Lawyer Insights

Navigating Over-The-Counter Product Ads After FTC Warning

By Armin Ghiam, Jeremy Boczko and Jeremy King
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Earlier this year, the Federal Trade Commission sent letters to nearly 700 companies involved in marketing over-the-counter products, informing them that their product claims must be substantiated by scientific evidence.[1]

The FTC routinely brings claims against companies for unsubstantiated advertising.[2] In addition to the FTC, however, advertising claims can implicate the Lanham Act.

Because of the FTC letter, increasing numbers of clients across the legal community have approached intellectual property attorneys with concerns about ubstantiation requirements under the Lanham Act. But are the substantiation requirements under the Lanham Act the same as the Federal Trade Commission Act? No.

The false advertising burden of proof differs depending on which statute a plaintiff chooses to rely on. The FTC requires advertisers to substantiate all representations in advertising, but the Lanham Act does not mention substantiation, and for this reason, many believe that the Lanham Act does not require substantiation at all.

In most Lanham Act false advertising cases, the burden of proof rests with the plaintiff, or challenger. But in some cases — e.g., when a defendant, or advertiser, alleges that its claim is supported by data, the courts require the defendant to substantiate its statements.

For a successful false advertising claim under the Lanham Act, a plaintiff must prove that:

- The statement was false or misleading;
- It deceived, or had the capacity to deceive, consumers;
- The deception had a material effect on purchasing decisions;
- The misrepresented product or service affects interstate commerce; and
- The challenger has been, or is likely to be, injured as a result of the false advertising.[3]

There are varying levels of false or misleading claims. These include: misleading statements, literally false statements, false statements by necessary implication and establishment claims.[4] Each claim can have its own nuanced burden of proof requirement.

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Proof of consumer deception is required for misleading statements, but not false statements.[5] Consumer deception is usually proven by consumer surveys that demonstrate consumers were misled, confused or deceived by the advertisement.[6] No substantiation is required.

For literally false statements, a plaintiff must prove the statement's falsity.[7] For example, for a superiority claim, the plaintiff must affirmatively prove that the defendant's product is equal or inferior to the plaintiff's product.[8] Again, no substantiation is required — except Armin Ghiam Jeremy Boczko Jeremy King for establishment claims, which are discussed below.

False statements by necessary implication are claims that when considered in their entirety, would be recognized by consumers as if they had been explicitly stated.[9] Like literally false statements, most courts require the plaintiff to prove false statements by necessary implication.

The U.S. Court of Appeals for the Third Circuit, however, is an outlier. It has held that completely unsubstantiated claims by defendants can constitute both literally false statements and false statements by necessary implication, without additional evidence from the plaintiff.[10]

For example, in the 2002 the Novartis Consumer Health Inc. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co. decision, the Third Circuit held that calling an antacid "nighttime strength" was literally false by necessary implication because consumers would believe the product has specified ingredients for nighttime relief.[11]

Establishment claims are express or implied messages that suggest tests or studies support a particular attribute of a product.[12] Unlike other types of false advertising claims, defendants have a burden to substantiate establishment claims with corresponding tests or studies.

To shift the burden to the plaintiff, the defendant's substantiating evidence must adequately establish the proposition in the claim and be sufficiently reliable.[13] The plaintiff then has a lower burden to prove that the defendant's tests are not sufficiently reliable to permit one to conclude with reasonable certainty that the defendant established the claim made.[14]

That burden is not met by merely demonstrating that the defendant's tests are unpersuasive.[15]

Take, for example, in the 1997 Southland Sod Farms v. Stover Seed Co. decision in the U.S. Court of Appeals for the Ninth Circuit. After the defendant supported a bar chart advertisement with two tests, the plaintiff refuted the tests' reliability with expert witnesses and six of its own independently conducted tests.[16]

In the 1996 Gillette Co. v. Norelco Consumer Products Co. decision, however, the U.S. District Court for the District of Massachusetts found the plaintiff's highlighting of some flaws in the defendant's proffered studies was not enough to prohibit the defendant from using "clinically proven" language in its establishment claim.[17]

Overall, courts have required substantiation in Lanham Act cases when: (1) a reasonable consumer would conclude that a claim or attribute is supported by tests or studies; or (2)

the advertisement includes a literally false statement or a false statement by necessary implication and the case is brought in the Third Circuit.

