

FOR PUBLICATION
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

<p>POM WONDERFUL LLC, a Delaware limited liability company, <i>Plaintiff-Appellant,</i></p> <p style="text-align: center;">v.</p> <p>THE COCA-COLA COMPANY, a Delaware corporation, <i>Defendant-Appellee.</i></p>
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No. 10-55861
D.C. No.
2:08-cv-06237-
SJO-FMO
OPINION

Appeal from the United States District Court
for the Central District of California
S. James Otero, District Judge, Presiding

Argued and Submitted
February 8, 2012—Pasadena, California

Filed May 17, 2012

Before: Dorothy W. Nelson, Diarmuid F. O’Scannlain, and
N. Randy Smith, Circuit Judges.

Opinion by Judge O’Scannlain

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COUNSEL

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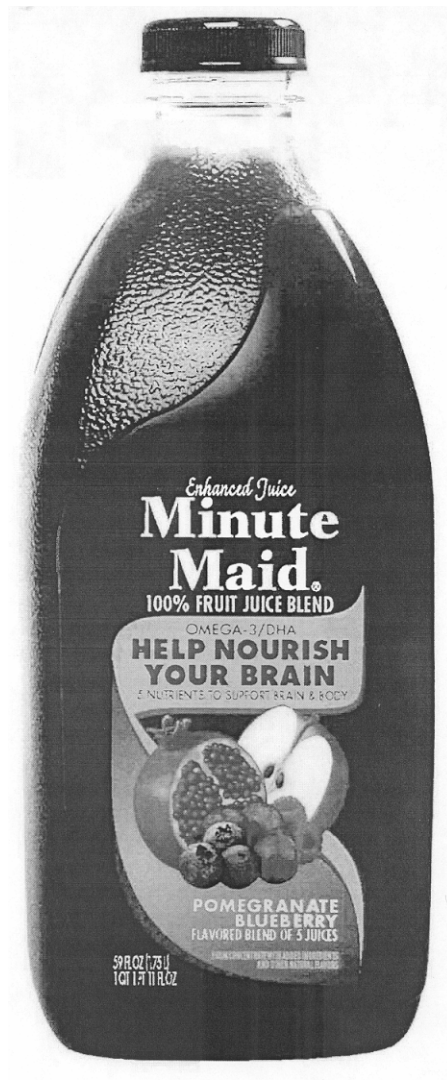
OPINION

O'SCANNLAIN, Circuit Judge:

We must decide whether the Food, Drug, and Cosmetic Act bars a Lanham Act claim alleging that the name and labeling of a juice beverage are deceptive.

I

Pom Wonderful LLC produces, markets, and sells bottled pomegranate juice and pomegranate juice blends, including a pomegranate blueberry juice blend. The Coca-Cola Company markets and sells bottled juices and juice blends under the Minute Maid brand. In September 2007, Coca-Cola announced a new product called “Pomegranate Blueberry” or “Pomegranate Blueberry Flavored Blend of 5 Juices.” (The parties dispute the name. We at times refer to Coca-Cola’s product as “Pomegranate Blueberry” but take no view on whether this is its actual name.) This product contains about 99.4% apple and grape juices, 0.3% pomegranate juice, 0.2% blueberry juice, and 0.1% raspberry juice. The front label displays the product’s name and a vignette depicting each of those fruits:



Believing that it was losing sales to Pomegranate Blueberry, Pom sued Coca-Cola in September 2008. Pom alleged that Coca-Cola misled consumers to believe that Pomegranate Blueberry consists primarily of pomegranate and blueberry

juices when it actually consists mainly of (the cheaper) apple and grape juices. Pom challenged the name, labeling, marketing, and advertising of Pomegranate Blueberry. It claimed that Coca-Cola violated the false-advertising provision of the Lanham Act, which authorizes suit against those who use a false or misleading description or representation about any goods. *See* 15 U.S.C. § 1125(a). Pom also claimed that Coca-Cola violated California's Unfair Competition Law (UCL) and its False Advertising Law (FAL), which prohibit deceptive practices and misleading advertising. *See* Cal. Bus. & Prof'l Code §§ 17200 *et seq.*; *id.* §§ 17500 *et seq.*

