutional challenge.<sup>45</sup> Though the United States Court of Appeals for the Second Circuit recognized that “the line between

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<sup>41</sup> See, e.g., *C.B. Fleet Co., Inc. v. SmithKline Beecham Consumer Healthcare, L.P.*, 131 F.3d 430, 437 (4th Cir. 1997) (noting that the district court conducted a three-day trial focused largely on expert testimony related to scientific tests); *Castrol Inc. v. Pennzoil Co.*, 799 F. Supp. 424, 427 (D.N.J. 1992) (deciding claims regarding motor oil’s effect on viscosity breakdown and engine wear), *aff’d*, 987 F.2d 939 (3d Cir. 1993); *McNeil-P.P.C., Inc. v. Bristol-Myers Squibb Co., Inc.*, 755 F. Supp. 1206, 1217–18 (S.D.N.Y. 1990) (basing decision on medical studies), *aff’d*, 938 F.2d 1544 (2d Cir. 1991); *Procter & Gamble Co. v. Chesebrough-Pond’s Inc.*, 588 F. Supp. 1082, 1093–94 (S.D.N.Y. 1984) (describing seven days of testimony from more than a dozen expert witnesses, including statisticians, dermatologists, chemists, and physicists, noting that “much of their testimony was incomprehensible”), *aff’d*, 747 F.2d 114 (2d Cir. 1984).

<sup>42</sup> Rebecca Tushnet, *Running the Gamut from A to B: Federal Trademark and False Advertising Law*, 159 U. PA. L. REV. 1305, 1320 (2011).

<sup>43</sup> *Am. Home Prods. Corp. v. Johnson & Johnson*, 577 F.2d 160, 165 (2d Cir. 1978).

<sup>44</sup> See, e.g., *Milkovich v. Lorain Journal Co.*, 497 U.S. 1, 20 (1990) (“[A] statement of opinion relating to matters of public concern which does not contain a provably false factual connotation will receive full constitutional protection.”); *Eastman Chem. Co. v. PlastiPure, Inc.*, 775 F.3d 230, 234 (5th Cir. 2014) (“Essential to any claim under [§] 43(a) of the Lanham Act is a determination of whether the challenged statement is one of fact—actionable under [§] 43(a)—or one of general opinion—not actionable under [§] 43(a).” (quoting *Pizza Hut, Inc. v. Papa John’s Int’l, Inc.*, 227 F.3d 489, 495–96 (5th Cir. 2000))); *Groden v. Random House, Inc.*, 61 F.3d 1045, 1051 (2d Cir. 1995) (“[S]tatements of opinion are generally not the basis for Lanham Act liability.”).

<sup>45</sup> 134 CONG. REC. H10420 (daily ed. Oct. 19, 1988) (statement of Rep. Kastenmeier).

fact and opinion is not always a clear one,"<sup>46</sup> a fact is one that can be proven through some verification or establishment of certainty.<sup>47</sup>

"A plaintiff can succeed on a false advertising claim by proving either that the defendant's advertisement is literally false or implicitly false—that is, the advertisement is true or ambiguous yet misleading."<sup>48</sup> Where the advertisement is literally false, a violation may be established without evidence of consumer deception.<sup>49</sup> Where the advertisement is implicitly false, however, "an additional burden is placed upon the plaintiff to show that the advertisement . . . conveys a misleading message to the viewing public."<sup>50</sup>

Different burdens of proof exist depending upon whether the suit seeks injunctive relief or monetary damages under the Lanham Act.<sup>51</sup> Showing that the defendant's activities are likely to cause confusion or to deceive customers is sufficient to warrant injunctive relief, but a plaintiff seeking monetary damages must show actual harm to its business.<sup>52</sup>

## 2. Has the Tendency To Deceive—a Likelihood of Confusion Standard by Another Name

To be actionable under the Lanham Act, a plaintiff must do more than merely demonstrate that a statement of fact used in advertising or promotion is false or misleading. In addition, the Lanham Act requires plaintiffs to demonstrate that the alleged misrepresentation deceived a substantial portion of the

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<sup>46</sup> *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 496 (2d Cir. 2013).

<sup>47</sup> *Eastman Chem. Co.*, 775 F.3d at 235 ("[T]he challenged statement must make a 'specific and measurable claim, capable of being proved false or of being reasonably interpreted as a statement of objective fact.'" (internal quotation marks omitted) (quoting *Pizza Hut, Inc.*, 227 F.3d at 496)); *Presidio Enters, Inc. v. Warner Bros. Distrib. Corp.*, 784 F.2d 674, 679 (5th Cir. 1986) (defining a statement of fact as "one that (1) admits of being adjudged true or false in a way that (2) admits of empirical verification").

<sup>48</sup> *Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave.*, 284 F.3d 302, 311 (2d Cir. 2002).

<sup>49</sup> *Balance Dynamics Corp. v. Schmitt Indus., Inc.*, 204 F.3d 683, 693 (6th Cir. 2000) (noting that "when a statement is literally false, a plaintiff need not demonstrate actual customer deception in order to obtain relief").

<sup>50</sup> *Clorox Co. P.R. v. Proctor & Gamble Commercial Co.*, 228 F.3d 24, 33 (1st Cir. 2000).

<sup>51</sup> *Cashmere & Camel Hair Mfrs. Inst.*, 284 F.3d at 311.

<sup>52</sup> *Quabaug Rubber Co. v. Fabiano Shoe Co.*, 567 F.2d 154, 160–61 (1st Cir. 1977).

consuming public.<sup>53</sup> Plaintiffs whose claims allege that a statement is literally false do not need to prove consumer deception.<sup>54</sup> Literally false advertisements are presumptively deceptive,<sup>55</sup> and courts will presume that consumer confusion existed.<sup>56</sup>

When evaluating whether an advertising claim is literally false, the claim must always be analyzed in its full context.<sup>57</sup> Consequently, a claim can be literally false “by necessary

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<sup>53</sup> See *Wells Fargo & Co. v. ABD Ins. & Fin. Servs., Inc.*, 758 F.3d 1069, 1071 (9th Cir. 2014); *Clorox Co. P.R.*, 228 F.3d at 33 n.6; *Johnson & Johnson-Merck Consumer Pharm. Co. v. Rhone-Poulenc Rorer Pharm., Inc.*, 19 F.3d 125, 129 (3d Cir. 1994); *Pfizer, Inc. v. Miles, Inc.*, 868 F. Supp. 437, 442 (D. Conn. 1994) (“The [Lanham Act] embraces false impressions, innuendo and ambiguous suggestions.”).

<sup>54</sup> See *B. Sanfield, Inc. v. Finlay Fine Jewelry Corp.*, 168 F.3d 967, 971 (7th Cir. 1999) (“Where the statement in question is actually false, then the plaintiff need not show that the statement either actually deceived consumers or was likely to do so.”); *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 943 (3d Cir. 1993) (“[A] plaintiff must prove either literal falsity or consumer confusion, but not both.” (emphases omitted)); *Johnson & Johnson v. GAC Int’l, Inc.*, 862 F.2d 975, 977 (2d Cir. 1988) (“When a . . . representation is literally or explicitly false, the court may grant relief without reference to the advertisement’s impact on the buying public.” (quoting *Coca-Cola Co. v. Tropicana Prods., Inc.*, 690 F.2d 312, 317 (2d Cir. 1982))).

