12-761

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

—v.—

THE COCA-COLA COMPANY,

Respondent.

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

SUPPLEMENTAL BRIEF FOR RESPONDENT

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SUPPLEMENTAL BRIEF FOR RESPONDENT

The United States correctly recommends that this Court deny certiorari because, *inter alia*, there is no circuit conflict (U.S. Br. 19-21) and the FDA has adequate resources to regulate the content of food and juice labels (U.S. Br. 15, 17-18).

I. THE UNITED STATES CONFIRMS THAT NO CIRCUIT CONFLICT IS PRESENTED

Petitioner originally (Pet. 19-24), and again in its supplemental brief (Pet. Supp. Br. 9-11), alleges a conflict between the Ninth Circuit's decision below, on the one hand, and decisions of the Third (*Sandoz Pharm. Corp.* v. *Richardson-Vicks, Inc.*, 902 F.2d 222 (1990)), Eighth (*Alpharma, Inc.* v. *Pennfield Oil Co.*, 411 F.3d 934 (2005)), and Tenth (*Cottrell, Ltd.* v. *Biotrol Int'l, Inc.*, 191 F.3d 1248 (1999)) Circuits, on the other hand. Petitioner is incorrect, as the United States agrees (U.S. Br. 19-21).

a. *Sandoz* does not conflict with the decision below because, most obviously, both decisions *rejected* a Lanham Act claim. See *Sandoz*, 902 F.2d at 232; Pet. App. 10a. The Third Circuit reasoned in *Sandoz* that the proposed Lanham Act claim would require resolution of a question that the FDA had not yet answered: whether consumers would be misled by the defendant's labeling of a certain cough-syrup ingredient as "inactive." 902 F.2d at 231 ("Sandoz's position would require us to usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations."). This holding applies *a fortiori* here because the issue whether a multi-fruit juice name or label is deceptive is not

only within the FDA's expertise, but is a topic that the FDA *has already addressed* in detailed and specific regulations.

First, as to the name, 21 C.F.R. § 102.33(d)(1) authorizes a name that "[i]ndicate[s] that the named juice is present as a flavor or flavoring (e.g., 'Raspcranberry'; raspberry and cranberry flavored juice drink)." FDA adopted this regulation only after "discuss[ing] at length why it would not be misleading to describe such a beverage as 'flavored' with a non-predominant juice, even while not listing by name or percentage the other juices present." U.S. Br. 18 (citing 58 Fed. Reg. 2897, 2918-2921 (Jan. 6, 1993)). As the United States correctly observes, the regulation "reflect[s] the agency's balance of competing considerations in a specific setting that could easily be upset by the intrusion of a general private remedy such as that provided under Section 43(a) of the Lanham Act." U.S. Br. 18;[1] see also *ibid.* (explaining further, in accord with respondent's brief in opposition (at 9), that a Lanham Act Section 43(a) claim "is not 'capable of coexistence' with those [FDA] regulations" and therefore may not be asserted) (quoting *J.E.M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143 (2001)).

Second, as to the relative font sizes of "POMEGRANATE BLUEBERRY" and "FLAVORED BLEND OF 5 JUICES" (see Pet. App. 2a), accepting

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[1] See also Pet. App. 10a (decision below) ("In extensively regulating the labeling of foods and beverages, the FDCA and its implementing regulations have identified the words or statements that must or may be included on labeling ….").

arguendo the United States' view that the FDA has *not* yet specifically regulated this issue (U.S. Br. 19), *Sandoz* is on all fours with the decision below. Both in *Sandoz*, and in this case concerning the font-size issue as the United States conceives it, the FDA has authority to regulate the issue but has not yet done so. Compare *Sandoz*, 902 F.2d at 231 ("We decline to find … that which the FDA, with all of its scientific expertise, has yet to determine."), with U.S. Br. 19 ("[T]he FDCA and FDA have not specifically addressed 'how [respondent] presents the words 'Pomegranate Blueberry' and 'Flavored Blend of 5 Juices' on the product's label.'") (quoting Pet. App. 10a). In fact, the United States and petitioner overlook that FDA has specifically addressed the font-size issue in 21 C.F.R. § 101.22(i)(1)(i), which provides that the "characterizing flavor … shall be immediately followed by the word 'flavored' *in letters not less than one-half the height of the letters in the name of the characterizing flavor*" (emphasis added). Here, the letters "FLAVORED BLEND OF 5 JUICES" comply with this specific regulation because, as is clear from the image at Pet. App. 2a, they are *more* than one-half the height of the words "POMEGRANATE BLUEBERRY."[2] Thus, *Sandoz* applies *a fortiori* here with respect to the font-size issue just as it does with respect to the name issue.

b. *Alpharma* and *Cottrell* do not conflict with the decision below because, unlike here, the Lanham Act

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[2] The FDA has explained that 21 C.F.R. § 101.22(i)(1)(i) applies to blended juices such as the one at issue here. See 56 Fed. Reg. 30,452, 30,462, Proposed Rule (July 2, 1991) ("Any pertinent provisions in § 101.22(i) are applicable to the labeling of the various juice beverages.").

claim in those cases was that the defendant had misrepresented that a federal agency had approved its product. *Alpharma*, 411 F.3d at 935 (plaintiff alleged that defendant "falsely advertis[ed] that one of its antibiotic animal feed additives was approved for certain uses by the [FDA]"); *Cottrell*, 191 F.3d at 1254 (plaintiff alleged that defendant's "advertising deceives customers 'by implying that EPA approval or clearance has been obtained [for the seven-day efficacy claim]'") (brackets in original). Here, by contrast, petitioner's Lanham Act claim *does not allege that respondent's label made any representation that the FDA had approved the label or the juice*; rather, petitioner's claim does not concern FDA approval and instead alleges that respondent's label misleads consumers as to the content of the juice. See Pet. Supp. Br. 2 ("Coca-Cola's misleading label causes consumers to believe that the juice actually contains significant amounts of [pomegranate and blueberry juice] when in fact it contains only trivial amounts.").

