No. 12-761

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

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

BRIEF OF *AMICUS CURIAE* THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF NEITHER PARTY

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STATEMENT OF INTEREST

The American Intellectual Property Law Association ("AIPLA") is a voluntary bar association with approximately 15,000 members who are lawyers in both private and corporate practice, judges, patent agents, academics, law students, and USPTO professionals. Our members practice in a wide and diverse spectrum of intellectual property fields, including patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. They represent owners and users of intellectual property, as well as those who litigate and prosecute before patent and trademark offices.[1]

AIPLA has no interest in any party to this litigation and has no stake in the outcome of this case, other than its interest in seeking a correct and consistent interpretation of the laws affecting intellectual property.[2]

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1. In accordance with Supreme Court Rule 37.6, AIPLA states that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than AIPLA or its counsel. After reasonable investigation, AIPLA believes that (i) no member of its Board or *Amicus* Committee who voted to file this brief, or any attorney in the law firm or corporation of such a member, represents a party to this litigation in this matter, (ii) no representative of any party to this litigation participated in the authorship of this brief, and (iii) no one other than AIPLA, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief.

2. AIPLA sought consent to file this brief from the counsel of record for all parties, pursuant to Supreme Court Rule 37.3(a). Counsel for Petitioner and Respondent informed AIPLA of their consent by countersigned letters, and the letters have been filed with this brief.

SUMMARY OF ARGUMENT

The appellate court interpreted too broadly the potential conflict between the regulations promulgated under the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA") and the Nutrition Labeling and Education Act ("NLEA"), Pub. L. No. 101-535, 104 Stat. 2353 (1990), and the section of the Lanham Act providing for a private right of action for false and misleading advertising, 15 U.S.C. § 1125(a)(1). This ruling has the potential to severely undermine the ability of parties to use the Lanham Act to prevent false and misleading advertising in areas where the FDA also regulates (or has the authority to regulate) such information.

The appellate court affirmed the dismissal of Pom's false advertising claim under Section 43(a)(1) of the Lanham Act, 15 U.S.C. § 1125(a)(1), with respect to the naming and labeling of Coca-Cola's "Pomegranate Blueberry Flavored Blend of 5 Juices" product. *Pom Wonderful LLC v. The Coca-Cola Co.*, 679 F.3d 1170, 1179 (9th Cir. 2012). In its Lanham Act claim, Pom asserted that the name of the juice blend was misleading notwithstanding the fact that the naming method employed by Coca-Cola purported to follow regulations promulgated under the FDCA and the NLEA. Regulations enacted thereunder at 21 C.F.R. § 102.33(c) and (d) regulate the juice names and certain information contained on juice labels. Section 102.33(c) recognizes that a juice blend can use a juice component in its name or label even if the blend "also contains a juice other than the . . . juice" named or represented on the label. A "named" juice need "not [be] the predominant juice" by volume. 21 C.F.R. § 102.33(d). The juice in this case contained 0.3% pomegranate juice, 0.2% blueberry

juice and over 99% apple and grape juice. *Pom Wonderful*, 679 F.3d at 1172.

The court of appeals noted that the FDCA "comprehensively regulates food and beverage labeling." *Id.* at 1175. The court sought "to give as much effect to both statutes as possible, . . . to strike a balance that disrupts the two statutory schemes as little as it can." *Id.* at 1176. The court held that "[t]he naming component of Pom's claim is barred because, as best as we can tell, FDA regulations authorize the name Coca-Cola has chosen." *Id.*

The reasons given for affirmance are overly broad and are prone to misinterpretation. The court of appeals observed that, with respect to its determination, it was "primarily guided . . . 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." 679 F.3d at 1178. It declined to disturb the FDA's "judgments" (though, in a literal sense, there was no judgment or approval of the name or label by the FDA, but instead a regulation governing them), "[o]ut of respect for the statutory and regulatory scheme." *Id.*

On this point, the court of appeals is mistaken: its determination should have been guided by Respondent's compliance with particularized FDA regulations. It is not enough to have a comprehensive set of regulations. The regulation itself must expressly allow the act complained of for there to be a conflict with the Lanham Act.

This particular case provides a compelling illustration for why the Lanham Act should be broadly applied. Petitioner claims that the inclusion of literally one teaspoon of pomegranate and blueberry juice transforms a quart of apple and grape juice into a "Pomegranate Blueberry Flavored Blend of 5 Juices." The public is not well served by this deception.