<sup>55</sup> See *Balance Dynamics Corp. v. Schmitt Indus., Inc.*, 204 F.3d 683, 693 (6th Cir. 2000) (“Because proof of ‘actual confusion’ can be difficult to obtain, most of the circuits have rules that when a statement is literally false, a plaintiff need not demonstrate actual customer deception in order to obtain relief under the Lanham Act.” (citation omitted)).

<sup>56</sup> See, e.g., *Pizza Hut, Inc. v. Papa John’s Int’l, Inc.*, 227 F.3d 489, 497 (5th Cir. 2000) (“[W]hen the statements of fact at issue are shown to be literally false, the plaintiff need not introduce evidence on the issue of the impact the statements had on consumers.”); *Porous Media Corp. v. Pall Corp.*, 110 F.3d 1329, 1334–35, 1337 (8th Cir. 1997) (determining that proof of consumer confusion was unnecessary where a jury determines that a defendant advertised in bad faith); *William H. Morris Co. v. Group W, Inc.*, 66 F.3d 255, 258 (9th Cir. 1995) (“If [defendant] intentionally misled consumers, we presume consumers were in fact deceived . . . .”); *Johnson & Johnson-Merck Consumer Pharm. Co.*, 19 F.3d at 131 (presuming consumer injury where plaintiff proves intent to deceive and egregious conduct); *Coca-Cola Co.*, 690 F.2d at 317 (“When a merchandising statement or representation is literally or explicitly false, the court may grant relief without reference to the advertisement’s impact on the buying public.”); *Am. Brands, Inc. v. R. J. Reynolds Tobacco Co.*, 413 F. Supp. 1352, 1356 (S.D.N.Y. 1976) (“[A] court can grant relief on its own findings without recourse to a survey of consumer reaction.”).

<sup>57</sup> *Castrol Inc.*, 987 F.2d at 946; *Am. Home Prod. Corp. v. FTC*, 695 F.2d 681, 687 (3d Cir. 1982); *Cuisinarts, Inc. v. Robot-Coupe Int’l Corp.*, No. 81 Civ 731-CSH, 1982 WL 121559, at \*2 (S.D.N.Y. June 9, 1982) (“[I]n determining facial falsity the court must view the face of the statement in its entirety, rather than examining the eyes, nose, and mouth separately and in isolation from each other.”).

implication.”<sup>58</sup> Still, to prove that an advertising claim based on product testing is literally false, “a plaintiff must do more than show that the tests supporting the challenged claim are unpersuasive.”<sup>59</sup> Additionally, the plaintiff must demonstrate that such tests are not sufficiently reliable to permit one to conclude with reasonable certainty that the tests established the claim made.<sup>60</sup> To meet such a standard, a plaintiff may attack the validity of the defendant’s tests directly or use other scientific testing to show that the defendant’s tests are contradicted or unsupported.<sup>61</sup> Moreover, if the plaintiff can show that the tests, even if reliable, do not establish the proposition asserted by the defendant, the plaintiff has obviously met its burden of demonstrating literal falsity.<sup>62</sup>

In the absence of the allegation of a literal falsity, the plaintiff must show that the advertisement, though explicitly true, nonetheless conveys a misleading message to the viewing public.<sup>63</sup> To satisfy its burden, the plaintiff must show how consumers have actually reacted to the challenged advertisement rather than merely demonstrating how they could have reacted.<sup>64</sup>

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<sup>58</sup> *Castrol Inc.*, 987 F.2d at 946; *Tambrands, Inc. v. Warner-Lambert Co.*, 673 F. Supp. 1190, 1193–94 (S.D.N.Y. 1987).

<sup>59</sup> *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir. 1991); see also *Procter & Gamble Co. v. Chesebrough-Pond’s, Inc.*, 747 F.2d 114, 119 (2d Cir. 1984).

<sup>60</sup> *McNeil-P.C.C., Inc.*, 938 F.2d at 1549; *Procter & Gamble Co.*, 747 F.2d at 119.

<sup>61</sup> *Castrol, Inc.*, 977 F.2d at 62–63 (distinguishing product superiority claim not based on testing, which must be proven false by affirmative evidence, from product superiority claim explicitly or implicitly based on tests or studies, which may be proven false by showing that the tests did not establish the proposition for which they were cited).

<sup>62</sup> *Id.* at 63.

<sup>63</sup> See *United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1183 (8th Cir. 1998) (stating that when there is no finding of a willful violation or an intent to deceive, evidence of consumer impact is essential—usually through consumer or market research—unless the commercial claim is literally false); *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 228 (3d Cir. 1990) (“[A] Lanham Act plaintiff must prove deceptiveness in court.”).

<sup>64</sup> See *Cottrell, Ltd. v. Biotrol Int’l, Inc.*, 191 F.3d 1248, 1256 (10th Cir. 1999) (holding that if the plaintiff can establish by consumer surveys or other means that the defendant’s advertising is likely to confuse or actually confuses consumers, any false implication is as damaging for a Lanham Act claim as an express false claim); *Johnson & Johnson \* Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 298 (2d Cir. 1992) (requiring plaintiff to demonstrate that a “statistically significant part of the commercial audience holds the false belief allegedly communicated by the challenged advertisement”); *Sandoz Pharm. Corp.*, 902 F.2d at 228–29 (“[Where an advertising statement is not literally false, the]

Consumer deception is often demonstrated through surveys that establish that consumers were misled by the alleged misrepresentations.<sup>65</sup> For example, in a suit involving the naming, labeling, and advertising of a competitor's juice product, the plaintiff claimed that the defendant's product misled consumers regarding the quantity of pomegranate in its juices.<sup>66</sup> To support its claim, the plaintiff offered a field survey that showed a thirty-five percent differential between the test and control groups who mistakenly believed that the defendant's product mainly contained pomegranate and blueberry juice, rather than a fruit juice blend where pomegranate and blueberry are the third and fourth most used juices.<sup>67</sup> Though the defendant challenged the plaintiff's survey methodology and applicability, the district court determined that consumer deception was a disputed question of fact, and, consequently, the court denied summary judgment.<sup>68</sup> In cases involving alleged consumer confusion, the court has generally set a fairly low threshold bar for consumer deception demonstrated through surveys in order for a claim to proceed.<sup>69</sup>

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plaintiff bears the burden of proving actual deception by a preponderance of the evidence. Hence, it cannot obtain relief by arguing how consumers *could* react; it must show how consumers *actually do* react.”)

<sup>65</sup> See *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 191 (2d Cir. 1980) (claiming consumers were misled by defendant's ad that claimed its product contained baby oil through introducing surveys that indicated that some people, after viewing defendant's ads, thought they would not have to use baby oil if they used defendant's product); see also *Johnson & Johnson \* Merck*, 960 F.2d at 298; *U-Haul Int'l, Inc. v. Jartran, Inc.*, 522 F. Supp. 1238, 1249–50 (D. Ariz. 1981).

<sup>66</sup> *POM Wonderful LLC v. Coca Cola Co.*, 727 F. Supp. 2d 849, 856 (C.D. Cal. 2010), *aff'd in part, vacated in part, remanded sub nom. Pom Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170 (9th Cir. 2012), *rev'd*, 134 S. Ct. 2228 (2014).

