Lack Of Prior Substantiation For Advertised Claims Is Generally Not A Cognizable Theory Of Recovery In Consumer Products Class Actions

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An increasing trend in consumer class action litigation, particularly in cases dealing with dietary supplements, over-the-counter drugs, or food products, is for a plaintiff to allege that claims about a product’s benefits cannot be substantiated by scientific evidence and are therefore false and misleading. Many courts have recognized, however, that alleging no more than “lack of prior substantiation” does not state a claim for consumer fraud because actual falsity of the claims must be alleged or proved. Regardless, the Federal Trade Commission (“FTC”) is vested with the exclusive authority to require a manufacturer to provide a reasonable basis for advertising, or cease and desist from making unsubstantiated advertising claims. See Federal Trade Commission Act (“FTCA”), 15 U.S.C. 45, et seq. Given the wide range of “economic loss only” class actions attacking well-established products and brands, practitioners and in-house counsel should consider this developing jurisprudence as a means of achieving early dismissal of such lawsuits.

California Leads The Way In Rejecting This Theory

California courts set the trend for dismissal of putative class actions resting on a lack of prior substantiation theory of liability. In Nat’l Council Against Health Fraud, Inc. v. King Bio. Pharm., Inc., 107 Cal. App. 4th 1336 (2003), plaintiff filed a representative action alleging that defendants’ advertising of homeopathic remedies was false and misleading because the products were ineffective and there was “no scientific basis for the [products’] efficacy.” Id. at 1340-41. The trial court granted defendant’s motion for directed verdict because plaintiff failed to prove that the advertising was actually false or misleading. Id. On appeal, plaintiff argued the burden of proof should be shifted to a defendant in a false advertising action. Id. at 1340. The appellate court explained that California statute “established an administrative procedure by which prosecuting authorities may demand such [claim] substantiation,” and “[p]rivate plaintiffs are not authorized to demand substantiation for advertising claims.” Id. at 1345. The appellate court characterized this distinction as “rational” because it would prevent the “undue harassment of advertisers and is the least burdensome method of obtaining substantiation for advertising claims.” Id. Thus, a plaintiff alleging false advertising has the burden to demonstrate that the advertising claims are actually false or misleading. Id.

Later, a California district court issued a now-often-cited opinion dismissing a nationwide class action alleging lack of prior substantiation, Fraker v. Bayer Corp., No. CV F 08-1564 AWI GSA, 2009 U.S. Dist. LEXIS 125633, at *3-5 (E.D. Cal. Oct. 2, 2009). In Fraker, plaintiff alleged that Bayer could not substantiate its claims of weight loss benefits for its “One A Day” line of vitamin supplements. The Court described the lawsuit as “[a]n attempt to shoehorn an allegation of violation of the [FTCA] into a private cause of action.” Id. at *19. As the district court explained when dismissing the false advertising claims, “the government, representing the [FTC], can sue an advertiser for making unsubstantiated advertising claims; a private plaintiff cannot.” Id. at *21. The district court emphasized that “there is no private remedy for unsubstantiated advertising”; instead, the plaintiff must show that a defendant’s product claims are actually false, “not simply that they are not backed up by scientific evidence.” Id. at *22-23.

Following Fraker, California courts continued to dismiss proposed class actions at the pleading stage or granted summary judgment when plaintiffs claimed only that defendants lacked scientific support for their claims. See Chavez v. Nestle USA, Inc., No. 09-9192-GW (CWx), 2011 U.S. Dist. LEXIS 58733, at *3, 15-16 (C.D. Cal. May 2, 2011), affirmed in part, reversed in part, 2013 U.S. App. LEXIS 4758, at *2 (9th Cir. Mar. 8, 2013) (relying upon Fraker to dismiss a lawsuit alleging that Nestlé deceptively and falsely advertised its kids’ beverages because it could not substantiate the claimed benefits of the products’ nutrients); Bronson v. Johnson & Johnson, Inc., No. 12-04184, 2013 U.S. Dist. LEXIS 54029, at *22 (N.D. Cal. Apr. 16, 2013) (in granting a motion to dismiss false advertising claims based upon lack of prior substantiation, observing “[c]laims

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that rest on a lack of substantiation, instead of provable falsehood, are not cognizable under the California consumer protection laws.”); 

*Johns v. Bayer Corp.*, No. 09-1935, 2013 U.S. Dist. LEXIS 51823, at *115-133 (S.D. Cal. Apr. 10, 2013) (granting summary judgment in favor of Bayer because plaintiff did not offer any affirmative proof that the prostate health claims for One-A-Day vitamins were actually false and misleading, and that the “strength of Bayer’s evidence is irrelevant” because plaintiff has the burden to prove actual falsity); 

*Stanley v. Bayer Healthcare LLC*, No. 11-862-IEG (BLM), 2012 U.S. Dist. LEXIS 47895, at *5, 14-16 (S.D. Cal. Apr. 3, 2012) (granting summary judgment where plaintiff cited studies that defendant’s probiotics had “little effect on human digestive or immune health,” but did not offer any evidence as to why the probiotics’ claims were “actually false”).

**Other Jurisdictions Reject Lack Of Substantiation Claims**

Other federal and state courts have followed California’s lead to require a showing of actual falsity, not just lack of substantiation. In affirming summary judgment to Coca-Cola in a proposed class action alleging that it had engaged in false and deceptive advertising of a soft drink as “calorie-burning” without any scientific support, the Third Circuit observed that “[n]o New Jersey or Third Circuit decision has applied the prior substantiation theory to the New Jersey Consumer Fraud Act, and we, therefore, decline to do so here.” 


