'Can't Beat the Real Thing,' Unless Perhaps it Isn't:
Supreme Court to Define Interplay Between False Advertising and Federal Food, Drug, and Cosmetic Act

By James R. Lawrence III

Is prominently labeling a juice "Pomegranate Blueberry" when it actually contains less than 1% pomegranate blueberry juice actionable false advertising under the federal Lanham Act or is such a claim barred by the Federal Food, Drug, and Cosmetic Act ("FDCA")? The Ninth Circuit found the claim precluded. The Supreme Court appears poised to reverse.

POM Wonderful, LLC v. Coca-Cola Co. involves Coca-Cola's Minute Maid "Pomegranate Blueberry" juice. Despite its label, Coca-Cola's beverage is 99.4% apple and grape juice. POM Wonderful makes a more expensive juice that contains only pomegranate and blueberry juice. Concerned it was losing sales to Coca-Cola's cheaper beverage, POM Wonderful sued Coca-Cola for false advertising under the federal Lanham Act and for violations of California state law. Both the federal district court and the Ninth Circuit Court of Appeals rejected POM Wonderful's Lanham Act claim, finding it precluded by the FDCA. Now POM Wonderful's false advertising claim lives to see another day. This essay reviews the history of the case before briefly considering the implications for industries regulated by the FDA.

Proceedings Below

POM Wonderful's false advertising theory was straightforward. Its complaint alleged that Coca-Cola's marketing of a beverage consisting mostly of apple and grape juices as a pomegranate blueberry juice materially misled consumers in violation of 15 U.S.C. § 1125(a), the false advertising provision of the Lanham Act, and California state law. **POM Wonderful LLC v. Coca-Cola Co.**, 679 F.3d 1170, 1174 (9th Cir. 2012). The district court denied Pom's Lanham Act claims. *See id.* at 1174–75. The court held that FDA regulations governing juice labeling permitted Coca-Cola's labeling. *Id.* at 1175. As a result, since Coca-Cola's labeling conformed to FDA standards, "Pom's claim challenging the name and labeling of [Coca-Cola's] Pomegranate Blueberry was barred." *Id.* Pom appealed. *Id.*

The Ninth Circuit affirmed the district court's Lanham Act decision. *Id.* at 1179. The court started its analysis by noting that "the Lanham Act and the FDCA can conflict with each other." *Id.* at 1175. While the court recognized that it is important to construe both the Lanham Act and the FDCA to give both statutes the broadest possible effect, it emphasized "Congress's decision to entrust to the FDA the task of interpreting and enforcing the FDCA." *Id.* Thus, "[w]here the FDA has not concluded that particular conduct violates the FDCA, we have held that a Lanham Act claim may not be pursued if the claim would require litigating whether the conduct violates the FDCA." *Id.* at 1176 (citing **PhotoMedex, Inc. v. Irwin**, 601 F.3d 919, 924 (9th Cir. 2010)).

Applying these principles to the facts at hand, the court held that the FDCA barred POM Wonderful's false advertising claim. FDA regulations, the court explained, permit juice manufacturers to "name a beverage using the name of a flavoring juice that is not predominant by volume." *Id.* at 1176–77 (citing 21 C.F.R. § 102.33(c), (d)). The same is true for the beverage's label. *See id.* "Congress and the FDA have thus considered and spoken to what content a label must bear . . . so as not to deceive," the court explained. *Id.* The court continued: "[i]f the FDA believes that more should be done to prevent deception, or that Coca-Cola's label misleads consumers, it can act. But, under our precedent, for a court to act when the FDA has not despite regulating extensively in this area would risk undercutting the FDA's expert judgments and authority." *Id.*

Importantly, the court did not go as far as to "suggest that mere compliance with the FDCA or with FDA regulations will always (or will even generally) insulate a defendant from Lanham Act liability." *Id.* at 1178. Instead, it indicated that it was deferring to "Congress's decision to entrust matters of juice beverage labeling to the FDA." *Id.* It affirmed the district court's Lanham Act ruling and remanded POM Wonderful's state law claims to determine, among other things, whether they are preempted by the FDCA. *Id.* at 1179. At the same time, the Ninth Circuit invited POM Wonderful to take its grievances to the FDA. *Id.* at 1178. That invitation likely gave POM Wonderful little solace. The reason is that the FDCA has no private right of action. *See* 21 U.S.C. § 337(a). The decision of whether and when to enforce the FDCA is committed to the discretion of the FDA. *See* **Heckler v. Chaney**, 470 U.S. 821, 837–38 (1985) (holding that the FDA's decision not to take action is not reviewable under the Administrative Procedure Act). Since the agency has limited enforcement resources, this often leaves aggrieved parties like POM Wonderful without a remedy.