<sup>67</sup> *Id.* at 857–58.

<sup>68</sup> *Id.* at 875–76 (holding that, though the district court recognized questions regarding the reliability of the survey, “whether the Field Survey actually meets the *Daubert* standards is best considered at trial”).

<sup>69</sup> *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 594 (3d Cir. 2002) (finding that 15.5% would be sufficient to support a finding of substantial consumer confusion); *Coca-Cola Co. v. Tropicana Prods., Inc.*, 690 F.2d 312, 317 (2d Cir. 1982) (holding that a consumer survey that demonstrated 7.5% consumer deception constituted “a significant number of consumers . . . likely to be misled”).

### 3. Materiality

The materiality prong requires the plaintiff to demonstrate that the other party's falsities or misrepresentations were "likely to influence the purchasing decision" of consumers,<sup>70</sup> though some commentators argue that, in practice, the materiality analysis merges with the second prong regarding an advertisement's tendency to deceive.<sup>71</sup> The materiality requirement recognizes that not all alleged deceptions affect consumer purchasing decisions,<sup>72</sup> thereby allowing courts to implement a common-sense approach to the materiality

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<sup>70</sup> *Aristotle Int'l, Inc. v. NGP Software, Inc.*, 714 F. Supp. 2d 1, 9 (D.D.C. 2010) (quoting *Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave.*, 284 F.3d 302, 311 (1st Cir. 2002)); *see also* *3M Innovative Prop. Co. v. Dupont Dow Elastomers LLC*, 361 F. Supp. 2d 958, 971 (D. Minn. 2005) ("Materiality . . . considers whether the false or misleading statement is likely to make a difference to purchasers." (internal quotation mark omitted) (quoting *Cashmere & Camel Hair Mfrs. Inst.*, 284 F.3d at 312 n.10)); *Am. Brands, Inc. v. R. J. Reynolds Tobacco Co.*, 413 F. Supp. 1352, 1357 (S.D.N.Y. 1976) ("[W]e are asked to determine whether a statement acknowledged to be literally true and grammatically correct nevertheless has a tendency to mislead, confuse or deceive. As to such a proposition the public's reaction to (the) advertisement will be the starting point in any discussion of the likelihood of deception." (internal quotation mark omitted) (quoting 1 RUDOLF CALLMANN, *THE LAW OF UNFAIR COMPETITION, TRADEMARKS & MONOPOLIES* § 19.2(a)(1) (3d ed. 1967))).

<sup>71</sup> For example, some commentators contend that the second and third elements merge in a practical Lanham Act legal analysis so that the "materiality" element only requires deception or the capacity to deceive. Given that the language of § 43(a) does not speak of "materiality" per se, the elements often combine to be a false or material statement that is material in that it deceives or is likely to deceive. Moreover, although courts require a showing of "likely effect on consumer decisions," this is in connection with the fifth element, proving the fact or threat of injury to a claimant. *See* Courtland L. Reichman & M. Melissa Cannady, *False Advertising Under the Lanham Act*, 21 *FRANCHISE L.J.* 187, 187–88 (2002) (noting the merging of elements in many Lanham Act analyses).

<sup>72</sup> *William H. Morris Co. v. Grp. W, Inc.*, 66 F.3d 255, 258 (9th Cir. 1995) (holding that a letter from the distributor of a dietary supplement did not affect purchasing decisions because only three percent of pharmacists interviewed interpreted the letter as referring to plaintiff's product); *U.S. Healthcare, Inc. v. Blue Cross*, 898 F.2d 914, 922 (3d Cir. 1990) (stating that misrepresentations in an advertisement must "influence the purchasing decision" of the buying public to satisfy the materiality requirement).

analysis.<sup>73</sup> For example, the materiality requirement allows the court to accept certain advertising campaigns as puffery if the claims are sufficiently vague to prevent consumer confusion.<sup>74</sup>

As one scholar has argued, on a practical basis, the materiality test also serves an effective gatekeeping function for the courts.<sup>75</sup> Materiality is a mixed question of law and fact,<sup>76</sup> and as a result, a court can dismiss a case on the pleadings or on summary judgment if the plaintiff fails to make a sufficient showing.<sup>77</sup> Still, materiality is not a particularly significant burden for plaintiffs; evidence of materiality can come through consumer surveys that are already employed in standard false advertising litigation.<sup>78</sup> Alternatively, where a survey question is so distant from the questions a consumer is likely to ask in a

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<sup>73</sup> *Nat'l Basketball Ass'n v. Sports Team Analysis & Tracking Sys., Inc.*, 939 F. Supp. 1071, 1110 (S.D.N.Y. 1996), *aff'd in part, vacated in part sub nom.* *Nat'l Basketball Ass'n v. Motorola, Inc.*, 105 F.3d 841 (2d Cir. 1997) ("The insignificance of the statement 'from the arena' is illustrated further by omitting it entirely from the clause in which it is found. If the clause simply stated, 'Nationwide game updates,' I find it difficult to envision (and NBA has not shown otherwise) that consumers suddenly would reassess their decisions to purchase SportsTrax.").

<sup>74</sup> Tushnet, *supra* note 42, at 1344–45 ("Materiality, among other concepts, allows courts to bless certain ad claims on their face as nonactionable puffery. . . . [I]t is the law that consumers are irrebuttably presumed not to rely on sufficiently vague or exaggerated claims.").

<sup>75</sup> Burns, *supra* note 16, at 882.

<sup>76</sup> *See, e.g., Nat'l Basketball Ass'n*, 105 F.3d at 855 (holding that even if claim is literally false, plaintiff must still show materiality); *Am. Tel. & Tel. Co. v. Winback & Conserve Program, Inc.*, 42 F.3d 1421, 1428 n.9 (3d Cir. 1994) (plaintiff alleging false advertising must prove "that the deception is material in that it is likely to influence purchasing decisions"); *ALPO Petfoods, Inc. v. Ralston Purina Co.*, 913 F.2d 958, 964 (D.C. Cir. 1990) (false or misleading ads must be "material in their effects on buying decisions"); *Taquino v. Teledyne Monarch Rubber*, 893 F.2d 1488, 1500 (5th Cir. 1990) (deception must be "material, in that it is likely to influence the purchasing decision"); *Tire Kingdom, Inc. v. Morgan Tire & Auto, Inc.*, 915 F. Supp. 360, 366 (S.D. Fla. 1996) (granting summary judgment on claim because, even if false, the representation was not material); *Compaq Comput. Corp. v. Procom Tech., Inc.*, 908 F. Supp. 1409, 1426–27 (S.D. Tex. 1995) (dismissing claim based on technically false picture that was found to have little chance of misleading customers).

<sup>77</sup> *See* Burns, *supra* note 16, at 882 (arguing that the materiality element allows the court to function as a gatekeeper to spurious false advertising claims).