Thereafter, federal district courts in New Jersey built upon *Fralunovic* to reaffirm that lack of prior substantiation is not a cognizable cause of action. For example, in *Gaul v. Bayer Healthcare LLC*, No. 12-5110 (SRC), 2013 U.S. Dist. LEXIS 22637, at *2, 3 (D.N.J. Feb. 11, 2013), the district court dismissed a class action complaint alleging that Bayer falsely advertised a dietary supplement. In granting Bayer’s motion to dismiss, the court reasoned that “the Third Circuit distinguishes inadequate substantiation from false advertising.” 

*Id.* Recently, in *Hodges v. Vitamin Shoppe, Inc.*, No. 13-3381, 2014 U.S. Dist. LEXIS 5109, *6-19 (D.N.J. Jan. 15, 2014), plaintiffs sought to extend the lack of substantiation rationale, claiming that certain physical fitness dietary supplements contained well-known ingredients but were “under dosed,” rendering the product ineffective and the product claims false. The district court determined that plaintiff’s speculation about the dosage was insufficient and concluded that the allegations were impermissibly “rooted” in lack of prior substantiation. 

*Id.*

In *Scheuerman v. Nestle Healthcare Nutrition, Inc.*, Nos. 10-3684, 10-5628 (FSH) (PS), 2012 U.S. Dist. LEXIS 99397, at *3, 22-23 (D.N.J. Jul. 17, 2012), the court dismissed a class action complaint alleging that Nestle deceptively advertised “clinically shown” health benefits for a beverage “without any reasonable basis for doing so and without substantiating [the claims].” The Court held that the “core allegations of fraud in the Complaint are clearly grounded in a prior substantiation theory of liability,” and that “the case law is clear . . . that prior substantiation claims are not cognizable under the NJCFA . . . .” (citing *Fralunovic, Stanley, Fraher, and Chavez*).

Moreover, an appellate court in Illinois affirmed the dismissal of a class action lawsuit claiming that a pharmaceutical company falsely advertised cough and cold remedies because there was no scientific support for the advertised claims. See *Gredell v. Wyeth Laboratories, Inc.*, 367 Ill. App. 3d 287 (2006) (“Lack of substantiation is deceptive only when the claim at issue implies there is substantiation for that claim, i.e., if defendants had claimed something along the lines of ‘tests show that [the cough expectorant] is effective for cough suppression’”).

**Courts Will Examine Whether More Than Lack Of Substantiation Is Alleged**

Lack of substantiation claims tend to fail where the complaints lack a sufficient factual basis for the court to infer some falsity in advertising. But heed warning: courts will examine whether a plaintiff goes beyond alleging lack of scientific support. In *Eckler v. Wal-Mart Stores, Inc.*, No. 12-727, 2012 U.S. Dist. LEXIS 157132, at *4-11 (S.D. Cal. Oct. 31, 2012), plaintiff alleged that defendant’s claims about Equate Glucosamine MSM Advanced Triple Strength were both unsubstantiated and “disproved by the scientific community.” 

*Id.* at *7. The court reasoned that claims that have been disproved are “closer to an affirmative misrepresentation,” so since the plaintiff relied upon studies that “debunk[ed] the purported benefits of glucosamine hydrochloride, she isn’t just saying those benefits are unsubstantiated. She is saying they are positively false.” 

*Id.* at *10.

Notably, some courts have acknowledged that other jurisdictions reject lack of prior substantiation claims, but have not dismissed any lawsuits rooted in this theory. For example, though Florida courts have not expressly adopted a bright-line rule barring claims that rely solely on lack of scientific substantiation, several courts have acknowledged that federal pleading standards require more than alleging a statement is not supported by existing studies. See *Toback v. GNC Holdings, Inc.*, No. 13-80526, 2013 U.S. Dist. LEXIS 131135, at *10 (S.D. Fla. Sept. 13, 2013) (concluding that plaintiff “goes further than alleging that Defendants have failed to substantiate their representations with scientific evidence, but instead alleges that scientific evidence exists to contradict Defendants’ representations and demonstrate their falsity”); 

*In re Horizon Organic Milk Plus DHA Omega-3 Mktg. & Sales Practice Litig.*, 955 F. Supp. 2d 1311, 1344 (S.D. Fla. 2013) (plaintiffs “are not claiming that there is no scientific evidence to support [the defendant’s] brain health representations; instead, they are claiming that the competent scientific evidence shows that [the defendant’s] representations are actually false”).

Likewise, in *Hughes v. Ester C Co.*, 930 F. Supp. 2d 439, 459 (E.D.N.Y. 2013), the district court agreed that “plaintiffs, at first blush, seem to be bringing a lack of substantiation claim,” but then concluded that “[p]laintiffs go several steps further, thereby removing their claims from the lack of substantiation sphere and into the affirmative misrepresentation realm.” Plaintiffs relied upon studies claiming the product was not efficacious, “[t]hus, plaintiffs are not simply stating that defendants have no credible science backing up their claims. Instead, they are affirmatively claiming that defendants’ representations are positively false.” 

*Id.* at 460.

**Evidence of Actual Falsity Distinguishes Lack Of Prior Substantiation Claims**

In sum, actual falsity will be required to show false advertising or consumer fraud. Private plaintiffs cannot act on behalf of the FTC to demand substantiation or claim that it does not exist in order to seek certification of a class; instead, they must affirmatively show that the advertised claims are actually false and misleading.