POM Wonderful's Appeal to the Supreme Court

POM Wonderful asked the Supreme Court to review the Ninth Circuit's decision. The Court asked the Solicitor General for his views on the petition. The Solicitor General recommended that the Court deny POM Wonderful's petition so that lower courts could continue to examine the issue. Typically the Court follows the Solicitor General's advice. David C. Thompson & Melanie F. Watchell, "An Empirical Analysis of Supreme Court Certiorari Petition Procedures: The Call for Response and the Call for the Views of the Solicitor General," 16 *Geo. Mason L. Rev.* 237, 295 (2009) (finding that "[t]he Court follows the recommendation of the [Solicitor General] to grant or deny a case roughly 80% of the time"). The Court declined to do so in this case and granted POM Wonderful's petition.

Oral Arguments Go Poorly for Coca-Cola

When a Supreme Court Justice suggests your product's label "cheats consumers" that is probably not a good sign. When your brand is famous for slogans like "Can't Beat the Real Thing" the observation likely carries a special sting.

At oral arguments, the Supreme Court appeared ready to reverse the Ninth Circuit. The Justices expressed varying degrees of skepticism that Coca-Cola's compliance with the FDCA could insulate it from Lanham Act liability.

Coca-Cola rested its position on preemption. Coca-Cola pointed to provisions in a 1990 amendment to the FDCA that preempt state laws related to food labeling. The goal of that preemption provision, Coca-Cola counsel Kathleen Sullivan argued to the Court, was to create uniform national food labeling standards. Coca-Cola explained that "it cannot be that Congress meant to preempt these [state law] claims" that require more than just compliance with the federal standard while leaving similar theories based on federal law untouched. In Coca-Cola's view, since its label complies with the FDCA, POM Wonderful's false advertising claims are barred as a matter of law.

The Court challenged Coca-Cola's preemption argument. Justice Kennedy was incredulous. "Is it part of Coke's narrow position that national uniformity consists in labels that cheat the consumers like this one did?" he asked. "[If] Coca-Cola stands behind this label as being fair to consumers, then I think you have a very difficult case to make."

Justice Ginsburg echoed Justice Kennedy. "You are asking us to take what [the FDA] has said about juice as blessing this label, saying it's not misbranding, when its regulations aren't reviewed by the Court, when there is no private right of action, and say that that overtakes the Lanham Act," she said. "[I]t's really very hard to conceive that Congress would have done that."

Justice Sotomayor pressed Coca-Cola on how this case is any different from **Wyeth v. Levine**, 555 U.S. 555 (2009). In **Wyeth**, the Supreme Court held that FDA approval of a medication and its label did not automatically insulate a drug manufacturer from liability under state tort law. "How is **Wyeth** any different?" Justice Sotomayor asked. "The FDA here—it's even worse, this case. The FDA doesn't approve the [juice] labels. It never looks at them and says they are okay or not okay unless they decide to enforce the statute."

Coca-Cola's response was strained at best and dubious at worst. **Wyeth** was an implied preemption case, Coca-Cola argued. By contrast, "the express preemption provision here . . . says that Congress wanted nationally uniform labeling regulations." The trouble with this position is that earlier in its argument Coca-Cola conceded that its case is not based on express preemption. Coca-Cola earlier explained that since the "express preemption provision would make POM's claims expressly preempted under State law, it follows a matter of inference from the national uniform scheme that Congress set up, that Lanham Act claims are precluded . . . to the extent the state claims would have been preempted." That sounds a lot like implied preemption and, by extension, **Wyeth**.

Ronald Mann, a professor at Columbia Law School, called the Court's reception of Coca-Cola's case "the closest thing I've ever experienced to an oral argument signaling a unanimous reversal." Ronald Mann, *Argument analysis: Justices skeptical of Coke's right to "cheat consumers"*, SCOTUSBlog (Apr. 22, 2014, 6:00 PM), ***http://www.scotusblog.com/2014/04/argument-analysis-justices-skeptical-of-cokes-right-to-cheat-consumers/***. Professor Mann would know. He clerked for Justice Lewis F. Powell, Jr. on the Supreme Court.