Any decision of this Court should make clear that a Lanham Act claim alleging the confusing or deceptive character of a product label, asserted for consumer protection and to prevent unfair competition, is not barred by the jurisdiction of the FDA to generally regulate the content of such labels where the particular conduct alleged is not specifically governed by express regulations, or approved by specific administrative review, even where regulatory authority for such regulations is available but unexercised. It should also confirm that a Lanham Act plaintiff may assert a false advertising claim that a label is misleading in part because it does not conform to the requirements of an FDA regulation.

ARGUMENT

I. WHERE LABELING CONDUCT IS COMPLETELY GOVERNED BY REGULATIONS THAT STATE EXPRESS REQUIREMENTS OR PROVIDE FOR AGENCY REVIEW, A LANHAM ACT CHALLENGE TO THE PROPRIETY OF FOLLOWING SUCH REGULATIONS OR RELYING ON THE AGENCY IS BARRED.

Where labeling conduct is completely governed by regulations that state express requirements or provide for agency review, a Lanham Act challenge to the propriety of following such regulations or relying on the agency is barred.

To hold otherwise would undermine the authority of the FDCA, the NLEA, and the related regulations, and the FDA's pronouncements that certain methods of naming juices are allowable when they meet the criteria established in the regulation. For example, the FDA considered it appropriate to label a drink as "flavored" by the named juice, concluding that such labeling "will adequately deal with the kinds of misleading labeling discussed in the comments from consumer groups." *Pom Wonderful LLC v. The Coca-Cola Co.*, 727 F. Supp. 2d 849, 864-865 (C.D. Cal. 2010) (citing Food Labeling; Declarations of Ingredients; Common or Usual Name for Nonstandardized Foods; Diluted Juice Beverages, 58 Fed. Reg. 2900 (Jan. 6, 1993) (to be codified at 21 C.F.R. §§ 101, 102)). If the juice otherwise complied with the regulations (such as by satisfying the juice flavoring requirements specified to permit the use of this naming method), then there should be no Lanham Act claim available to assert

that a name that meets the express requirements of the regulation is nonetheless itself a violation of the Lanham Act.

Where relief sought under the Lanham Act is not "capable of coexistence" with the FDCA, and its regulations, the Lanham Act claim should be barred. *See J. E. M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143-144 (2001). It is the obligation of the courts to give full effect to both statutes where possible: "The courts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective." *Morton v. Mancari*, 417 U. S. 535, 551 (1974).

Giving full effect to the FDA regulations and the Lanham Act may not be possible with respect to certain aspects of the regulation where one federal statute expressly prohibits conduct that is expressly allowed by the other. *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861 (2000), a state law preemption case, is instructive on this point. In *Geier*, the plaintiffs brought a state tort claim against an automobile manufacturer alleging product defect and negligence in failing to install an air bag into its vehicles. In *Geier*, as in this case, there was no indication that Congress intended to preempt the field and the federal law contained a savings clause. 529 U.S. at 867-68.[3] This Court held that there was an actual conflict

3. *See* 21 U.S.C. § 343-1(a) note (1990) (Construction of Pub. L. 101-535: The statute "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted" thereunder.)

with federal law that preempted the state law claims. *Id.* at 861. It found that the federal motor vehicle regulations provided manufacturers an alternative to installing air bags, including the use of automatic belts or passive interiors. A state cause of action predicated on the theory that a vehicle without an air bag installed is defectively or negligently designed would thus stand "'as an obstacle to the accomplishment and execution of' the important means-related federal objectives." *Id.* at 881-82 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1940)).

A conflict between two federal statutes, or between a statute and a set of regulations duly authorized by federal statute, should be treated similarly. The conflict between them should be read narrowly, to give full effect to both, and certainly to an extent similar to that provided in the preemption cases. This is the approach taken by courts considering the potential conflict between a federal statute or regulation and the Lanham Act in cases where an agency provided express approval and or where a party complied with an express regulation.[4]

4. *See, e.g. Cottrell, Ltd. v. Biotrol Inter., Inc.*, 191 F.3d 1248, 1254-56 (10th Cir. 1999) (rejecting Lanham Act claim "requir[ing] the court to interpret and apply regulations that are exclusively in the province of the EPA"); *Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145 (S.D.N.Y. 1987) (holding FDA's express approval of a drug label cannot be attacked through Lanham Act claims); *VP Racing Fuels, Inc. v. Gen. Petroleum Corp.*, 673 F. Supp. 2d 1073, 1085 (E.D. Cal. 2009) (representation of octane level based on certification complying with federal Petroleum Marketing Practices Act cannot give rise to Lanham Act claim).

