No. 12-761

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

REPLY BRIEF FOR PETITIONER

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Coca-Cola's opposition rests on the assertion (at 1) that the Ninth Circuit rejected Pom's Lanham Act challenge because it concluded that the label of Coca-Cola's "Pomegranate Blueberry" juice product was "specifically authorized" by the Food, Drug and Cosmetic Act ("FDCA"). But that assertion ignores the key portions of the court's opinion making clear that it was the FDA's regulatory authority that the court found dispositive. The Ninth Circuit's holding that Pom's Lanham Act claim could not proceed because Coca-Cola's label is subject to regulation by the FDA conflicts with decisions of this Court prescribing when one federal law can displace another and with decisions of other circuits permitting Lanham Act challenges de-

spite agency regulation. The court's decision also will have significant consequences: In a significant portion of the country, false and misleading labeling will no longer be subject to challenge by private citizens under the Lanham Act, leaving labels to be policed only by the understaffed and underfunded FDA.

I. COCA-COLA MISCHARACTERIZES THE NINTH CIRCUIT'S DECISION

Coca-Cola's arguments in opposition to certiorari are premised almost entirely on its contention that the court of appeals concluded that its label was "specifically authorized" by the FDCA. Opp. 1, 4; *see also, e.g.*, *id.* at 6 ("expressly 'authorize[d]'"), 10 ("FDA's specific determination"; "expressly approved"), 12 ("expressly authorized"), 15 ("authorize[d]"), 16 ("explicitly approve[d]" by FDA). This contention is the basis for Coca-Cola's denial that the Ninth Circuit disregarded this Court's precedent on reconciling federal statutes and departed from decisions of its sister courts of appeals on the important question whether mere agency regulation forecloses Lanham Act challenges by private parties. *See* Opp. 9-10, 15. But Coca-Cola's reading of the decision below is demonstrably wrong.

The Ninth Circuit recognized that Coca-Cola's label has never been reviewed by the FDA, *see* Pet. App. 11a-12a, and the court avoided making any definitive pronouncement about whether the label is "specifically authorized" by the FDA's regulations. To the contrary, the court explained that it was "primarily guided" in its 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." *Id.* at 12a. Because the court's decision rested on the

FDA's "comprehensive regulation" of juice labeling, and not Coca-Cola's alleged "compliance with FDA regulations," the court *did not even mention* the district court cases assertedly supporting an FDA compliance defense that Coca-Cola claims the Ninth Circuit "agreed with," Opp. 7-8, 16.

Rather than finding Coca-Cola's label "specifically authorized" by the FDCA, the Ninth Circuit recognized that the FDA might at some point conclude that the label as a whole is misleading in violation of the FDCA, *see* 21 U.S.C. § 343(a)—particularly in its use of a significantly smaller font size for the words "Flavored Blend of 5 Juices" than for the words "Pomegranate Blueberry," *see* Pet. 7. For example, after reviewing the FDA's juice-labeling regulations, the court stated:

> In concluding that Pom's claim is barred, we do not hold that Coca-Cola's label is non-deceptive. … If the FDA believes that [the relative font sizes used in the label] mislead[] consumers, it can act. But the FDA has apparently not taken a view on whether Coca-Cola's labeling misleads consumers ….

Pet. App. 11a-12a. In its discussion of Coca-Cola's use of a reduced font size for the words "Flavored Blend of 5 Juices," the court similarly stated (in language Coca-Cola omits from its block quote with an ellipse): "If the FDA believes that more should be done to prevent deception, or that Coca-Cola's label misleads consumers, it can act." *Id.* at 11a; *compare* Opp. 6.

The Ninth Circuit made clear that the most that could be said about the FDA's font-size regulation was that the agency had not "*required* that all words in a juice blend's name appear on the label in the same size …." Pet. App. 10a (emphasis added). The failure by

the FDA to require all of the words in a juice's name to be in the same font is a far cry from an affirmative *authorization* of the significantly reduced font size Coca-Cola used. *See* Pet. 7. Even here, the court hedged. It noted merely that "*so far as we can tell*," the FDA had not required all words in a name to be in the same font size. Pet. App. 10a (emphasis added); *compare* Opp. 5 (omitting the phrase "so far as we can tell").