<sup>78</sup> *See, e.g., Johnson & Johnson \* Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 298 (2d Cir. 1992) (stating consumer surveys may be used to establish consumer confusion); *Vidal Sassoon, Inc. v. Bristol-Myers Co.*, 661 F.2d 272, 275–76 (2d Cir. 1981) (stating consumer preference studies were used to prove consumer confusion). *But see* Tushnet, *supra* note 42, at 1347 ("Materiality can also be used more indirectly to evaluate the relevance of survey evidence that allegedly shows a likelihood of consumer confusion.").

marketplace context, courts may determine that the value of questions renders the survey unreliable.<sup>79</sup> Given a general trust of science, the materiality prong is particularly likely to be met where there are claims of scientific validity to support the promotion. Consumers are likely to perceive as true such claims that appear to be based upon scientific evidence.<sup>80</sup>

These elements—(1) a false or misleading statement of fact, (2) with a tendency to deceive, and that (3) materially affects a consumer purchasing decision—constitute the key elements required for a traditional analysis of a false advertising claim. As the next Part demonstrates, determining what constitutes commercial speech falling under the purview of the Lanham Act can be a challenging endeavor. Such analysis is particularly complicated when the speech in question involves scientific inquiry that is protected by the First Amendment.

## II. ONY'S POTENTIAL CHILLING EFFECT ON LANHAM ACT LITIGATION

Taken to its logical conclusion, the United States Court of Appeals for the Second Circuit's *ONY* decision has the potential to foreclose adjudication of false advertising disputes in industries where marketing relies heavily upon scientific validation. As discussed below, the publication of scientific research is protected First Amendment speech, and courts have often been cautious to allow the regulation of commercial speech to intrude upon the protection of First Amendment speech rights. The *ONY* decision, which would allow commercial entities to adopt and distribute the language of academic publications without regulation under the Lanham Act, is a step too far. Under *ONY*, a commercial entity could immune itself from a Lanham Act claim by creating marketing based upon scientific articles in academic publications without regard to the veracity of the scientific findings upon which the marketing is based.

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<sup>79</sup> See *Procter & Gamble Co. v. Kimberly-Clark Corp.*, 569 F. Supp. 2d 796, 804–05 (E.D. Wis. 2008) (finding that a survey asking which of the parties' diapers had a more "natural fit" posed an epistemological question that survey evidence could not satisfactorily answer).

<sup>80</sup> See *POM Wonderful LLC v. Coca Cola Co.*, 727 F. Supp. 2d 849, 857–58 (C.D. Cal. 2010) (consumers are likely to perceive certain types of claims, such as health and nutrition claims, as being based upon scientific evidence), *aff'd in part, vacated in part, remanded sub nom.* *POM Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170 (9th Cir. 2012), *rev'd*, 134 S. Ct. 2228 (2014).

A. *Scientific Journals, the Lanham Act, and the First Amendment*

The Lanham Act only prohibits false “commercial advertising or promotion,” namely commercial speech<sup>81</sup> The core notion of commercial speech, as defined by the United States Supreme Court, is “speech which does no more than propose a commercial transaction.”<sup>82</sup> Under its broadest definition, commercial speech is an “expression related solely to the economic interests of the speaker and its audience.”<sup>83</sup>

The definition of advertising and promotion under the Lanham Act extends beyond traditional advertising campaigns, however.<sup>84</sup> For example, § 43(a) has been found applicable to the fundraising letters of a nonprofit pregnancy counseling group,<sup>85</sup> to the distribution of marketing information to retailers at a trade show,<sup>86</sup> and has even been found to extend to an individual’s “badmouthing” of her former employer in telephone calls made to colleagues and friends.<sup>87</sup> In effect, the standard has become that while the false representations need not be made in a classic advertising campaign, the representation must be in the context of commercial speech, the representation must be made for the purposes of consumers to purchase goods or services, and

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<sup>81</sup> 15 U.S.C. § 1125(a)(1)(B) (2012).

<sup>82</sup> See *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 422 (1993) (quoting *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66 (1983)); see also *Bolger*, 463 U.S. at 68 (holding that informational pamphlets addressing “important public issues[,] such as venereal disease and family planning,” constituted commercial speech where communications were conceded to be advertisements in that they referred to specific products sold by the defendant, and that the defendant had an economic motivation for the speech).

<sup>83</sup> *City of Cincinnati*, 507 U.S. at 422.

<sup>84</sup> *Gordon & Breach Sci. Publishers S.A. v. Am. Inst. of Physics*, 859 F. Supp. 1521, 1534–35 (S.D.N.Y. 1994).

<sup>85</sup> *Birthright v. Birthright, Inc.*, 827 F. Supp. 1114, 1138 (D.N.J. 1993).

<sup>86</sup> *Am. Needle & Novelty, Inc. v. Drew Pearson Mktg., Inc.*, 820 F. Supp. 1072, 1078 (N.D. Ill. 1993) (recognizing that “[t]he level of circulation required to constitute advertising and promotion will undeniably vary from industry to industry and from case to case”).

<sup>87</sup> *Nat’l Artists Mgmt. Co., Inc. v. Weaving*, 769 F. Supp. 1224, 1235 (S.D.N.Y. 1991) (“It is true that defendants’ conduct—speaking by telephone with a number of friends, acquaintances, and colleagues about the reasons for terminating their relationships with [the company]—is not ‘commercial advertising and promotion’ in the traditional sense of large-scale, nationwide commercial advertising campaigns. In the context of the theatre-booking industry, however, ‘services’ are ‘promoted’ by word-of-mouth and information is spread through a network of telephone contacts with producers, promoters, and presenters.”).

the representation must be disseminated sufficiently to the relevant purchasing public to constitute “advertising” or “promotion” within that industry.<sup>88</sup>

*B. Scientific Articles as Protected Speech*

Given that the Lanham Act has the potential to chill First Amendment speech rights, courts have been somewhat reluctant to extend the reach of the Lanham Act into areas that may intrude upon the First Amendment.<sup>89</sup> Academic research is one such area. For example, the Supreme Court has determined that academic freedom, including academic scientific research, constitutes a “special concern of the First Amendment.”<sup>90</sup>

The First Amendment protects “scientific speech.”<sup>91</sup> Consequently, a debate that takes place in academic journals is part of the marketplace of ideas protected by the First Amendment.<sup>92</sup> As a result, the publication of an article addressing scientific findings in a peer-reviewed journal does not constitute commercial speech, even if there is the potential for erroneous content.<sup>93</sup>

In addition to “pure” science articles, there is the publication of an article that appears to serve dual masters. From one perspective, this article can be speech that is noncommercial in nature and addresses a significant public issue, thereby

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<sup>88</sup> *Gordon & Breach Sci. Publishers S.A.*, 859 F. Supp. at 1535–36.

<sup>89</sup> *Boule v. Hutton*, 328 F.3d 84, 91 (2d Cir. 2003) (noting the general approach of being “careful not to permit overextension of the Lanham Act to intrude on First Amendment values” (quoting *Groden v. Random House, Inc.*, 61 F.3d 1045, 1052 (2d Cir. 1995))).

<sup>90</sup> *Keyishian v. Bd. of Regents*, 385 U.S. 589, 603 (1967).

<sup>91</sup> *Miller v. California*, 413 U.S. 15, 34 (1973) (“The First Amendment protects works which, taken as a whole, have serious literary, artistic, political, or scientific value, regardless of whether the government or a majority of the people approve of the ideas these works represent.”); *Bd. of Trs. of Leland Stanford Junior Univ. v. Sullivan*, 773 F. Supp. 472, 474 (D.D.C. 1991) (“It is equally settled, however, though less commonly the subject of litigation, that the First Amendment protects scientific expression and debate just as it protects political and artistic expression.”).