Implications of POM Wonderful for FDA-Regulated Industries

Given the facts, it is easy to think of **POM Wonderful** as a case solely about juice labeling. That would be a mistake. The decision will impact a number of industries regulated by the FDA.

"All Natural" Foods and the Food Industry

Demand for healthy, natural foods is growing. That much is evident from McDonald's recent announcement that it plans to offer fruits and vegetables in place of fries. Understandably, large food manufacturers want to be part of the market. One need only stroll down the aisle of a local grocery store to find "all natural" potato chips and other snacks. The problem is many of those products are not "all natural." They might contain preservatives or genetically modified organisms. To date, the FDA has not opined on the definition of "natural." Given the lack of definitive guidance, plaintiffs have brought false advertising claims against food manufactures that make questionable "all natural" products. Those claims have had varying levels of success. *Compare* **Holk v. Snapple Beverage Corp.**, 574 F. Supp. 2d 447, 456 (D.N.J. 2008) (granting defendant's motion to dismiss), *with* **Bruton v. Gerber Prods. Co.**, No. 12-CV-02412-LHK, 2013 WL 4833413, at *7–11 (N.D. Cal. Sept. 6, 2013) (denying defendant's motion to dismiss). **POM Wonderful** will shed light on whether such claims are barred by the FDCA.

Dietary and Nutritional Supplements Industry

Multivitamin and dietary supplement makers have come under fire. A December 2013 editorial in the journal *Annals of Internal Medicine* took direct aim at the multi-billion dollar nutritional supplements industry. After summarizing the results of three studies of the impact of supplements on chronic diseases, the editorial delivers this verdict: "Most supplements do not prevent chronic disease or death, their use is not justified, and they should be avoided." Eliseo Guallar et al., "Enough is Enough: Stop Wasting Money on Vitamin and Mineral Supplements," 159 *Annals Internal Med.* 850, 850 (2013). That conclusion is difficult to square with how dietary supplements are marketed. Claims on packaging like "cellular age defying formula," "boosts your immune system," and "improves digestive health" are commonplace. While those claims are a far cry from the "fair balance" required in prescription drug marketing, statements on the label of a dietary supplement that describe the "general well-being from consumption of a nutrient or dietary ingredient" are acceptable under the FDCA so long as the supplement manufacturer "has substantiation that the statement is truthful and not misleading" and the claim is accompanied by a disclaimer. 21 U.S.C. § 343(r)(6); 21 C.F.R. § 101.93.

Those provisions of the FDCA have not deterred false advertising plaintiffs. In the past, plaintiffs have brought suit against supplement manufacturers alleging false advertising and related

Continued on page 6

Real Thing, continued on page 6

state law claims. *See, e.g.*, **Stanley v. Bayer Healthcare**, LLC, No. 11cv862-IEG(BLM), 2012 WL 1132920 (S.D. Cal. 2012) (plaintiff asserting false advertising claim against probiotic supplement manufacturer). The studies published in the *Annals of Internal Medicine* will embolden these plaintiffs. Supplement companies have defended these suits by arguing that the FDCA precludes Lanham Act claims and pre-empts state law claims. The Supreme Court's **POM Wonderful** decision will inform these defenses.

Medical Device Industry

Advertisements about "FDA approved" medical devices are legion. Many of those advertisements are inaccurate. The reason is that most medical devices are on the market through the 510(k) clearance process. This means the device manufacturer has shown that its device is "substantially equivalent" to another legally marketed device. A medical device has been "approved" by FDA when the agency approves a manufacturer's (expensive) premarket approval application ("PMA"). If a device is on the market through a PMA that means the FDA has found the device safe and effective for its intended use.

Medical device manufacturers that have invested resources in the PMA process might be interested in using the Lanham Act to prevent manufacturers of 510(k) devices from using "FDA approved" to market their 510(k) device. For reasons similar to the ones the Ninth Circuit gave in **POM Wonderful**, those claims have failed in the past. *See, e.g.*, **PhotoMedex, Inc. v. Irwin**, 601 F.3d 919 (9th Cir. 2010). The Supreme Court may breathe new life into these claims.

James R. Lawrence III is an associate at Coats and Bennett, PLLC in Cary, NC. He litigates intellectual property matters and counsels clients in FDA-regulated industries. The article above is based on blog posts available at ***www.coatsandbennett.com***.