There is good reason to distinguish between a representation as to agency approval, on the one hand, and a representation as to the content of a juice, on the other hand. The determination whether a defendant has or has not obtained regulatory approval (which in turn will decide whether the representation as to such approval is misleading) is generally a true-or-false determination that calls for no particular agency expertise and can be made in the course of court adjudication of a private Lanham Act claim. By contrast, a determination whether other labeling content (not involving a representation as to agency approval) is misleading often does call for second-guessing the agency's expertise. As the Seventh Circuit explained:

> The FDA should be given a chance to opine on the proper labeling before a Lanham Act suit is filed since it has more experience with consumers' understanding of drug labels than judges do. *Alpharma*, in contrast, was a case in which the complaint under the Lanham Act was simply that the defendant had said that the FDA had approved its drug for a number of uses for which it had not been approved. Evaluating such a charge did not draw on the agency's insights into the understanding of consumers of drugs; allowing the suit to proceed without reference to the agency was therefore not objectionable as an attempt to use the Lanham Act as a vehicle for enforcing the Food, Drug, and Cosmetic Act, which does not authorize a private right of action.

Schering-Plough Healthcare Prods., Inc. v. *Schwarz Pharma, Inc.*, 586 F.3d 500, 508-09 (7th Cir. 2009) (internal citations omitted).

While the United States criticizes *Schering-Plough* as endorsing the view that the FDA's mere authority to regulate a particular drug label suffices to preclude a Lanham Act claim (U.S. Br. 14), that issue is not presented by the decision below and this case is therefore an improper vehicle in which to resolve the issue. As explained above, and as the Ninth Circuit correctly held, this case does not involve an as-yet unexercised power of the FDA, but specific FDA regulations that squarely address the naming and font-size issues of blended juice. See *supra*, at 2-3; Pet. App. 10a ("[T]he FDCA and its implementing regulations have identified the words or

statements that must or may be included on labeling and have specified how prominently and conspicuously those words and statements must appear.").[3]

c. The United States correctly observes that there is no conflict between the decision below and decisions that have proceeded to the merits of Lanham Act claims challenging food labels. See U.S. Br. 20. None of those decisions addressed whether a specific FDA regulation precluded the Lanham Act claim, and for good reason—unlike here, there was no specific FDA regulation in place concerning a label's claim regarding the popularity of the product or its quality compared to competitors' products. See *Mead Johnson & Co.* v. *Abbott Labs.*, 201 F.3d 883, 884 (7th Cir.) (formula is "1st Choice of Doctors"), cert. denied, 531 U.S. 917 (2000); *PBM Prods., LLC v. Mead Johnson & Co.*, 639 F.3d 111, 116-17 (4th Cir. 2011) (formula "[c]ompare[s] to [competitor brand]");[4] *American Italian Pasta Co. v. New World Pasta Co.*, 371 F.3d 387, 389 (8th Cir. 2004) (pasta is "America's Favorite Pasta").

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[3] Given this passage in the Ninth Circuit's decision below, the United States' suggestion that the Ninth Circuit's reasoning turned on the FDA's mere authority to regulate fruit juice labels (U.S. Br. 10) is incorrect. In any event, as the United States recognizes (U.S. Br. 19-21), this Court does not typically grant certiorari to review the *reasoning* of a circuit's decision where that decision is entirely consistent in *outcome* with decisions by other circuits.

[4] The FDA has extensively regulated labeling of infant formula, *e.g.*, 21 C.F.R. 107, Subpart B, but not the specific matter of claims regarding a formula's popularity or a formula's quality as compared to competitors' formulas.

II. THE UNITED STATES CONFIRMS THAT THE FDA HAS ADEQUATE RESOURCES TO REGULATE FOOD AND JUICE LABELS

This Court may have called for the view of the Solicitor General to advise on the correctness of petitioner's hyperbolic assertion that "the FDA woefully lacks the resources necessary" to regulate food labels (Pet. 25).

The United States' invitation brief provides reassurance that the FDA indeed has adequate resources. Specifically, the United States recounts that "FDA discussed *at length* why it would not be misleading to describe … a beverage as 'flavored' with a non-predominant juice, even while not listing by name or percentage the other juices present." U.S. Br. 18 (citing 58 Fed. Reg. at 2918-2921) (emphasis added). The United States also recognizes that the FDA's regulatory effort in this area "reflect[s] the agency's balance of competing considerations in a specific setting that could be easily upset by the intrusion of a general private remedy such as that provided under Section 43(a) of the Lanham Act." U.S. Br. 18. And the United States acknowledges the FDA's ability "to undertake a rulemaking to revise its labeling regulations for juice mixtures" (U.S. Br. 15) without casting any resource-related doubt on that ability.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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