Coca-Cola moved under Federal Rule of Civil Procedure 12(b)(6) to dismiss the complaint for failure to state a claim. The district court partially granted and partially denied the motion. The court ruled that Pom's Lanham Act challenge to Pomegranate Blueberry's name and labeling was barred because Pom's suit "may be construed as impermissibly challenging" Food and Drug Administration (FDA) regulations permitting the name and labeling that Coca-Cola uses and because Pom's claim could improperly require the court to interpret and to apply FDA regulations on juice beverage labeling. But the court also held that Pom's Lanham Act challenge could otherwise proceed. Specifically, the court ruled that, although Pom could not challenge Pomegranate Blueberry's name and labeling, it could challenge Coca-Cola's other advertising and marketing of the product because those components of the claim would not require the court to interpret FDA regulations. The court also held that the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.*, expressly preempted Pom's state law claims to the extent the UCL and FAL impose obligations that are not identical to those imposed by the FDCA and its implementing regulations.

After Coca-Cola refused to respond to discovery requests, Pom amended its complaint to bring itself within the scope of the court's earlier ruling on its Lanham Act claim. The amended complaint repleaded Pom's Lanham Act, UCL, and

FAL claims. In an apparent effort to overcome the court's preemption ruling, Pom added to its UCL claim a misbranding allegation under California's Sherman Law, which includes language that is materially identical to the FDCA's misbranding provision. *See* Cal. Health & Safety Code § 110660; *compare id. with* 21 U.S.C. § 343(a)(1).

Coca-Cola moved under Rule 12(b)(6) to dismiss the amended complaint. The court denied Coca-Cola's motion and ruled that Pom could conduct discovery to clarify which aspects of Coca-Cola's alleged conduct constituted labeling (and thus could not, under the court's earlier ruling, support Pom's Lanham Act claim) and which aspects constituted advertising or marketing (and thus could support the Lanham Act claim). The court did not address preemption. Discovery followed.

When discovery was completed, the district court partially granted summary judgment to Coca-Cola. The court reiterated that Pom's Lanham Act challenge to Pomegranate Blueberry's name and labeling was barred by the FDCA's implementing regulations. The court reasoned that through its regulations, the FDA "has directly spoken on the issues that form the basis of Pom's Lanham Act claim against the naming and labeling of the Juice, and has therefore[] reached a conclusion as to what is permissible." The court emphasized that the FDA "has concluded that manufacturers of multiple-juice beverages may identify their beverages with a non-primary, characteristic juice, as Coca[-]Cola does here." Because in its view Coca-Cola's label "sufficiently comports with the requirements of" FDA juice-labeling regulations—and because it believed that any further "determination that naming and labeling must be displayed in a particular way or fashion" must be made by the FDA—the court held that Pom's claim challenging the name and labeling of Pomegranate Blueberry was barred. The court reached a similar conclusion specifically about the label's fruit vignette.

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The court did not revisit its earlier preemption ruling. It simply ruled that Pom lacked statutory standing to pursue its state law claims. The court reasoned that Pom had not established the statutory standing prerequisite of “lost money or property,” Cal. Bus. & Prof’l Code §§ 17204, 17535, because Pom had not shown that it was entitled to restitution.

The court concluded that triable issues remained on the non-naming-and-labeling aspects of Pom’s Lanham Act claim and permitted Pom to proceed to trial on those matters. But Pom conceded that the summary judgment order prevented it from carrying its burden on the claim and the court therefore entered judgment for Coca-Cola. Pom timely appealed.

II

On appeal, Pom contends that the district court erred in its holdings that the FDCA bars its Lanham Act claim, that Pom lacks statutory standing to pursue its state law claims, and that the FDCA expressly preempts Pom’s state law claims against the name and labeling of Coca-Cola’s Pomegranate Blueberry.

