

## Supreme Court Unanimously Reverses Ninth Circuit's Decision in *POM Wonderful v. Coca-Cola*

### Ruling That Competitors May Bring Lanham Act Claims Challenging FDA-Regulated Food and Beverage Labels Could Impact Other Categories of FDA-Regulated Products

On June 12, 2014, the Supreme Court in *POM Wonderful LLC v. Coca-Cola Co.*, No. 12-761, ruled that a competitor may bring a Lanham Act false advertising claim challenging food and beverage labels regulated by the Food and Drug Administration (“FDA”) pursuant to the Federal Food, Drug, and Cosmetic Act (“FDCA”). Writing for a unanimous Court, Justice Kennedy concluded that POM’s Lanham Act claims were not “precluded” by the FDCA.

#### Facts of the Case

POM alleged that the name and overall labeling of competitor Coca Cola’s juice blend was false or misleading under the Lanham Act, a federal statute that provides a private right of action to challenge a competitor’s false advertising. Coca-Cola’s juice, sold under the Minute Maid brand, is labeled as “Pomegranate Blueberry” (with the words “Flavored Blend of 5 Juices” in a smaller font), yet it contains only 0.3% pomegranate juice and 0.2% blueberry juice. Coca-Cola asserted this name and label comply with the applicable FDA regulation addressing the labeling of juice blends. POM contended – despite the applicable FDA regulation – that the name of the juice, and presentation of this name on the product label, misleads and confuses consumers into believing that the product contains primarily pomegranate and blueberry juices. The Ninth Circuit had barred POM’s Lanham Act claim in part because of the FDA’s “comprehensive regulation” of food and beverage labeling, including the specific regulation addressing juice blends.

#### The Court’s Ruling

In reversing the Ninth Circuit, the Supreme Court observed that although this is not a state preemption case, preemption principles are nonetheless “instructive” for the applicable preclusion analysis. The Court noted that neither the Lanham Act nor the FDCA expressly prohibits or limits Lanham Act claims challenging labels of FDA-regulated products. Because the Lanham Act and the FDCA have coexisted for roughly 70 years, the Court viewed Congress’s decision not to adopt any preclusion provision as “powerful evidence” that Congress did not intend the FDCA to be the only means for ensuring proper food and beverage labeling. Moreover, the Court did not view Congress’s adoption in 1990 of a provision expressly preempting certain *state* food and beverage labeling requirements as suggesting an intent to preclude *federal* Lanham Act claims. The omission of any mention of preclusion of federal laws from the preemption provision suggested the opposite intent, if anything, according to the Court.

Moreover, the Court found that the FDCA and the Lanham Act complement each other in the area of food and beverage labeling. While the Lanham Act protects commercial interests against unfair competition, the FDCA protects public health and safety. The Court suggested that Lanham Act lawsuits that touch on the same subject matter as the FDCA “provide incentives for manufacturers to behave well” and reasoned that permitting such lawsuits “takes advantage of synergies among multiple methods of regulation.” The Court indicated that if Lanham Act claims challenging food and beverage labeling were to be precluded, then competitors (and indirectly the public) would have less effective protection from false advertising in the food and beverage industry than in other, less regulated industries because the FDA does not preapprove food and beverage labels and does not enforce against all objectionable labels.

The Court rejected Coca-Cola's argument that POM's claims should be precluded because Congress intended national uniformity in food and beverage labeling based on three aspects of the FDCA proffered by Coca-Cola. First, the Court thought that the vesting of enforcement authority under the FDCA solely in the federal government did not indicate Congress's intent to foreclose private enforcement under other federal statutes. Second, the Court recognized that the FDCA's preemption provision applicable to food and beverage labeling expressly applies only to certain state law requirements and not to federal law. Third, the Court acknowledged that the FDCA and FDA regulations address food and beverage labeling with far more specificity than the Lanham Act but indicated this specificity would only matter if the two statutes "cannot be implemented in full at the same time," which the Court thought was not the case.

The Court also rejected the argument of the federal Government, appearing as *amicus curiae*, that a Lanham Act claim is precluded to the extent the FDA or FDA regulations specifically require or authorize the challenged aspects of the label. The Court rejected the Government's premise that the FDCA and FDA regulations act as a "ceiling" on the regulation of food and beverage labeling in some instances. The FDA's rulemaking on juice blends did not address or even reference the Lanham Act, so the Court held that it was "a bridge too far" to accept an after the fact statement from the Government to justify using the FDA's regulation as a basis for finding preclusion of Lanham Act claims. Additionally, the Court thought the Government's proposed standard would also be impractical because of the difficult line-drawing exercise that would be necessary to distinguish a regulation that "specifically authorizes" conduct from a regulation that "merely tolerates" that conduct. Significantly, the Court did not directly address the aspect of the Government's argument focused on Lanham Act claims that implicate specific FDA *requirements* (e.g., a claim challenging the use of a word in a label that is expressly mandated, rather than merely authorized, by an FDA regulation).

### Implications for Manufacturers of FDA-Regulated Products

The Court's decision indicates that food and beverage labeling can still be false or misleading for Lanham Act purposes, even if such labeling complies with all applicable FDA regulations. Going forward, food and beverage manufacturers will need to recognize that compliance with FDA regulations may not necessarily insulate them from Lanham Act liability. Additionally, food and beverage companies may now be able to use the Lanham Act to challenge their competitors' labeling and promotional practices. Similarly, with respect to consumer class actions under state law challenging food and beverage labels, the Court's opinion said nothing to suggest that such claims, if not expressly preempted, are otherwise precluded.

Notably, throughout the opinion, the Court carefully avoided making a blanket statement that *all* Lanham Act claims challenging food and beverage labels are not precluded. Instead, the Court held that the FDCA does not preclude Lanham Act suits "like POM's" or "like the one brought by POM in this case." This limiting language appears to leave open the possibility that a Lanham Act suit *unlike* POM's – perhaps challenging an aspect of food and beverage labeling that would create a real conflict between the Lanham Act and a specific FDA requirement (as opposed to a mere authorization) – may still be barred.

The Court also carefully limited its holding to the context of food and beverage labeling, rather than the broader context of all FDA-regulated products. As part of its rationale for permitting Lanham Act claims challenging food and beverage labels, the Court noted that the FDA does not preapprove food and beverage labels, unlike certain drug labels, and observed that the FDA's oversight of food is "less extensive" than its oversight of drugs.

While the scope of the Court's decision was expressly limited to food and beverages, it may nonetheless have significant implications for other categories of FDA-regulated products, particularly dietary supplements,

cosmetics, and tobacco products, because, as with foods, the FDA does not review and pre-approve labeling for these categories of products. On the other hand, the Court's distinction between the FDA's oversight of foods versus drugs suggests that the logic of the Court's holding may not apply with the same force to an analogous case challenging a drug or medical device label that has been affirmatively approved by the FDA. The breadth of the decision, however, remains unclear – particularly for product categories like over-the-counter drugs marketed pursuant to an OTC monograph and 510(k)-exempt medical devices, where FDA does not review and approve labeling on a product-by-product basis. Also unclear is how the decision would apply to devices that FDA clears for marketing under the 510(k) premarket notification program, in which FDA reviews sample product labeling prior to clearance but does not officially “approve” it.

Ropes & Gray will continue to monitor the development of Lanham Act jurisprudence in the lower courts that impacts FDA-regulated products following the Supreme Court's decision in *POM Wonderful*. To find out how the decision in *POM Wonderful* affects your interest, please contact your usual Ropes & Gray attorney or one of the Ropes & Gray attorneys listed below.

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