Legal Backgrounder

Vol. 32 No. 28 November 3, 2017

Washington Legal Foundation
Advocate for Freedom and Justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302 wlf.org

Regulators, Not Private Plaintiffs, Should Judge Substantiation for Consumer-Product Health Claims

by Katie Bond and Glenn T. Graham

In 2003, a California Court of Appeal decided in *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm, Inc.*, 107 Cal. App. 4th 1336 (2003), that plaintiffs filing false advertising suits under California law bear the burden of proving falsity, and could not demand that the defendant substantiate its claims. That decision has stood the test of time, even in the face of plaintiffs' lawyers' recent success in using California consumer-protection laws to bring false-labeling, slack-fill, and other claims against consumer-product makers. This past August, the U.S. District Court for the Southern District of California reaffirmed the viability of, and rationale behind, *King Bio* a little over a year after a federal court in the state's Northern District called the precedent into serious question. *Korolshteyn v. Costco Wholesale Corp. and NBTY, Inc.*, No. 3:15-CV-709-CAB-RBB (S.D. Cal. Aug. 23, 2017).

The *King Bio* Precedent

In *King Bio*, a private litigant alleged that a seller of homeopathic remedies violated California's unfair competition and false advertising laws by disseminating health-benefit claims that lacked a "scientific basis." *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc.*, 107 Cal. App. 4th 1336, 1340-41 (2003). The plaintiff offered no evidence in support of its allegations; rather, the plaintiff argued that "the burden of proof should be shifted to [the defendant] to prove its products' efficacy." *Id.* The court rejected this theory.

The court reviewed California's Unfair Competition Law (UCL) (Bus. & Prof. Code § 17200 et seq.) and False Advertising Law (FAL) (Bus. & Prof. Code § 17500 et seq.) and determined that these statutes expressly empower State regulators to demand "evidence of the facts on which such advertising claims are based." *Id.* at 1343 (citing Bus. & Prof. Code § 17508). The court, however, found that private plaintiffs were in no way similarly empowered. *Id.* at 1345.

The court reasoned that because government actors are granted sole authority to undertake investigations into the weight and reliability of an advertiser's substantiation, only government actors may bring false-advertising cases based on a lack of substantiation. *Id.* at 1349. To allow private actors to also base cases on a lack of substantiation would "thwart the intent of the Legislature." *Id.* at 1345. The court thus held that private plaintiffs must actually prove that advertising claims are false, for example, by testing a product themselves. *Id.* at 1348.

Katie Bond is a Special Counsel in the Washington, DC office of Kelley Drye & Warren LLP, and **Glenn T. Graham** is a Senior Associate in the firm's Parsippany, NJ office. The authors filed an *amicus* brief in *Korolshteyn* on behalf of the Council for Responsible Nutrition, the leading trade association for the dietary supplement industry, representing more than 150 sellers, manufacturers, and ingredient suppliers worldwide.

In the fourteen years since *King Bio*, California courts—and courts in many other jurisdictions—have recognized the decision as well-established law. *Racies v. Quincy Bioscience, LLC*, No. 15-cv-00292-HSG, 2015 WL 2398268, at *3 (N.D. Cal. May 19, 2015) ("[i]t is well-settled that private litigants may not bring any UCL claims based on alleged lack of substantiation"); *Kwan v. SanMedica Int'l*, No. 15-15496, 2017 WL 1416483, at *6 (9th Cir. Apr. 21, 2017) ("[I]t is readily apparent that *King Bio's* holding is firmly established in California law.").

The vast majority of courts, moreover, have properly interpreted *King Bio* as requiring private plaintiffs to identify facts that, if proven, would demonstrate that claims are actually false. For example, in *Stanley v. Bayer Healthcare LLC*, the plaintiff challenged advertising claims stating that a probiotic supplement "helps defend against" symptoms, such as gas and bloating. No. 11cv862-IEG(BLM), 2012 WL 1132920, at *1-2 (S.D. Cal. Apr. 3, 2012). The plaintiffs alleged that the claims violated California law because no studies had been performed on the specific blend of probiotics in the product. *Id.* at *6. They also argued "a majority of data generated in peer reviewed, double blind, placebo controlled studies relating to probiotics, largely suggests that probiotics have little effect on human digestive or immune health." *Id.* at *5.