The Ninth Circuit was similarly noncommittal in its discussion of the name of Coca-Cola's "Pomegranate Blueberry" product. Coca-Cola contends (at 4-5) that the court concluded the name was affirmatively "authorized" by the FDA's regulations, but it fails to note that what the court actually said was, "*as best we can tell*, FDA regulations authorize the name Coca-Cola has chosen." Pet. App. 9a (emphasis added); *compare* Opp. 5.[1] Indeed, while the Ninth Circuit explained that under the FDA's regulations a product's name may reference non-predominant juices if they "provide the characterizing flavor," Pet. App. 9a, nowhere did the court point to any evidence that the trace amounts of pomegranate juice and blueberry juice (.3% and .2%, respectively) in Coca-Cola's product provide "characterizing flavor."

Thus, far from making a definitive pronouncement that Coca-Cola's label was "authorize[d]" by the FDA's regulations, the court of appeals expressly left any assessment of that kind to the agency: "[W]e must keep in mind that we lack the FDA's expertise …. In the

[1] Similarly, whereas the court of appeals referenced "FDA's *apparent* decision not to impose the requirements urged by Pom," Coca-Cola refers to the FDA's "*affirmative* decision." *Compare* Pet. App. 12a *with* Opp. 6 (emphases added).

circumstances here, the appropriate forum for [Pom's] complaints is the [FDA]." Pet. App. 12a (internal quotation marks omitted; second and third alterations in original)). The court of appeals precluded application of the Lanham Act to a broad range of potentially misleading statements solely on the ground that they are subject to FDA regulation. *See Id.* at 8a ("[T]he Lanham Act may not be used as a vehicle to usurp, preempt, or undermine FDA authority."). As explained below, this holding conflicts with precedent of this Court and decisions of other courts of appeals.

II. THE NINTH CIRCUIT'S DECISION CONFLICTS WITH THIS COURT'S PRECEDENTS

Coca-Cola concedes that under this Court's precedents, "a later-enacted statute will not be construed to silently repeal an earlier one unless the statutes cannot be reconciled." Opp. 10; *see Branch* v. *Smith*, 538 U.S. 254, 273 (2003) (setting forth "irreconcilable conflict" standard); *Morton* v. *Mancari*, 417 U.S. 535, 551 (1974). And Coca-Cola does not dispute that the Ninth Circuit failed to apply that standard in this case. Coca-Cola argues instead (at 10) that the "irreconcilable conflict" standard is inapplicable here because the Ninth Circuit held merely "that the FDA's specific determination … that juice labels like Coca-Cola's are not misleading precludes a private party from advancing the opposite position … under the Lanham Act." But this argument fails for the reasons set forth above: Coca-Cola has misread the Ninth Circuit's decision. The Ninth Circuit did not conclude that Coca-Cola's label was "not misleading" under the FDA's regulations. It held instead that the FDA's mere regulatory authority displaced the Lanham Act. *See supra* pp. 2-5.

Only by disregarding this Court's irreconcilable conflict standard was the Ninth Circuit able to conclude that the FDA's supposed "comprehensive regulation of [juice beverage] labeling," Pet. App. 12a, was sufficient to override the plain text of the Lanham Act. Coca-Cola has cited no decision of this Court holding that mere agency regulatory authority is sufficient to displace an otherwise applicable federal statute. *Cf. Credit Suisse Sec. (USA) LLC* v. *Billing*, 551 U.S. 264, 275-276 (2007) (requiring more than mere authority). Because Coca-Cola's label is not, in fact, "specifically authorized" by the FDCA or the FDA's regulations, application of the Lanham Act poses no irreconcilable conflict. This is not a case of a private litigant second-guessing a determination by the FDA. Moreover, as Pom explained in its petition (at 13-16), the FDCA and the Lanham Act are "fully capable of coexisting" because a party (like Coca-Cola) can comply with both statutes. *See United States* v. *Batchelder*, 442 U.S. 114, 122 (1979). As this Court held in *Wyeth* v. *Levine*, 555 U.S. 555, 577-578 (2009), the FDCA merely sets a "floor" for regulation of labels on which other laws can build. This is precisely what the Lanham Act does in this context by prohibiting companies from marketing products that mislead consumers. *See* Pet. 15-16.

