

Lanham Act False Advertising Litigation: A Potent Weapon in Prescription and OTC Drug Promotion

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More than ever before, pharmaceutical companies are suing competitors, alleging that a rival's advertising for its prescription or over-the-counter drugs is false or misleading. These suits are an effective means to compete for market share, and success or failure in the courtroom often has real and immediate business consequences. To resolve these disputes, the courts have developed a rich body of law that attempts to balance a private plaintiff's right to sue for false advertising with the extensive regulatory scheme governing the sale of drugs in the United States. This article describes the contours of federal false advertising suits, and addresses several issues unique to false advertising litigation involving prescription and OTC drugs.

False Advertising Under the Lanham Act

False advertising suits typically are brought under the federal trademark statute known as the Lanham Act. Section 43(a) of the Lanham Act authorizes a party to sue a competitor who, in connection with the sale of goods or services, uses a "false or misleading description of fact, or false or misleading representation of fact which . . . 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."¹ This language covers false claims about the advertiser's product, as well as false claims about the competitor's product, whether those claims are comparative or non-comparative. Lanham Act suits are typically brought in federal court, and generally are accompanied by a request for a preliminary injunction seeking an immediate halt to the offending ads pending a full trial on the merits.

A Lanham Act plaintiff usually has the burden of proving that the challenged claim is false or misleading, not merely that the claim is unsubstantiated by clinical testing or other proof. For example, if an ad declares, "Drug A is more effective than Drug B," a suit challenging that advertising brought by the manufacturer of Drug B will be successful only if it has clinical or other proof that, in fact, Drug A is not more effective than Drug B. Only when an advertisement makes what is called an "establishment claim" – a claim that the advertiser has clinical or other test proof that its product will perform a certain way – may the plaintiff prevail by showing that the advertiser has no such supporting clinical proof, that the cited study does not in fact support the claim, or that the supposed clinical proof is somehow flawed and unreliable. For example, the manufacturer of Drug B can prove false an advertisement claiming that "Clinical tests prove Drug A is more effective than Drug B," by showing that the clinical tests relied upon by the manufacturer of Drug A are not valid or reliable.

If a Lanham Act plaintiff persuades the court that the challenged advertisement is literally false or "false on its face," the court may grant relief without considering extrinsic evidence of consumer reaction to the advertisement. When a plaintiff claims that a competitor's advertisement is literally true but has a tendency to mislead, confuse, or deceive, or that the advertising makes or conveys what is called an "implied" claim, the plaintiff must come forward with extrinsic evidence, usually in the form of a consumer survey, demonstrating that a material number of consumers took away a misleading message from the advertisement.

A plaintiff who prevails on a Lanham Act false advertising claim can obtain relief that has an immediate impact. Most significantly, the court can issue an injunction barring the challenged advertisements. The court also can order corrective advertising or even a product recall if the offending claims are on the product's packaging and labeling. These powerful remedies, as well as the negative publicity that accompanies them, can embarrass the offending advertiser and damage its bottom line. Moreover, after a trial on the merits, a plaintiff can recover damages,

which may be trebled in “exceptional cases,” if the advertiser knew the claims in questions were false but aired them anyway.

Interplay Between the Lanham Act and the Food, Drug, and Cosmetic Act

One of the most important issues encountered by companies litigating false advertising cases addressing advertising for prescription or OTC drugs is the interplay between the Lanham Act and the Federal Food, Drug, and Cosmetic Act (FDCA), which governs the sale and to a certain extent the marketing of drugs in the United States.²

Responsibility for enforcement of the FDCA is placed exclusively in the hands of the federal government; enforcement actions may be brought by the Food and Drug Administration (FDA),³ Federal Trade Commission (FTC), and, in certain circumstances, the Department of Justice.³ Because there is no private right of action for violations of the FDCA, courts have consistently held that a private plaintiff cannot use the Lanham Act as a backdoor means to enforce the FDCA. Put another way, it is not enough for a Lanham Act plaintiff to prove that the defendant's claim is inconsistent with the FDCA or with product labeling approved by the FDA; rather, the plaintiff must prove the claim false. For example, a suit challenging an “off-label” claim cannot succeed merely by showing that the claim is not encompassed within an indication approved by FDA; rather, the plaintiff must affirmatively disprove the claim. Furthermore, courts are hesitant to allow Lanham Act claims that intrude into the FDA's bailiwick to the extent they require the interpretation or application of ambiguous FDA regulatory provisions.

