Tucker Ellis LLP

CLIENT ALERT

NINTH CIRCUIT RULES SUPPLEMENT COMPANIES CAN FEND OFF CHALLENGES TO STRUCTURE/FUNCTION CLAIMS WITH PREEMPTION ARGUMENTS, BUT THAT'S NO DEFENSE TO FALSE ADVERTISING

JANUARY 2019

You win some, you lose some. For defendants in false advertising lawsuits, two recent decisions from the United States Court of Appeals for the Ninth Circuit prove this adage true. While food and dietary supplement manufacturers got an invigorated preemption defense for structure/function claims in one case, they also received a reminder that they cannot avoid liability for false advertising in a second case, lowering the bar to defeat summary judgment motions involving expert testimony.

PROPER STRUCTURE/FUNCTION CLAIMS ARE PREEMPTED

In *Dachauer v. NBTY, Inc.*, the Ninth Circuit brought welcome clarity – and a stronger defense – to dietary supplement manufacturers concerned about consumer fraud false advertising lawsuits involving structure/function claims allowed by the Food and Drug Administration under the Federal Food, Drug and Cosmetics Act ("FDCA"). The Ninth Circuit established a bright line rule preempting state false and misleading advertising suits involving structure/function claims.

The FDCA distinguishes between a manufacturer's "structure/function claims" and "disease claims." A manufacturer makes a structure/function claim about its product when (a) it describes the intended role that a nutrient or dietary ingredient plays in affecting or maintaining the structure or function in humans, or (b) where it characterizes a documented mechanism by which the ingredient or nutrient acts to maintain that structure or function in the body. For instance, a manufacturer makes a structure/function claim if it explains that a nutrient "promotes immune function" or "supports cardiovascular health." In contrast, a "disease claim" is one that explicitly or implicitly "claims to diagnose, mitigate, treat, cure, or prevent disease." Food and supplement manufacturers cannot make disease claims about their products unless the FDA has authorized the claim as an approved health claim or approved the product as a drug.

Under the FDCA, manufacturers must meet three criteria in order to make structure/function claims. *First*, the manufacturer must have substantiation that the structure/function statement(s) is truthful and not misleading. *Second*, the structure/function statement must contain a prominent disclaimer that the FDA has not evaluated the statement and that the product "is not intended to diagnose, treat, cure, or prevent any disease." *Third*, the statement itself cannot "claim to diagnose, mitigate, treat, cure or prevent" disease." The second and third requirements emphasize the critical distinction between structure/function claims and disease claims.

In *Dachauer*, the Ninth Circuit made clear that structure/function claims are subject to the same preemption provisions as those involving other claims related to food, such that the FDCA preempts any state law about claims, including structure/function claims, that are "not identical" to those found in the FDCA and related regulations. This is the first court of appeal to provide such a bright line rule on preemption of these claims.

Importantly, however, false advertising claims still can be pursued *if* a plaintiff proves that a structure/function claim itself is false or misleading. The Ninth Circuit first reiterated the longstanding California rule that plaintiffs may not bring suit claiming a manufacturer lacks substantiation for its structure/function claim. It then observed that FDA regulations prohibit the failure to disclose material facts and California law prohibits any claim, literally true or not, that is likely to deceive a reasonable consumer. The *Dachauer* court ruled that one of three challenged structure/function claims was not preempted and could proceed because it was based on the manufacturer's alleged failure to disclose material harmful facts making the claim that vitamin E "promotes immune health" deceptive – that taking vitamin E supplements increased the risk of death. As for the merits of this claim, the Ninth Circuit ruled against the plaintiff, finding that the plaintiff failed to prove that taking vitamin E actually increases the risk of death, which implicates the Ninth Circuit's other recent decision, *Sonner v. Schwabe North America, Inc.*

PLAINTIFF CAN BEAT SUMMARY JUDGMENT WITHOUT FATALLY UNDERMINING THE DEFENSE EVIDENCE

In *Sonner v. Schwabe North America, Inc.*, the Ninth Circuit addressed the level of evidence required to defeat a summary judgment motion involving expert testimony. The plaintiff alleged that a manufacturer's claims that two supplements containing Ginkgo biloba extract benefitted "memory," "concentration" and "mental sharpness" were false. The manufacturer sought summary judgment based on expert testimony that randomized controlled trials involving Ginkgo biloba proved that it benefits cognitive function. The trial court granted the motion despite the conflicting expert testimony offered by the plaintiff that Ginkgo biloba is no better than a placebo at improving cognitive function, and that expert's reviews of studies other than the ones relied on by the defense. The trial court concluded that the plaintiff's criticism of the significance of the defense studies did not prove that the manufacturer's claims were false.

The Ninth Circuit reversed, finding that the trial court incorrectly applied a summary judgment standard to false advertising claims different from the standard for any other claim. It explained that there was a disputed issue for trial because "the plaintiff's evidence suggests that the products do not work as advertised and the defendant's evidence suggests the opposite." The Ninth Circuit commented on substantiation as well, reiterating again that the plaintiff must prove at trial that the claims are false (*i.e.*, that Ginkgo biloba does not provide the advertised benefits).

These two decisions reinforce the importance of developing sound evidence about any product to support advertising claims before they are made. Even under the FDCA, and even with structure/function claims, if a plaintiff can find an expert to testify that a claim is false or materially misleading, they stand a good chance of pleading around the preemption and substantiation defenses and the claim may survive summary judgment.

ADDITIONAL INFORMATION

For additional information, please contact:

- **Matthew Kaplan** | 213.430.3309 | matthew.kaplan@tuckerellis.com
- **Ronie Schmelz** | 213.430.3375 | ronie.schmelz@tuckerellis.com