A

[1] The Lanham Act broadly prohibits false advertising. It authorizes suit against those who use a false or misleading description or representation “in connection with any goods.” 15 U.S.C. § 1125(a). Such suits can be brought by any person “who believes that he or she is or is likely to be damaged by” the use of that false description or representation. *Id.*

[2] The FDCA, meanwhile, comprehensively regulates food and beverage labeling. It provides that a food is misbranded if “its labeling is false or misleading in any particular,” 21 U.S.C. § 343(a)(1), or “[i]f any word, statement, or other information required by” the FDCA or its regulations “to appear on the label or labeling is not prominently placed

thereon with such conspicuousness . . . and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use,” *id.* § 343(f). Though a private plaintiff may sue under the Lanham Act’s false-advertising provision, the FDCA may be enforced only by the FDA or the Department of Justice. *See id.* § 337(a). The FDA, for its part, has promulgated regulations that address how a manufacturer may name and label its juice beverages. *See, e.g.*, 21 C.F.R. § 102.33(c), (d).

As sometimes happens with two broad federal statutes, the Lanham Act and the FDCA can conflict with each other. When faced with a potential conflict, “[c]ourts try to give as much effect to both statutes as possible.” *Schering—Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 508 (7th Cir. 2009). In that effort, courts have focused on Congress’s decision to entrust to the FDA the task of interpreting and enforcing the FDCA.

In light of that focus, courts have agreed that the FDCA limits claims under the Lanham Act. A plaintiff may not, for example, sue under the Lanham Act to enforce the FDCA or its regulations because allowing such a suit would undermine Congress’s decision to limit enforcement of the FDCA to the federal government. *See, e.g., Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993). Nor may a plaintiff maintain a Lanham Act claim that would require a court originally to interpret ambiguous FDA regulations, because rendering such an interpretation would usurp the FDA’s interpretive authority. *See, e.g., Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231-32 (3d Cir. 1990) (claim that drug label falsely described ingredient as “inactive” was barred because FDA had not decided whether ingredient was active or inactive).

Where the FDA has not concluded that particular conduct violates the FDCA, we have even held that a Lanham Act claim may not be pursued if the claim would require litigating

whether that conduct violates the FDCA. *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010). In *PhotoMedex*, a manufacturer of a dermatological laser alleged that its competitor violated the Lanham Act by misrepresenting that its product had been “cleared” (approved) by the FDA. The FDCA allows a manufacturer to market such a laser only if the FDA has cleared the device or a similar device. *Id.* at 925-26. But the FDCA and FDA regulations permit a manufacturer to determine in the first instance whether its device is covered by an earlier clearance and to market the device even if the FDA has not stated that the device is cleared. *See id.* at 922, 925-26, 928. In keeping with the statute and regulations, the defendants in *PhotoMedex* represented that their device had been cleared based on the FDA’s approval of a similar device. The FDA had not weighed in on whether that representation was accurate. We held that the plaintiff’s Lanham Act claim against that representation was barred. Recognizing that the claim would have required us to “[t]est[] the truth” of the defendants’ clearance statement, we refused “to usurp the FDA’s prerogative to enforce the FDCA” by deciding whether the defendants’ device was covered by the FDA’s earlier clearance of a different device. *Id.* at 928.

[3] *PhotoMedex* teaches that the Lanham Act may not be used as a vehicle to usurp, preempt, or undermine FDA authority. That teaching, however, operates as a presumption or a general principle—not as an automatic trump or a firm rule. Our task in cases involving potentially conflicting statutes is “to give as much effect to both statutes as possible.” *Schering-Plough*, 586 F.3d at 508. To do that, a court must focus on the circumstances before it to strike a balance that disrupts the two statutory schemes as little as it can. Thus, in *PhotoMedex*, while we resolved not “to usurp the FDA’s prerogative” to enforce the FDCA or to apply its own regulations, 601 F.3d at 928, we grounded that resolution in “the particular circumstances of th[e] case,” *id.* at 922: the authority Congress entrusted to the FDA, the regulatory regime put in place by the FDA, the FDA’s actions relevant to the plain-

tiff's claim, and other similar factors, *id.* at 922, 925-28. In this case we must again focus on the circumstances before us to strike the right balance.