Coca-Cola contends that *Wyeth* is inapplicable because it "was a preemption case" and because in that case, Congress had chosen not to expressly preempt state drug-labeling laws. Opp. 12. But the conflict preemption standard at issue in *Wyeth* is functionally equivalent to the irreconcilable conflict standard applicable here. *See* Pet. 17-18. And here, Congress has chosen not to displace the federal Lanham Act. Coca-Cola points (at 13) to the express preemption provision in the Nutrition Labeling and Education Act, but that

provision only preempts *states* from regulating food labels in a manner that is not identical to the FDCA. *See* 21 U.S.C. § 343-1(a). It says nothing of *other federal statutes*, which is what is at issue in this case.

Coca-Cola cites instances in which the FDA has "directed manufacturers to make claims on their labels that are arguably false." Opp. 8-9. But this case does not involve direction of that sort. The provisions of the FDCA relevant here do *not*, as Coca-Cola suggests (at 11), contain "highly-specific prescriptions" governing juice labeling. For example, the FDA's regulations did not require Coca-Cola to place the words "Flavored Blend of 5 Juices" in significantly smaller font than the words "Pomegranate Blueberry" on its juice product made up almost entirely of apple and grape juices (99.4%, *see* Pet. App. 2a). To the contrary, the FDCA provides that words required to be on a label must be "prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual …." 21 U.S.C. § 343(f). Nor was the misleading name Coca-Cola chose mandated by the FDCA or the FDA's regulations. *See* Pet. 14.

In lieu of trying to explain why it believes the FDCA and the Lanham Act are in "irreconcilable conflict," Coca-Cola resorts (at 10-12) to alternative tools of statutory construction that even the Ninth Circuit did not invoke. But those canons of construction come into play only if a court has determined that two statutes conflict, which is not the case here. The first canon—that specific provisions trump general ones—applies where "a general permission or prohibition is contradicted by a specific prohibition or permission" or where the specific provision would be rendered superfluous by

the general one. *See RedLAX Gateway Hotel, LLC* v. *Amalgamated Bank*, 132 S. Ct. 2065, 2071 (2012). The second—the rule that a later statute controls the construction of an earlier one—is a tool used to "harmonize[]" "conflicting statutory provisions." *United States* v. *Estate of Romanil*, 523 U.S. 517, 534 (1998). Thus, neither standard has any relevance here.

Because the Ninth Circuit failed to adhere to this Court's precedents governing the implied repeal of a federal statute as well as the decision in *Wyeth*, this Court should grant review.

III. THE NINTH CIRCUIT'S DECISION CREATES A CONFLICT AMONG THE COURTS OF APPEALS

Coca-Cola makes almost no effort to reconcile the Ninth Circuit's sweeping displacement of the Lanham Act with decisions of at least three courts of appeals permitting Lanham Act claims to proceed in the face of agency regulation. In *Sandoz Pharmaceuticals Corp.* v. *Richardson-Vicks, Inc.*, 902 F.2d 222, 227-229 (3d Cir. 1990), the Third Circuit made clear that statements about a drug's effectiveness can be challenged under the Lanham Act if they are literally false or misleading even though such statements are also regulated by the FDA and FTC. In *Alpharma, Inc.* v. *Pennfield Oil Co.*, 411 F.3d 934, 939-941 (8th Cir. 2005), the Eighth Circuit permitted a Lanham Act challenge to the defendant's allegedly false assertion that its product had been approved by the FDA. And in *Cottrell, Ltd.* v. *Biotrol International, Inc.*, 191 F.3d 1248, 1254-1257 (10th Cir. 1999), the Tenth Circuit concluded that a Lanham Act challenge to certain statements about a product subject to regulation by the EPA could proceed.

All of these cases thus rejected the proposition that mere agency regulatory authority over a field—even if purportedly comprehensive—can displace the Lanham Act. Instead, the cases held that Lanham Act claims are barred only where they constitute an impermissible attempt by a private party to enforce the FDCA (or equivalent statute) or where they would necessarily require interpretation of FDA regulations or decisions (or their equivalent). *See* Pet. 19-23. As the court in *Cottrell* explained, a Lanham Act claim is not subject to dismissal just because it "touches on issues" subject to agency regulation: Unless a regulatory statute "explicitly precludes Lanham Act coverage, we refuse to limit the scope of the Lanham Act absent circumstances that inherently require interpretation" of relevant agency regulations or approvals. 191 F.3d at 1256.