So, how can advertisers avoid false advertising liability when promoting products?

First, when there is a possibility of jurisdiction in the Third Circuit, advertisers must be prepared to substantiate all statements that could be challenged by a competitor as false.[18] Documenting substantiation to back up advertising claims would be prudent.

Second, when advertising using statements touting, or even implying, the use of tests or studies, advertisers should be ready with reliable evidence to support the validity of the claim.[19]

For example, in the context of products regulated by the U.S. Food and Drug Administration, advertisers may lean on the applicable FDA monograph or FDA-approved label for substantiation.[20] Plaintiffs cannot simply meet their burden by showing the information is absent from the monograph — rather, they must show that the information is inconsistent with the monograph.[21]

While the Lanham Act does not require substantiation for the vast majority of claims, if an advertiser has evidence to substantiate its claims, a general rule of thumb is to keep the evidence just in case.

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Notes

1. https://www.ftc.gov/news-events/news/press-releases/2023/04/ftc-warns-almost-700-marketing-companies-they-could-face-civil-penalties-if-they-cant-back-their.
See Law360, FTC Warns Companies Not To Make Unbacked Health Claims, https://www.law360.com/articles/1596789/ftc-warns-companies-not-to-makeunbacked-health-claims?copied=1.

2. See, e.g., Federal Trade Commission v. Gravity Defyer Medical Technology Corporation et al, No. 1:22-cv-01464 (D.D.C. May 25, 2022).

3. See Suntree Techs. Inc. v. EcoSense Int'l Inc., 802 F. Supp. 2d 1273 (M.D. Fla. 2011), aff'd, 693 F.3d 1338 (11th Cir. 2012).

4. See Coca-Cola Co. v. Tropicana Prods. Inc., 690 F.2d 312, 216 U.S.P.Q. 272 (2d Cir. 1982).

5. Id.

6. See Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1139 (9th Cir. 1997).

7. Id.

8. See Castrol Inc. v. Quaker State Corp., 977 F.2d 57 (2d Cir. 1992).

9. See Scotts Co. v. United Indus. Corp., 315 F.3d 264 (4th Cir. 2002).

10. Id; see also Diamond Resorts U.S. Collection Dev. LLC v. US Consumer Att'ys P.A., No. 18-80311-CIV, 2020 WL 5514158 (S.D. Fla. July 31, 2020) (declining to follow the Novartis decision "Novartis has not been adopted by the Eleventh Circuit or any other U.S. Court of Appeals. I decline to adopt it here.").

11. Novartis Consumer Health Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co., 290 F.3d 578 (3d Cir. 2002).

12. See Southland Sod Farms, 108 F.3d at 1139.

13. See Munchkin Inc. v. Playtex Prods. LLC, No. CV 11-00503 AHM (RZx), 2011 U.S. Dist. LEXIS 58800, at *8-9 (C.D. Cal. Apr. 11, 2011).

14. See Southland Sod Farms, 108 F.3d at 1139.

15. See McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co., 938 F.2d 1544 (2d Cir. 1991).

16. Id.

17. Gillette Co. v. Norelco Consumer Prod. Co., 946 F. Supp. 115, 123-7 (D. Mass. 1996).

18. See Novartis Consumer Health Inc., 290 F.3d at 578.

19. See Southland Sod Farms, 108 F.3d at 1139.

20. See Church & Dwight Co. v. SPD Swiss Precision Diagnostics GmbH, 843 F.3d 48 (2d Cir. 2016).

21. See Apotex Inc. v. Acorda Therapeutics Inc., 823 F.3d 51, 64 (2d Cir. 2016).

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