B

Applying the teaching of *PhotoMedex* to the circumstances of this case, we conclude that the FDCA and its regulations bar pursuit of both the name and labeling aspects of Pom's Lanham Act claim.

[4] The naming component of Pom's claim is barred because, as best we can tell, FDA regulations authorize the name Coca-Cola has chosen. The FDA has concluded that a manufacturer may name a beverage using the name of a flavoring juice that is not predominant by volume. *See* 21 C.F.R. § 102.33(c), (d). Section 102.33(c) recognizes, for example, that a blend of juices can represent a juice in its name or label even if the blend "also contains a juice other than the . . . juice" named or represented on the label. And the FDA has explained, by way of example, that a three-juice blend where apple is the juice identified on the label can be named "Apple blend; apple juice in a blend of two other fruit juices." *Id.* § 102.33(c) (internal quotation marks omitted). The FDA has also said that a "named" juice need "not [be] the predominant juice" by volume. *Id.* § 102.33(d). Thus a raspberry-and-cranberry-flavored product whose predominant juice is not raspberry or cranberry can be called "'Raspcranberry'; raspberry and cranberry flavored juice drink." *Id.* § 102.33(d)(1). Taken together, these provisions reflect that: (1) Coca-Cola may give its product a name that refers to juices that provide the characterizing flavor, and (2) those juices need not be predominant by volume if Coca-Cola states that those juices are not predominant. Thus, Pom's challenge to the name "Pomegranate Blueberry Flavored Blend of 5 Juices" would create a conflict with FDA regulations and would require us to undermine the FDA's apparent determination that so naming the product is not misleading. *Cf. PhotoMedex*, 601 F.3d at

928. The district court was right to hold that Pom’s Lanham Act claim against Pomegranate Blueberry’s name is barred.

[5] The same goes for the labeling component of Pom’s claim. Pom focuses its labeling argument on how Coca-Cola presents the words “Pomegranate Blueberry” and “Flavored Blend of 5 Juices” on the product’s label. (Pom does not meaningfully contend, on appeal, that the label’s fruit vignette—which depicts all of the fruits of which the product is composed—is improper.) Pom apparently wants to force Coca-Cola to alter the size of the words on its labeling so that the words “Pomegranate Blueberry” no longer appear in larger, more conspicuous type on Coca-Cola’s label than do the words “Flavored Blend of 5 Juices.” But allowing Pom to achieve this result would again undermine the FDA’s regulations and expert judgments. In extensively regulating the labeling of foods and beverages, the FDCA and its implementing regulations have identified the words and statements that must or may be included on labeling and have specified how prominently and conspicuously those words and statements must appear. *See, e.g.*, 21 U.S.C. § 343(f), (i); 21 C.F.R. § 102.33(c), (d). These provisions ensure that statements are presented on labels in such a way “as to render [them] likely to be read and understood by the ordinary individual.” 21 U.S.C. § 343(f).

[6] Congress and the FDA have thus considered and spoken to what content a label must bear, and the relative sizes in which the label must bear it, so as not to deceive. Despite speaking extensively to how prominently required words or statements must appear, the FDA has not (so far as we can tell) required that all words in a juice blend’s name appear on the label in the same size or that words hew to some other standard that Pom might have us impose. If the FDA thought such a regulation were necessary “to render [that information] likely to be read and understood by the ordinary individual,” 21 U.S.C. § 343(f), it could have said so. If 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.