The seminal case expounding these principles is *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990). In *Sandoz*, Richardson-Vicks claimed in its advertising that its product, an OTC children's cough syrup, “starts to work the instant you swallow.” The claim was based on the action of the demulcent, the syrupy base of the product. Richardson-Vicks had conducted studies demonstrating that the claim was true. Sandoz asserted that the FDA's failure to categorize demulcents as safe and effective made the advertising claim a *per se* violation of the Lanham Act. Sandoz maintained that this argument could be overcome only by proof in the form of two adequate and well-controlled clinical tests within the meaning of the FDCA substantiating the claim, and that the FDA would not have accepted the types of studies conducted by Richardson-Vicks. Sandoz also argued that the Richardson-Vicks label was false because it failed to list the demulcent as an active ingredient (although listing it would have violated the FDCA).

The district court and then the Third Circuit Court of Appeals rejected these arguments. First, the Court of Appeals held that a Lanham Act plaintiff, unlike the FDA or FTC, cannot meet its burden of proof merely by showing a violation of the FDCA: “it is not sufficient for a Lanham Act plaintiff to show only that the defendant's advertising claims of its own drug's effectiveness are inadequately substantiated under the FDA guidelines; the plaintiff must also show that the claims are literally false or misleading to the public.” Second, the court rejected Sandoz' argument that a false advertising claim could be based on a labeling violation of the FDCA. The court noted that the Lanham Act and FDCA have different purposes: the FDCA is primarily concerned with protecting the public by passing on the safety and efficacy of new drugs, while the Lanham Act is focused on the truth or falsity of commercial advertising claims. Moreover, the court observed that the FDA monograph had not concluded that demulcents must be labeled as inactive or active; rather, FDA had made no finding on the issue. To base a Lanham Act claim on a labeling violation would require the court “to usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations” and indirectly create private rights of action under regulatory statutes.⁴

That does not mean, however, that regulatory standards have no place in Lanham Act litigation. For example, many Lanham Act cases involve alleged false statements made about products otherwise subject to regulation by the FDCA, and courts generally hold that an advertising claim is actionable under the Lanham Act when the truth or falsity of the claim may be determined

without necessarily having to interpret or apply the FDCA or regulations promulgated thereunder. Moreover, a Lanham Act plaintiff may sue a rival who has made an affirmative representation that a product has received FDA approval when in fact the product has no such approval.⁵

Courts also have held that while a plaintiff may not bring a Lanham Act claim that requires direct application or interpretation of the FDCA or FDA regulations, a claim that merely references FDA regulations to establish the standard for determining the truth or falsity of the advertising claim is not precluded.⁶ For example, when the FDA has made findings, there are circumstances under which a private party can use those findings to help establish or defend against a false advertising claim. Indeed, courts tend to reject arguments that would require them to second-guess the expert scientific judgment of the FDA on matters concerning the safety or efficacy of drugs. As a result, courts generally deny Lanham Act claims in which the challenged advertisement is consistent with labeling approved by the FDA.⁷ Courts also have given significant deference to the FDA's conclusions concerning clinical studies relied upon by parties to a false advertising case.