<sup>92</sup> *Gordon & Breach Sci. Publishers S.A.*, 859 F. Supp. at 1541 (citing *Keyishian*, 385 U.S. at 603).

<sup>93</sup> *See, e.g., Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 456 (D.N.J. 2009) (“[T]here is an abundance of case law to support the proposition that a scientific article is protected noncommercial speech despite the potential for erroneous content.”); *Sullivan*, 773 F. Supp. at 474 (“It is equally settled, however, though less commonly the subject of litigation, that the First Amendment protects scientific expression and debate just as it protects political and artistic expression.”).

constituting protected speech under the First Amendment.<sup>94</sup> From another perspective, however, such speech appears to propose a commercial transaction that would be regulated under the Lanham Act.<sup>95</sup>

Although the context was informational pamphlets rather than academic articles, the Supreme Court examined the nature of intertwined “commercial” and “noncommercial” speech in *Bolger v. Youngs Drug Products Corp.*<sup>96</sup> In *Bolger*, the Court examined the application of a federal statute that prohibited the mailing of unsolicited advertisements for contraceptives.<sup>97</sup> Youngs, a pharmaceuticals wholesaler, sought to undertake a campaign of unsolicited mass mailings promoting its products, including contraceptives, to the general public.<sup>98</sup> The majority of Youngs’s mailings consisted primarily of price and quantity information, and these mailings fell within the core notion of commercial speech.<sup>99</sup> Other mailings, however, were less explicitly commercial: these mailings consisted of informational pamphlets with titles such as “Condoms and Human Sexuality” and “Plain Talk about Venereal Disease.”<sup>100</sup> The pamphlets included references, of varying degrees of prominence, to Youngs and its Trojan-brand condoms.<sup>101</sup> The Supreme Court acknowledged that a mere economic motivation for the mailing is insufficient to render the materials commercial speech.<sup>102</sup> The same is true for a simple reference to a commercial product.<sup>103</sup> Though the Court recognized the commercial speech issue to be a close question, it concluded that “[t]he combination of *all* these

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<sup>94</sup> *Gordon & Breach Sci. Publishers S.A.*, 859 F. Supp. at 1539 (presenting, “from one perspective . . . the aspect of protected, noncommercial speech addressing a significant public issue, but which, from another perspective, appears primarily to be speech ‘proposing a commercial transaction.’”).

<sup>95</sup> *Id.*

<sup>96</sup> 463 U.S. 60 (1983).

<sup>97</sup> *Id.* at 61–62.

<sup>98</sup> *Id.* at 62.

<sup>99</sup> *Id.* at 66.

<sup>100</sup> *Id.* at 62 n.4.

<sup>101</sup> *Id.* (noting that for pamphlets regarding venereal disease, “[t]he only identification of Youngs or its products [was] at the bottom of the last page of the pamphlet, which state[d] that the pamphlet ha[d] been contributed as a public service by Youngs, the distributor of Trojan-brand prophylactics”).

<sup>102</sup> *Id.* at 66–67.

<sup>103</sup> *Id.*

characteristics . . . provides strong support for the . . . conclusion that the informational pamphlets are properly characterized as commercial speech."<sup>104</sup>

Courts applying this mixed commercial-noncommercial analysis to academic works have generally found their publication to be noncommercial and, therefore, outside the reach of the Lanham Act.<sup>105</sup> For example, the United States District Court for the Southern District of New York found that an article containing comparative surveys of scientific journals that rated its own publications as superior did not constitute commercial speech.<sup>106</sup> The nonprofit publisher's potential financial benefit was not outcome determinative.<sup>107</sup> Similarly, the author of the book *The Cure for All Cancers* suggested that readers refrain from ingesting a manufacturer's vitamins because the vitamins contained an ingredient that was allegedly carcinogenic.<sup>108</sup> The court held that allegedly false statements about the vitamin did not constitute commercial speech because "the commercial elements of the speech [were] intertwined with the central message" that was noncommercial in nature.<sup>109</sup> Additionally, a nonprofit medical association's publication of an article that contained allegedly false statements about the defendant's electrodiagnostic medical devices did not constitute commercial speech because the authors of the article did not advocate for a commercial transaction.<sup>110</sup> Even if some of the language in the article was commercial in nature, the article's public significance and status as an academic piece published by a nonprofit organization meant it was noncommercial speech.<sup>111</sup>

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<sup>104</sup> *Id.* at 67.

<sup>105</sup> *Gordon & Breach Sci. Publishers S.A., v. Am. Inst. Of Physics*, 859 F. Supp. 1521, 1541, 1545 (S.D.N.Y. 1994).

<sup>106</sup> *Id.* at 1523, 1545.

<sup>107</sup> *Id.* at 1541 ("The fact that AIP and APS stood to benefit from publishing Barschall's results—even that they *intended* to benefit—is insufficient by itself to turn the articles into commercial speech.")

<sup>108</sup> *Oxycal Labs., Inc. v. Jeffers*, 909 F. Supp. 719, 720 (S.D. Cal. 1995).

<sup>109</sup> *Id.* at 725.

<sup>110</sup> *Neurotron, Inc. v. Am. Ass'n of Electrodiagnostic Med.*, 189 F. Supp. 2d 271, 277 (D. Md. 2001) ("The Technology Review is published by AAEM, a non-profit organization, whose purpose is not only to lobby and advocate for its members, but also to provide educational services such as informing members of current trends in the industry through publications such as *Muscle & Nerve*, or by conducting educational seminars. None of these activities are commercial in nature.")

<sup>111</sup> *Id.*

Still, the publication of an article may constitute commercial speech if the statements in the article were made for an explicitly commercial purpose. For example, the United States Court of Appeals for the Sixth Circuit determined that the publication of an article in a trade-based journal fell under the ambit of the Lanham Act because the article contained demonstrably false information about a product that was likely to influence a purchasing decision.<sup>112</sup> Here, a trade journal asked the president of a manufacturer of beryllium-copper plunger tips to write an article about the manufacture of plunger tips.<sup>113</sup> The article submitted by the company president contained a number of self-serving statements about his company's products.<sup>114</sup> The journal, after removing some of the most self-serving comments, published the article.<sup>115</sup> After the article's publication, the defendant-manufacturer obtained reprints, made numerous copies, and used the article as a promotional brochure at trade shows.<sup>116</sup> A competitor filed suit, arguing that the article itself amounted to false advertising or promotion and violated the Lanham Act.<sup>117</sup> The Sixth Circuit agreed, holding that the article in the trade publication constituted commercial speech, and that any false statements would be actionable under the Lanham Act.<sup>118</sup>

*C. Scientific Statements in Academic Publications: Statements of Fact or Opinion?*

In *ONY*, the Second Circuit held that a pharmaceutical manufacturer's dissemination of an academic article and the company's press release quoting those scientific findings did not constitute commercial speech.<sup>119</sup> Because the Lanham Act only prohibits false or misleading statements of fact, statements of

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<sup>112</sup> *Semco, Inc. v. Amcast, Inc.*, 52 F.3d 108, 113–14 (6th Cir. 1995) (holding that an article was commercial speech under the Lanham Act where the publication author “presented an article peppered with advertising for Amcast—and that advertising, which the trade publication did not solicit, allegedly contained material misrepresentations of Amcast products”).