Pom urges us to follow three district courts that concluded that similar Lanham Act claims brought by Pom may proceed because those claims did not require the court to interpret or to apply FDA regulations. See *Pom Wonderful, LLC v. Tropicana Prods., Inc.*, 2010 WL 3590162, at *1-*2 (C.D. Cal. Sept. 7, 2010); *Pom Wonderful LLC v. Ocean Spray Cranberries, Inc.*, 642 F. Supp. 2d 1112, 1119-20 (C.D. Cal. 2009); *Pom Wonderful LLC v. Welch Foods, Inc.*, CV 09-567 AHM, D.E. 29, at 6-7 (C.D. Cal. June 23, 2009). These decisions cannot be harmonized with *PhotoMedex*. Although these courts were right to recognize that a Lanham Act claim is barred when it would require a court to interpret ambiguous FDA regulations, that is not the only circumstance in which such a claim is barred. *PhotoMedex* teaches that courts must generally prevent private parties from undermining, through private litigation, the FDA's considered judgments.

[7] In concluding that Pom's claim is barred, we do not hold that Coca-Cola's label is non-deceptive. Pom contends that the words "Pomegranate Blueberry" appear in larger, more conspicuous type on Coca-Cola's label than do the words "Flavored Blend of 5 Juices." If the FDA believes that this context misleads consumers, it can act. But the FDA has apparently not taken a view on whether Coca-Cola's labeling misleads consumers—even though it has acted extensively and carefully in this field. (The FDA has not established a general mechanism to review juice beverage labels before they reach consumers, but the agency may act if it believes that a label in the market is deceptive.) As best we can tell, Coca-Cola's label abides by the requirements the FDA has established. We therefore accept that Coca-Cola's label presumptively complies with the relevant FDA regulations and thus accords with the judgments the FDA has so far made.

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Out of respect for the statutory and regulatory scheme before us, we decline to allow the FDA's judgments to be disturbed.

[8] We do not suggest that mere compliance with the FDCA or with FDA regulations will always (or will even generally) insulate a defendant from Lanham Act liability. We are primarily guided in our decision not by Coca-Cola's apparent compliance with FDA regulations but by Congress's decision to entrust matters of juice beverage labeling to the FDA and by the FDA's comprehensive regulation of that labeling. To give as much effect to Congress's will as possible, we must respect the FDA's apparent decision not to impose the requirements urged by Pom. And we must keep in mind that we lack the FDA's expertise in guarding against deception in the context of juice beverage labeling. In the circumstances here, "the appropriate forum for [Pom's] complaints is the [FDA]." *PhotoMedex*, 601 F.3d at 929.

III

Which brings us to the question of whether Pom's state law claims may proceed.

[9] To have standing to bring a claim under the UCL, a private plaintiff must show that it "has suffered injury in fact and has lost money or property as a result of" unfair competition; to have standing under the FAL, a private plaintiff must make the same showing of injury and loss as a result of an FAL violation. Cal. Bus. & Prof'l Code §§ 17204, 17535. The district court interpreted the "lost money or property" language to require a plaintiff to show that it is entitled to restitution from the defendant—even if the plaintiff seeks only injunctive relief. That was error. The California Supreme Court has now made clear that standing under section 17204 (the UCL standing provision) does not depend on eligibility for restitution. See *Kwikset Corp. v. Superior Ct.*, 246 P.3d 877, 895 (Cal. 2011); *Clayworth v. Pfizer, Inc.*, 233 P.3d 1066, 1088 (Cal. 2010). We are inclined to interpret the materially identical

language in section 17535 (the FAL standing provision) the same way. Nevertheless, because these cases came down after the district court entered judgment in this case, we will vacate the judgment as to Pom's state law claims and remand to the district court to rule on standing in light of *Kwikset* and *Clayworth*.

If the district court concludes that Pom has statutory standing, it may need to address such issues as whether Pom's state law claims are expressly preempted and whether California's safe-harbor doctrine insulates Coca-Cola from liability on any of Pom's state law claims. We leave those matters to the district court to address as needed.

IV

To summarize: We affirm the district court's summary judgment to the extent it barred Pom's Lanham Act claim with respect to Pomegranate Blueberry's name and labeling. We vacate the summary judgment to the extent it ruled that Pom lacked statutory standing on its UCL and FAL claims; we remand so that the district court can rule on the state claims in accordance with this opinion.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED. Each party shall bear its own costs.