For example, in *Zeneca Inc. v. Eli Lilly & Co.*, No. 99 Civ. 1452, 1999 WL 509471 (S.D.N.Y. July 19, 1999), the court held that "the FDA's expert conclusions [are] relevant evidence in determining whether a party violated the Lanham Act." In that case, Eli Lilly instructed its sales representatives to make the claim that Lilly's osteoporosis drug Evista had been proven to reduce the risk of breast cancer based on the results of a clinical study known as the MORE trial. As such, the sales representatives were making establishment claims, and the only relevant issue was whether the MORE study proved such a reduction in the risk of breast cancer. Lilly had submitted the MORE study to the FDA, which had found that the study did not establish that Evista reduced the risk of breast cancer. The court gave significant deference to the FDA's findings, holding that "as a recognized expert in evaluating data from clinical trials, the FDA's conclusion as reflected in the Evista label and various FDA documents that '[t]he effectiveness of [Evista] in reducing the risk of breast cancer has not yet been established' is persuasive evidence that Eli Lilly's claims to the contrary are untrue." Thus, while the FDA conclusions were not in and of themselves definitive proof that the promotional claim was false, that the studies were not reliable enough for the FDA was evidence that they were not reliable enough to support the advertising claims.⁸

Oral Statements by Pharmaceutical Sales Representatives

While direct-to-consumer advertising, especially on television, is perhaps the most visible form of advertising for prescription drugs today, promotional activities by sales representatives play an integral role in the promotion of prescription drugs. Consumers cannot purchase prescription drugs without a prescription from their doctor, and therefore drug companies direct a significant portion of their efforts to persuading physicians to prescribe a particular drug treatment for their patients. A key method drug companies use to reach doctors is called physician detailing, in which a drug company's sales representatives visit physicians in person. Doctors rely on statements made by sales representatives during detailing as one of their primary sources of information about prescription drugs. Because this information is then filtered through doctors to their patients, and because patients are likely to trust the information they receive from their doctors and ultimately are the ones making the informed decision to proceed with a particular treatment, physician detailing is an indirect means of marketing drugs to consumers.

Considering the continued importance of physician detailing, it is not surprising that drug companies have sued competitors when they believe a competitor's sales representatives have been spreading false or misleading information during visits with doctors. The law is fairly well settled that oral communications by sales representatives, if they are sufficiently widespread and systematic, constitute "commercial advertising or promotion" under the Lanham Act, and those oral statements are actionable if proven false. But false advertising suits attacking oral statements to physicians by a competitor's sales representatives give rise to a special challenge: how can a plaintiff prove the sales representatives were actually making the statements? After all, the

statements are oral, not written or otherwise recorded, and obtaining the testimony of hundreds of sales representatives and doctors usually is not a serious option.

Courts have relied upon several different sources of evidence to establish that oral representations were made by pharmaceutical sales representatives. In *Schering Corp. v. Pfizer, Inc.*, Schering relied on physician surveys that asked physicians to record — either immediately or shortly after the visit by the Pfizer representatives — their memories, and sometimes their impressions, of statements made by the representatives during their brief visits. The district court initially rejected these surveys, finding that they did not fall within the state of mind exception to the hearsay rule set forth in Fed. R. Evid. 803(3) or the residual hearsay exception contained in Fed. R. Evid. 807.⁹ The Second Circuit Court of Appeals reversed. First, the court held that two of the surveys, which had also asked physicians their impressions of the main messages of the visits by the sales representatives, were admissible under Rule 803(3), for the limited purpose of demonstrating that Schering had communicated impliedly false claims. In other words, these two surveys could be used to demonstrate that Pfizer representatives were making statements which, regardless of their truth, left the physicians with false impressions, a typical use of a Lanham Act survey. Second, and more importantly, the Court of Appeals remanded on the issue of the applicability of the residual hearsay exception to all of Schering's surveys. The court ruled that the district court had erred in relying on a *per se* rule against memory surveys, and directed the lower court to consider the methodology and reliability of those surveys.