The court reviewed the plaintiff's expert testimony, but ultimately determined that "none of the Plaintiff's experts opine that the claims [at issue] are actually false." *Id.* at *5. The court observed that "[i]nstead, Plaintiff's experts repeatedly assert the [advertising claims] are rendered false or misleading due to a lack of substantiation." *Ibid.* The court pointed to statements by one of the plaintiff's experts who testified that the effects of probiotics "var[y] dramatically between individuals" and that the science is "inconclusive" on whether probiotics might work for some people. *Id.* at *5-6.

The court dismissed the plaintiff's allegations, finding that that "[t]he burden is upon Plaintiff to present evidence that Defendant's advertising claims are *actually false or misleading*." *Id.* at *9 (emphasis added); *see also, e.g.*, *Bronson v. Johnson & Johnson, Inc.*, No. C 12-04184 CRB, 2013 WL 1629191, at *8 (N.D. Cal. Apr. 16, 2013) ("Claims that rest on a lack of substantiation, instead of provable falsehood, are not cognizable under the California consumer protection laws."); *Quinn v. Walgreen Co.*, 958 F. Supp.2d 533, 544 (S.D.N.Y. 2013) (private litigant must present facts that, if true, would show that advertising claims are "affirmatively false").

In *In re GNC*, 789 F.3d 505 (4th Cir. 2015), the U.S. Court of Appeals for the Fourth Circuit reached a similar holding. The plaintiffs challenged advertising that claimed a supplement containing glucosamine, chondroitin, and other ingredients provides benefits such as "promot[ing] joint health and mobility" and "protect[ing] from wear and tear of exercise." *Id.* at 509-510. Plaintiffs alleged that "the vast weight of competent and reliable scientific evidence" proved that the claims were false. *Id.* at 510 (internal citation omitted). The Fourth Circuit found this allegation lacking. The court reasoned that the plaintiffs' own arguments revealed that the evidence on glucosamine and chondroitin "is equivocal." *Id.* at 515. It further observed that "[w]hen litigants concede that some reasonable and duly qualified scientific experts agree with a scientific proposition, they cannot also argue that the proposition is literally false." *Id.* at 515 (internal quotation omitted). According to the court, in order to state an actionable claim, a plaintiff must have alleged "that *all* reasonable experts in the field agree that the representations are false" *and* that "*all* of the ingredients contained in the products are incapable of providing the represented benefits." *Id.* at 516 (emphasis added).

These two decisions, among many others, aptly recognize that private plaintiffs seeking to challenge a company's advertising must identify facts that could affirmatively demonstrate falsity.

The Northern District of California's Divergent *Mullins* Decision

In *Mullins v. Premier Nutrition Corp.*, 178 F. Supp. 3d 867 (N.D. Cal. 2016), however, the Northern District of California departed from the sound legal standard set forth in *King Bio*. The plaintiffs challenged advertising claims for Joint Juice, a liquid dietary supplement containing glucosamine and chondroitin. 178 F. Supp. 3d at 875. The defendant offered expert evidence in support of its claims and pointed to studies showing beneficial effects. *Id.* at 884-86. In response, the plaintiff offered expert evidence and clinical studies which allegedly showed that the weight of evidence failed to support the claims. *Id.* at 882-86. The court refused to grant summary judgment in favor of the defendants, finding that the plaintiff could properly show that the claims were misleading if she could show that "the vast weight of competent evidence establishes that the [defendant's] health claims are false." *Id.* at 895. The court further found that the plaintiff had made a threshold showing by offering "principled critiques" of the defendant's studies. *Id.* at 895-96.

The Southern District of California Rejects *Mullins*

Korolshteyn involved the substantiation underlying claims for a gingko biloba products. No. 3:15-CV-709-CAB-RBB, at *1. The plaintiffs urged the court to follow *Mullins*. The court, however, correctly found that the rationale in *Mullins* "is difficult to reconcile with *King Bio*." *Id.* at *9. It reviewed case law that had correctly interpreted *King Bio* and concluded that "regardless of whether a plaintiff's burden of proof is characterized as (1) all reasonable experts in the field agree that the representations are false, or (2) the evidence is unequivocal that the representations are false, a plaintiff cannot survive summary judgement when a defendant presents admissible expert testimony that there is scientific support for the alleged misrepresentations." *Id.* at *11-12. The court, next, considered whether the defense had offered admissible expert testimony and found that it had. *Id.* at 24. The court granted summary judgment in favor of the defense.