<sup>113</sup> *Id.* at 110.

<sup>114</sup> *Id.*

<sup>115</sup> *Id.*

<sup>116</sup> *Id.* at 111.

<sup>117</sup> *Id.* at 110.

<sup>118</sup> *Id.* at 114.

<sup>119</sup> *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 492 (2d Cir. 2013).

opinion are outside the bounds of traditional Lanham Act analysis.<sup>120</sup> The Second Circuit's *ONY* analysis determined that scientific discourse constitutes opinion, thereby finding that scientific discourse falls outside the scope of Lanham Act regulation.<sup>121</sup> Still, the Second Circuit recognized that scientific academic discourse poses a peculiar problem in the fact-opinion paradigm.<sup>122</sup> Facts are statements that can be verified,<sup>123</sup> and the very nature of scientific publication is to establish facts that hold up to rigorous research and testing.<sup>124</sup> Moreover, most conclusions in scientific journal articles are "capable of verification or refutation by means of objective proof."<sup>125</sup> While these scientific conclusions are subject to proof, the Second Circuit has argued that the essence of the scientific method is marked by tentative conclusions.<sup>126</sup> A key point in the Second Circuit's *ONY* analysis is that these scientific statements are made for the scientific community and not for the general public.<sup>127</sup> As the Second Circuit explained, "These conclusions are then available to other scientists who may respond by attempting to replicate the described experiments, conducting their own experiments, or analyzing or refuting the soundness of the experimental design or the validity of the inferences drawn from the results."<sup>128</sup> Therefore, although the matters presented

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<sup>120</sup> 15 U.S.C. § 1125(a)(1) (2012).

<sup>121</sup> *ONY, Inc.*, 720 F.3d at 497–98.

<sup>122</sup> *Id.* at 496–97.

<sup>123</sup> *Presidio Enters., Inc. v. Warner Bros. Distrib. Corp.*, 784 F.2d 674, 679 (5th Cir. 1986) ("A statement of fact is one that (1) admits of being adjudged true or false in a way that (2) admits of empirical verification.").

<sup>124</sup> *ONY, Inc.*, 720 F.3d at 496 ("Indeed, it is the very premise of the scientific enterprise that it engages with empirically verifiable facts about the universe.").

<sup>125</sup> *Phantom Touring, Inc. v. Affiliated Publ'ns*, 953 F.2d 724, 728 n.7 (1st Cir. 1992).

<sup>126</sup> *ONY, Inc.*, 720 F.3d at 496 ("[I]t is the essence of the scientific method that the conclusions of empirical research are tentative and subject to revision, because they represent inferences about the nature of reality based on the results of experimentation and observation.").

<sup>127</sup> *Id.* at 496–97 ("Importantly, those conclusions are presented in publications directed to the relevant scientific community, ideally in peer-reviewed academic journals that warrant that research approved for publication demonstrates at least some degree of basic scientific competence.").

<sup>128</sup> *Id.* at 497.

within scientific journal articles might be verifiable, the Second Circuit determined that information offered in scientific journals is more akin to opinion.<sup>129</sup>

In contrast, the Fifth Circuit's *Eastman* decision offers a more balanced approach. As that court made clear, "it is of no moment that the commercial speech in this case concerned a topic of scientific debate. Advertisements do not become immune from Lanham Act scrutiny simply because their claims are open to scientific or public debate."<sup>130</sup> As the Fifth Circuit suggested, the distribution of scientific literature or a scientific article for promotional purposes transforms that speech into commercial speech that may be regulated by the Lanham Act.<sup>131</sup>

#### D. *Distribution Transforms Noncommercial Speech into Commercial Speech*

In addition to holding that the publication of statements and research results do not constitute facts under the Lanham Act, the Second Circuit in *ONY* determined that the subsequent distribution of the article was similarly not commercial speech.<sup>132</sup> Although the court used explicit language holding that distribution of the article did not trigger the Lanham Act, the Second Circuit's analysis only considered whether publication of the article was commercial speech itself, finding that it was not.<sup>133</sup> Given that it was not commercial speech, the Second Circuit concluded that further dissemination of the article was similarly inactionable.<sup>134</sup>

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<sup>129</sup> *Id.* ("[W]hile statements about contested and contestable scientific hypotheses constitute assertions about the world that are in principle matters of verifiable 'fact,' for purposes of the First Amendment and the laws relating to fair competition and defamation, they are more closely akin to matters of opinion, and are so understood by the relevant scientific communities.")

<sup>130</sup> *Eastman Chem. Co. v. PlastiPure, Inc.*, 775 F.3d 230, 236 (5th Cir. 2014).

<sup>131</sup> *Id.* at 237.

<sup>132</sup> *ONY, Inc.*, 720 F.3d at 492 ("We conclude that, as a matter of law, statements of scientific conclusions about unsettled matters of scientific debate cannot give rise to liability for damages sounding in defamation. We further conclude that the 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.")

<sup>133</sup> *Id.* at 497–98 (addressing the dissemination of the article only in the context of tortious interference claims and dismissing those claims on the basis that dissemination of the article was not misleading).

<sup>134</sup> *Id.*

As a practical matter, *ONY* seems to run counter to the stringent requirements in place with respect to the Food and Drug Administration's ("FDA") analysis of pharmaceuticals. The FDA regulates all forms of prescription drug advertising, including direct-to-consumer advertising, thereby ensuring that the advertising claims are supported by credible evidence.<sup>135</sup> The FDA evaluates scientific studies and determines whether they support the health-related claims the manufacturer wishes to make for the drug. If the FDA finds the study insufficient, the claim may not be legally made. A manufacturer may not claim that a substance treats, cures, or diagnoses a disease without FDA approval. Moreover, a pharmaceutical manufacturer cannot circumvent such a requirement by merely asserting that "study X supports" such a panacea.

The Second Circuit's *ONY* analysis has a number of problems. As an initial matter, the dissemination of an article is a separate step from the writing and publication of one. Although the writing of scientific articles falls within the First Amendment protections for academic freedom,<sup>136</sup> the dissemination of that article by a company is a separate step deserving additional scrutiny.<sup>137</sup> As the Fifth Circuit noted, "The First Amendment ensures a robust discourse in the pages of academic journals, but it does not immunize false or misleading commercial claims."<sup>138</sup> Consequently, the distribution of an article may have commercial implications beyond the academic speech.<sup>139</sup>

Second, the general distribution of a scientific article will extend the reach of the scientific findings beyond the small, specialized audience of the scientific community. In its *ONY* decision, the Second Circuit noted that conclusions in scientific journals are directed to the relevant scientific community.<sup>140</sup>

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<sup>135</sup> 21 C.F.R. § 202.1(j)(1)(i)-(ii) (2017).

<sup>136</sup> See, e.g., *Keyishian v. Bd. of Regents*, 385 U.S. 589, 603 (1967).

<sup>137</sup> See *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 638 (1985) ("The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading . . .").

<sup>138</sup> *Eastman Chem. Co. v. PlastiPure, Inc.*, 775 F.3d 230, 237 (5th Cir. 2014).

<sup>139</sup> *Id.*

<sup>140</sup> *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 496–97 (2d Cir. 2013) ("[I]t is the essence of the scientific method that the conclusions of empirical research are tentative and subject to revision, because they represent inferences about the nature of reality based on the results of experimentation and observation.