Addressing the issue of potential insincerity and faulty narration, the court observed that four of the five surveys were performed within a day of the sales representative visits, and the fifth was performed within a week. The court also noted that the advertising claim at issue concerned a critical factor in a physician's decision to prescribe either Schering or Pfizer's drug, and thus the physicians surveyed presumably would have been poised to look for and remember that type of information in a representative's presentation. The court went on to note that all the surveys tended to corroborate one another. Finally, the court cited independent evidence corroborating the surveys in the form of Pfizer training manuals, which contained instructions to sales representatives to make the allegedly false claim.¹⁰ On remand, the district court admitted the surveys, citing several of the factors noted by the Court of Appeals, including the consistency of results across the surveys and the brief lapse of time between the representatives' visits and the surveys. The district court went on to find that the surveys were sufficiently trustworthy and issued a preliminary injunction.¹¹

In *Zeneca Inc. v. Eli Lilly & Co.*, Zeneca relied upon other, more direct sources to support its allegation that Lilly sales representatives were falsely claiming that Lilly's osteoporosis drug Evista had been proven to reduce the risk of breast cancer. First, several Zeneca sales representatives had, coincidentally, overheard Lilly representatives making the challenged claims while the Zeneca representatives were waiting in the physicians' offices to conduct their own in-person detailing visits with physicians. Second, Zeneca cited Lilly's detailing scripts — instructions to the Lilly sales representatives as to what the representatives should tell physicians during their visits. In those scripts, Lilly directed its representatives to tell physicians in response to questions, that Evista had been proven to reduce the risk of breast cancer. Third, Zeneca used the scripts to induce Lilly's executives to admit during cross examination that they had directed their representatives to make the offending claims. Finally and most importantly, Zeneca relied upon hundreds of "call notes" produced by Lilly during the litigation. These were notes prepared by Lilly representatives in the ordinary course of business, in which they recorded in their computers, typically the day they had visited physicians, a summary of what they told the physicians during their visits.¹²

Lilly challenged the call notes on hearsay grounds, but the court found that the notes were admissible both under the business records exception, Fed. R. Evid. 803(6), and as party admissions, Fed. R. Evid. 801(d)(2)(D). To qualify under the business records exception, the record must be prepared at or near the time of the occurrence and must be made in the course of a regularly conducted business activity. The court found that the call notes unquestionably met

these criteria because they were a required part of the regularly conducted business of Lilly sales representatives, and were supposed to be prepared as soon as possible after visits with physicians. The court also noted that “[a]s contemporaneous written accounts, [the call notes] are the best evidence of what the reps communicated to doctors during their detail visits.” Finally, the court held that because the statements recorded in the notes concerned matters within the scope of the representatives’ agency relationship with Lilly, they were also party admissions under Rule 801(d)(2).¹³ Based on these multiple forms of evidence, the court issued a preliminary injunction.

Whenever a company finds that a competitor is making materially false claims in its advertising, a Lanham Act false advertising suit should be considered. Although, as in any litigation, there is no guarantee of success, Lanham Act suits are a potent weapon, particularly in the case of prescription and OTC drug advertising.

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¹ 15 U.S.C. § 1125(a).

² 21 U.S.C. §§ 301-395.

³ 21 U.S.C. § 337.

⁴ 902 F.2d at 228-31.

⁵ See, e.g., *Alpharma, Inc. v. Pennfeild Oil Co.*, 411 F.3d 934, 939-41 (8th Cir. 2005).

⁶ See *Healthpoint, Ltd. v. Allen Pharm., LLC*, No. SA-07-CA-0526-XR, 2008 BL 55555, at *16 (W.D. Tex. Mar. 18, 2008).

⁷ See, e.g., *SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 95 Civ. 7011, 1996 WL 280810, at *13 (S.D.N.Y. May 24, 1996).

⁸ 1999 WL 509471, at *3, *34. FDA findings on scientific issues are admissible as public records. See *id.* at * 3.

⁹ No. 98 Civ. 7000, 1999 WL 144921, at *4-*7 (S.D.N.Y. Mar. 16, 1999).

¹⁰ 189 F.3d 218, 228-39 (2d Cir. 1999).

¹¹ 2000 WL 718449 (S.D.N.Y. June 5, 2000).

¹² 1999 WL 509471, at *10-*16.

¹³ *Id.* at *3, *8.