Notably, Coca-Cola does not deny that the Third, Eighth, and Tenth Circuits have all "held that false or misleading product labels are actionable under the Lanham Act even though they are regulated by FDA." Opp. 16. In fact, Coca-Cola adds two more circuits to the tally, arguing that decisions of the Seventh and Second Circuits have also "recognized that false or misleading label statements concerning FDA-regulated products are open to Lanham Act attack." *Id.* (citing *Mead Johnson & Co.* v. *Abbott Labs.*, 201 F.3d 883 (7th Cir. 2000), and *Johnson & Johnson* v. *Carter-Wallace, Inc.*, 631 F.2d 186, 188 (2d Cir. 1980)). Coca-Cola's only response is to argue that the Ninth Circuit "did not contradict this well-accepted principle in its ruling" and that Pom's contrary reading of the Ninth Circuit's opinion is "flawed." Opp. 15-16. But it is Coca-Cola that has misread the Ninth Circuit's decision. As explained above, the Ninth Circuit held that Pom's Lanham Act claim could not proceed in light of the FDA's mere reg-

ulatory authority over juice labeling. *See supra* pp. 2-5. That holding cannot be reconciled with the decisions in *Alpharma*, *Sandoz*, and *Cottrell*. Indeed, Coca-Cola does not contest that *if* the Ninth Circuit's decision is taken at face value to preclude Lanham Act challenges to labels that are subject to "FDA's comprehensive regulation," Pet. App. 12a, then it conflicts with those decisions.

IV. THE QUESTION PRESENTED IS IMPORTANT

This case presents an important question regarding the interaction of the Lanham Act and federal agency regulatory regimes. *See* Pet. 24-28. Coca-Cola does not dispute that "FDA lacks the resources to pursue individual actions against each manufacturer that adopts a deceptive label." Opp. 16. It argues instead (at 17) that the FDA has "regulat[ed] extensively in this area" by promulgating rules governing juice labeling. But merely enacting rules, without the ability to enforce them, is insufficient to ensure that food products are not misleadingly labeled.

Coca-Cola also argues (at 17) that permitting Lanham Act suits challenging food labeling would lead to "confusion." But Coca-Cola does not explain why that would be the case. Companies face the possibility of Lanham Act challenges all the time. Every advertisement they run and every piece of promotional material they publish is subject to a Lanham Act challenge. One way to mitigate potential Lanham Act liability is to refrain from using product labels that your own employees have flagged as raising "a risk from a misleading standpoint." App. 35a. The FDCA expressly preempts *state* law in certain respects, *see* 21 U.S.C. § 343-1, but no provision of the Act indicates any intent by Congress to displace *federal* laws applicable to food labeling.

Coca-Cola does not dispute that the impact of the Ninth Circuit's opinion will extend beyond federal Lanham Act challenges involving juice labels. *See* Pet. 27-28. Indeed, recent events have only highlighted the need to clarify the standard for preclusion of food-labeling claims. On February 13, 2013, the district court in this case relied in part on the Ninth Circuit's analysis in finding Pom's *state-law* claims preempted. *See Pom Wonderful LLC* v. *Coca Cola Co.*, No. 2:08-cv-06237, 2013 WL 543361, at *4 n.1 (C.D. Cal. Feb. 13, 2013). Other district courts have likewise applied the decision to state-law claims. *See, e.g.*, *Ivie* v. *Kraft Foods Global Inc.*, No. 12-cv-2554, 2013 WL 685372, at *6-7 (N.D. Cal. Feb. 25, 2013).

Finally, the Court could consider holding the petition in this case pending resolution of *Mutual Pharmaceutical Co.* v. *Bartlett*, No. 12-142, which is set for argument on March 19, 2013. *Bartlett* addresses whether the FDCA preempts state-law design-defect claims against generic drugs where it would be impossible for the generic-drug manufacturer to comply with state law by altering the labeling of the drug required by the FDA or the FDA-approved design of the drug. The decision in *Bartlett* may inform the proper resolution of this case, where it was not impossible for Coca-Cola to comply with both the Lanham Act and the FDCA, and where the FDA did not review and approve, much less require, Coca-Cola's label.

CONCLUSION

For the foregoing reasons, Pom's petition for a writ of certiorari should be granted.

Respectfully submitted.

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