While such an observation is certainly true, a company's distribution of a scientific article moves the scientific findings from the scientific community and into the realm of the general public. Moreover, because the public is the ultimate consumer of a medical product, any distribution of the article beyond a small subset of academic researchers is likely to reach members of the general public.<sup>141</sup> The general public has much less knowledge about the science in question and likely lacks an in-depth understanding of the research methodology used to achieve the scientific results.<sup>142</sup> Even a targeted distribution to doctors, health care providers, or those within the greater scientific community is likely to reach individuals with less ability to analyze the scientific methodology and weigh the studies' conclusions compared to those who read the article in a specialized scientific journal.<sup>143</sup>

Notably, the Second Circuit in *ONY* determined that a subsequent press release touting the scientific findings did not transform scientific speech into commercial speech. As the *ONY* decision notes, "After the article's publication, Chiesi and Cornerstone issued a press release touting its conclusions and distributed promotional materials that cited the article's findings."<sup>144</sup> Such a holding is contrary to earlier case law.

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Importantly, those conclusions are presented in publications directed to the relevant scientific community . . .").

<sup>141</sup> See *Kos Pharm., Inc. v. Andrx Corp.*, 369 F.3d 700, 715 n.12 (3d Cir. 2004) (noting the increasing prevalence of prescription medication advertisements that are aimed directly at influencing patient choices).

<sup>142</sup> For a general analysis of how the public analyzes scientific evidence, see Jennifer L. Mnookin, *Idealizing Science and Demonizing Experts: An Intellectual History of Expert Evidence*, 52 VILL. L. REV. 763, 767 (2007) ("Our desire to idealize science runs, I fear, rather deep; we do not actually want science to be muddy, complex, pragmatic, methodologically imperfect and messy. When the science offered in court is all of these things, as it so often is, we therefore tend to blame the science itself, rather than our own unrealistic desires."). Similarly, writing about jurors' analyses of scientific evidence, Valerie Hans notes that "jurors themselves have identified the task of interpreting scientific and technical evidence . . . as particularly challenging." Valerie P. Hans, *Judges, Juries, and Scientific Evidence*, 16 J.L. & POL'Y 19, 23 (2007).

<sup>143</sup> See, e.g., *Genzyme Corp. v. Shire Human Genetic Therapies, Inc.*, 906 F. Supp. 2d 9, 17 (D. Mass. 2012) ("[A] pharmaceutical manufacturer's selective promotion of favorable scientific information could be potentially misleading even to sophisticated and experienced doctors.").

<sup>144</sup> *ONY, Inc.*, 720 F.3d at 495.

Instead, most courts agree that a company's accompanying press release or explanatory letter touting its scientific findings constitutes commercial speech and therefore triggers regulation under the Lanham Act.<sup>145</sup> For example, the secondary dissemination to potential customers of a survey article from the *New England Journal of Medicine* comparing two x-ray contrast media in a head-to-head competition constituted commercial speech that could be regulated under the Lanham Act.<sup>146</sup> As the Massachusetts District Court made clear, "The press release was not a scientific publication."<sup>147</sup> Given that a press release has a target audience beyond a specific scientific community, a manufacturer's press release moves the speech out of First Amendment-protected scientific expression and into the realm of regulated commercial speech.<sup>148</sup>

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<sup>145</sup> See *United States v. Harkonen*, No. C 08-00164 MHP, 2009 WL 1578712, at \*6 (N.D. Cal. June 4, 2009) ("That the speech is a press release and not a peer-reviewed publication, that it refers to a specific commercial product on the market . . . and that it was unquestionably disseminated for commercial benefit (e.g., the first line notes [defendant]'s Nasdaq stock symbol), are allegations that take the speech at issue outside the realm of pure science speech and move it towards the realm of commercial speech.").

<sup>146</sup> See *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 458–59 (D.N.J. 2009); see also *Genzyme Corp.*, 906 F. Supp. 2d at 16 ("[W]hile the original presentation of the comparative data at the EWGGD convocation was protected scientific expression, its secondary dissemination in a press release by Shire HGT was not.").

<sup>147</sup> *Genzyme Corp.*, 906 F. Supp. 2d at 16–17 (noting, also, that "the press release selectively disseminated information favorable to Shire HGT's VPRIV and unflattering to Cerezyme to an audience that included both physicians who prescribe Gaucher disease treatments and patients (e.g., those served by the National Gaucher Foundation) who might request a specific treatment").

<sup>148</sup> *Id.* at 17. (noting that "the press release selectively disseminated information favorable to Shire HGT's VPRIV and unflattering to Cerezyme to an audience that included both physicians who prescribe Gaucher disease treatments and patients (e.g., those served by the National Gaucher Foundation) who might request a specific treatment"); see also *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 62–65 (D.D.C. 1998) (finding that a secondary dissemination of that research constitutes commercial speech if it is given a pecuniary gloss), *vacated in part on other grounds sub nom. Washington Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000). In *Washington Legal Foundation*, the court considered whether, under the commercial speech doctrine, the FDA could regulate the dissemination of medical textbook and journal reprints and continuing medical education ("CME") seminars that promote off-label uses for prescription drugs. The court concluded that selective and/or targeted secondary dissemination of scientific research "is properly classified as commercial speech." *Id.* at 65. "It is beyond dispute that when considered outside of the context of manufacturer promotion of their drug products, CME seminars, peer-reviewed medical journal articles[,] and commercially-available [sic] medical textbooks merit the highest degree of constitutional protection." *Id.* at 62. However,

Similarly, academic speech is not immune from the Lanham Act when it is further disseminated. Nonprofit organizations are free to publish on any topic, even those that lead to their financial benefit, without fear of Lanham Act liability, but the same does not apply to subsequent or prior promotional uses of that speech.<sup>149</sup> As the Southern District of New York explained:

The situation is similar to that of a restaurant or movie review or a *Consumer Reports* product report. While the restaurant review or product report itself constitutes exactly the type of “consumer or editorial comment” that “raise[s] free speech concerns” and which Congress explicitly intended to exclude from [§] 43(a)’s scope, a restaurant clearly engages in commercial speech when it posts the New York Times review in its window, and General Motors engages in commercial speech when it announces in a television commercial that its car was ranked first by *Consumer Reports*. The *Consumer Reports* article, of course, does not somehow become commercial speech; rather, G.M.’s use of the article is commercial speech. Consequently, G.M. may be sued under the Lanham Act, and *Consumer Reports[s]* testing methodology may become subject to judicial scrutiny to determine whether G.M. “use[d] in commerce” a “false or misleading representation of fact.”<sup>150</sup>

The fact that the First Amendment protected the initial creation is immaterial when that creator uses the speech for a secondary use.<sup>151</sup>

The distribution of a scientific article is further complicated because the Lanham Act is a strict liability statute, and whether the defendant intended to deceive consumers is immaterial to any legal analysis.<sup>152</sup> If a statement or scientific finding is false or misleading when used in commercial speech, the defendant is liable. A plaintiff does not need to show intent to deceive, knowledge of falsity, or even negligence on the part of the

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“[t]he peculiarities of the prescription drug industry make dissemination of scientific research results an especially important and prevalent marketing tool.” *Id.* at 63.