The Ninth Circuit Should Uphold Cases Correctly Interpreting *King Bio*

The debate over *King Bio* will now shift to the Ninth Circuit, to which the *Korolshteyn* plaintiffs have appealed. Another case where the Court correctly interpreted and followed *King Bio*, decided by the Central District of California, is also currently on appeal before the Ninth Circuit. *See Sonner v. Schwabe North America, Inc.*, 5:15-CV-01358 (9th Cir.).

Given the complexities of nutrition science and the unique expertise—and public-health role—of regulators, government officials should continue to be the sole arbiters in determining whether substantiation is adequate in a given case. The Council for Responsible Nutrition (CRN) provided a real-world, on-the-ground perspective of its dietary-supplement-manufacturer members in an *amicus* brief that the *Korolshteyn* court accepted over the plaintiffs' vigorous objection.[1]

State regulators, the Food and Drug Administration (FDA) and Federal Trade Commission (FTC) share jurisdiction over labeling and advertising claims for dietary supplements. *See* 21 U.S.C. § 331; 15 U.S.C. §§ 45(a)(1), 52(a). These regulators regularly review and assess claim support either as a part of a pre-approval process or enforcement. CRN pointed to FDA's approval of a health claim for folic acid as an example illustrating the complexity of nutritional science and how regulators act in a unique and invaluable capacity in considering the public health in assessing claims and substantiation. *See* Notice of Motion for Permission to File Amicus Curiae, No. 3:15-CV-709-CAB-RBB, at Exhibit A, at 10 (May 15, 2017).

[1] *Korolshteyn v. Costco Wholesale Corp. and NBTY, Inc.*, No. 3:15-CV-709-CAB-RBB, *Amicus* Brief of Council for Responsible Nutrition, May 15, 2017.

ISBN 1056 3059

While most government assessments of claim substantiation occur without the opportunity for public observation or participation, FDA's approval of "health claims" (claims associating a substance and disease risk) utilizes notice-and-comment rulemaking.[2] In determining whether to authorize a health claim associating folic acid with a reduced risk of neural tube defects, FDA and other stakeholders carefully reviewed the science and considered the public-health implications. *See* 61 Fed. Reg. 8752 (Mar. 5, 1996). Only a small number of relevant studies existed: two randomized controlled studies, one of which was conducted in Hungary, and five observational studies. *Id.* at 8756. In order to assist in its assessment, FDA convened the Folic Acid Subcommittee and reviewed comments from "invited guest consultants; other Federal agencies; a foreign government; State departments of agriculture, consumer services, or health; health care professionals; consumers; consumer advocacy groups; [and] manufacturers and suppliers of vitamins to the conventional food industry and the dietary supplement industry," among others. *Id.* at 8755.

FDA received a wide range of comments representing divergent views, and even its own panel did not reach consensus on authorizing the claim. "[M]embers of the Folic Acid Subcommittee who opposed a health claim cited the weakness of the data supporting the relationship, including the very small number, and observational nature, of studies relating intake of folate at levels attainable from usual diets to reduced risk of neural tube defects and the many issues associated with the interpretation of these studies." *Id.* at 8756. FDA itself acknowledged that "there are still significant gaps in our knowledge about the etiology of neural tube defects; about how folate, either alone or in combination with other nutrients, reduces the risk of neural tube defects; about dose-response relationships between folate intake and reduction in risk of neural tube defect-affected pregnancies; and about the role of other essential nutrients in the etiology of neural tube defects." *Ibid.*

Despite the divergent views, FDA ultimately authorized a claim. *Id.* at 8752; 21 C.F.R. § 101.79 (rule authorizing folic acid health claim). The agency determined that enough consistent evidence existed, and it stated that "it ... expected that consumption of adequate folate will avert some, but not all, neural tube defects." *Id.* at 8780. The authorized folic acid health claim remains in place and provides a uniform standard that may be used in the labeling or advertising of any dietary supplement or food that meets the standard.

Based on this example, CRN argued that if private actors are allowed to seize on any inconsistency or weakness that might be found in a complex body of research, both advertisers—and consumers who rely on their products—stand to be harmed. Allowing a patchwork of conflicting private-actor-driven decisions on any single dietary ingredient stands to dilute the significance and authority of government regulators who necessarily consider public health implications in reviewing claims and substantiation. The Ninth Circuit should consider practical ramifications like these as it considers the appeals in *Korolshteyn* and *Sonner.*

[2] FDA has the authority to authorize "health claims" which are claims that associate a dietary substance with a reduction in disease risk. 21 U.S.C. § 343(r)(1)(b); 21 C.F.R. § 101.14(a)(1).

  ISBN 1056 3059