<sup>149</sup> *Gordon & Breach Sci. Publishers S.A. v. Am. Inst. of Physics*, 859 F. Supp. 1521, 1544–45 (S.D.N.Y. 1994) (holding that, while the publication of a comparative survey of academic publishers was protected speech under the First Amendment, the dissemination of the results to librarians were subject to the Lanham Act).

<sup>150</sup> *Id.* at 1544 (first and fourth alterations in original) (citation omitted).

<sup>151</sup> *Id.* at 1544–45.

<sup>152</sup> *See, e.g., POM Wonderful LLC v. Purely Juice, Inc.*, 362 F. App’x 577, 579 (9th Cir. 2009) (“It is settled that intent is not an element of a Lanham Act false advertising claim.”).

defendant in order to succeed with a claim.<sup>153</sup> For a defendant, honest intentions or good intent is no defense.<sup>154</sup> Where a hard, verifiable statement is made that is capable of scientific verification, courts and agencies will assume that the recipient of the communication will treat the statement as including an implicit representation by the advertiser that such verification has been made.<sup>155</sup> Misstatements in advertising cannot be protected by ambiguities and relied upon as defenses.<sup>156</sup>

As an advertising vehicle, "scientific establishment claims" that rely on a scientific study in order to establish the superiority of one product over another are particularly effective.<sup>157</sup> As a result, case law has consistently applied a stricter standard of review for marketing activities that purport to be based on scientific testing<sup>158</sup> or that compare one company's product with that of a competitor.<sup>159</sup>

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<sup>153</sup> See, e.g., *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 189 (2d Cir. 1980) (stating that the false advertising tort "differs from the common law action for trade disparagement in two important respects: (1) it does not require proof of intent to deceive, and (2) it entitles a broad range of commercial parties to relief"); *Am. Broad. Co. v. Maljack Prods., Inc.*, 34 F. Supp. 2d 665, 677 (N.D. Ill. 1998) ("[In a false advertising suit about footage of Princess Diana's funeral, the] BBC's good faith but mistaken belief in its copyright is not a defense to an action under § 43(a). 'The well-settled rule is that there is no requirement under the Lanham Act that a false representation be made willfully or with the intent to deceive.'" (quoting *Zenith Elecs. Corp. v. Exzec, Inc.*, No. 93 C 5041, 1997 WL 798907, at \*12 (N.D. Ill. Dec. 24, 1997))).

<sup>154</sup> See, e.g., *Am. Broad. Co.*, 34 F. Supp. 2d at 677 ("[The] BBC's good faith but mistaken belief in its copyright is not a defense to an action under § 43(a).").

<sup>155</sup> See, e.g., *Am. Home Prods. Corp. v. Johnson & Johnson*, 577 F.2d 160, 169 (2d Cir. 1978) (analyzing competing Lanham Act claims by the producers of over-the-counter pain medications where advertising claims were based on clinical trials).

<sup>156</sup> *Id.* at 166.

<sup>157</sup> Charles J. Walsh & Marc S. Klein, *From Dog Food to Prescription Drug Advertising: Litigating False Scientific Establishment Claims Under the Lanham Act*, 22 SETON HALL L. REV. 389, 392 (1992) (citing research that notes the effectiveness of comparative advertising that includes a source of higher credibility).

<sup>158</sup> See, e.g., *Rhone-Poulenc Roror Pharm., Inc. v. Marion Merrell Dow, Inc.*, 93 F.3d 511, 514-15 (8th Cir. 1996) (holding that "where defendant has hyped the claim of superiority by attributing it to the results of scientific testing, plaintiff must prove only 'that tests [relied upon] were not sufficiently reliable to permit one to conclude with reasonable certainty that they established the proposition for which they were cited.'" (alteration in original) (quoting *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 62-63 (2d Cir. 1992))).

<sup>159</sup> See, e.g., *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 944 (3d Cir. 1993) (enjoining claims that Pennzoil motor oil outperformed Castrol motor oil with respect to viscosity breakdown); *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir. 1991) (enjoining claims that Excedrin was scientifically superior to Tylenol at relieving pain); *Church & Dwight Co. v. Clorox Co.*, 840 F.

## CONCLUSION

The United States Supreme Court has noted that “advertising which ‘links a product to a current public debate’ is not thereby entitled to the constitutional protection afforded noncommercial speech.”<sup>160</sup> *ONY* has the potential to blur this rule and further complicate the already-complex jurisprudence surrounding the regulation of commercial speech. The *ONY* decision sets a precedent that could foreclose adjudication of false advertising disputes in industries where marketing relies heavily on claims based upon scientific validation. Under *ONY*, an advertiser could immune itself to a Lanham Act claim by simply relying on peer-reviewed scientific articles in academic publications. These scientific articles would be outside the scope of the Lanham Act, even if the author of the scientific journal article received financial support from the future advertiser.<sup>161</sup>

The *Eastman* decision returns the boundaries between commercial and noncommercial speech to their appropriate spheres. Under *Eastman*, advertisers are responsible for the truth of the material they distribute—including the use of peer-reviewed academic articles—in advertising or promotion, regardless of its original source. As the United States Court of Appeals for the Fifth Circuit noted, the application of the Lanham Act will not stifle academic freedom or intrude on the First Amendment.<sup>162</sup> The Lanham Act only applies to statements made “in connection with any advertising, promotion, offering for sale, or sale of goods or services.”<sup>163</sup> Under *Eastman*, scientists and academics will continue to be able to research and publish.

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Supp. 2d 717, 722–23 (S.D.N.Y. 2012) (enjoining commercial claims as literally false because tests supporting the claims regarding each party’s cat litter were unreliable).

<sup>160</sup> *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 68 (1983) (quoting *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 563 n.5 (1980)); see also *Eastman Chem. Co. v. PlastiPure, Inc.*, 775 F.3d 230, 236 (5th Cir. 2014) (“Advertisements do not become immune from Lanham Act scrutiny simply because their claims are open to scientific or public debate.”).

<sup>161</sup> See *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 493–94, 497 (2d Cir. 2013) (noting that advertiser Chiesi hired several medical doctors to present findings regarding infant mortality rates, and that these findings ultimately led to publication in the peer-reviewed journal).

<sup>162</sup> *Eastman Chem. Co.*, 775 F.3d. at 237 (“Application of the Lanham Act to Appellants’ promotional statements will not stifle academic freedom or intrude on First Amendment values.”).

<sup>163</sup> *Id.*

It is only those who distribute or use those research findings in subsequent advertising or promotion who could find themselves subject to a Lanham Act claim.<sup>164</sup>

Although the *ONY* decision may seem on its face to only impact the use of science in advertising, the decision has the potential to greatly affect the public. First, as noted earlier, the decision has the potential to foreclose adjudication of false advertising disputes in industries where marketing relies heavily upon scientific validation. Most significantly, a company's distribution of a scientific article moves the scientific findings from the scientific community and academics and into the realm of the general public, which is more likely to trust scientific claims and much less likely to understand or investigate the research methodology behind those scientific claims. For that reason, the Fifth Circuit's *Eastman* decision reflects the proper scope of the Lanham Act's application for the use of scientific research findings.

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<sup>164</sup> *Id.* ("Appellants may continue to pursue their research and publish their results; they simply may not push their product by making the claims the jury found to be false and misleading.").