II. WHERE LABELING CONDUCT IS NOT COMPLETELY GOVERNED BY EXPRESS FDA REGULATIONS, SUCH CONDUCT CAN BE THE BASIS OF A LANHAM ACT CLAIM.

Where the regulations do not expressly govern product labeling, or where the FDA has not expressly reviewed the exact label at issue and passed on its acceptability with respect to those regulations, there should be room to argue that the labeling conduct constitutes advertising that is actionable under the Lanham Act. Indeed, for years courts have recognized that literally true statements can be misleading, depending on context and use. *See, e.g.*, 5 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* § 27:53 (4th ed. 2013). For example, Coca-Cola's use of pomegranate and blueberry in its juice name was predicated on it "provid[ing] the characterizing flavor." *See Pom Wonderful*, 679 F.3d at 1177; Reply Brief for Petitioner on Petition for Writ of *Certiorari* at 4, *Pom Wonderful, LLC v. The Coca Cola Co.*, No. 12-761 (March 2013). A Lanham Act claim should be available to explore whether including minute amounts of pomegranate and blueberry juice supplies the characterized "flavoring" contemplated in the regulations to allow for the naming method employed. *See* 21 C.F.R. 102.33(b). In the absence of the product tasting like pomegranate and blueberry juice or containing more than a trace amount of these fruits, a plaintiff should be allowed to explore whether such labeling is misleading under the Lanham Act, regardless of the regulations.

This should also be the case for another aspect of the FDA regime governing labels; *i.e.*, determining whether the text placement and relative font size of Coca-Cola's label violate 21 U.S.C. § 343(f). That statute requires

wording on a label to be "prominently placed" so "as to render it likely to be read and understood by the ordinary consumer under customary conditions of purchase and use." *Id.*

Similarly, in this case, there is potential ambiguity as to what the juice is and what the flavoring is. The label could plausibly be read to identify the product as pomegranate juice that has blueberry flavoring, or, as Respondent is contending, it could be read to identify it as a pomegranate-and-blueberry flavored juice. The failure to use a signaling word like "and" or a hypen "Pomegranate-Blueberry Flavored" could suffice to make the label deceptive and actionable under the Lanham Act.

A Lanham Act claim alleging the confusing or deceptive character of a product label, asserted for consumer protection and to prevent unfair competition, may not be barred merely by the jurisdiction of the FDA to regulate the content of such label. Where the label is not specifically authorized by the FDCA or FDA regulations, even where regulatory authority for such regulations is available but unexercised, this Court should hold that a Lanham Act claim may proceed.

The Lanham Act provides a cause of action against false advertising, which may be directed at "any goods . . . or any container for goods." 15 U.S.C. § 1125(a)(1). In enacting the Lanham Act, Congress expressly stated its goal to protect commercial interests against particular forms of unfair competition, including false advertising. *Id.* at § 1127; *see also Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763, 767–68 (1992). Congress intended not only to protect "the good will of" businesses, but also to "protect[] the public against spurious and falsely marked goods." S. Rep. No.

79-1333, at 3 (1946), reprinted in 1946 U.S.C.C.A.N. 1274, 1274-75; *see also* McCarthy § 27:31.

The FDA has acknowledged the limitations of its regulatory scheme. In the context of "multiple-juice beverages that name one or more but not all of the juices present" such as Respondent's, the FDA has recognized the "great potential for the label to misrepresent the contribution of the named juice to the product" under its regulations. 58 Fed. Reg. 2897-901, 2920 (Jan. 6, 1993). The availability of Lanham Act relief to redress such misrepresentations thus aligns with the FDA's purposes.

To the extent the Lanham Act can coexist with the other federal statutes, it must be given effect. *See Morton*, 417 U. S. at 550-551 (construing the potential conflict between the Equal Employment Opportunity Act of 1972 and the Indian Reorganization Act of 1934). This Court "has not hesitated to give effect to two statutes that overlap, so long as each reaches some distinct cases." *J. E. M. Ag Supply,* 534 U.S. at 144 (citation omitted). The NLEA does not purport to limit the Lanham Act, and in the nearly twenty-four years since its enactment, Congress has not deemed it necessary to do so.

The court of appeals based its improperly broad approach primarily on another recent decision in that circuit, *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010): "*PhotoMedex* teaches that courts must generally prevent private parties from undermining, through private litigation, the FDA's considered judgments." *Pom Wonderful*, 679 F.3d at 1178. The court in *PhotoMedex* refused to allow a Lanham Act claim that, among other things, challenged the truth of a claim that a product was "cleared" by the FDA. *See id.* at 1176.

To the extent the *PhotoMedex* holding was based solely on the premise that the FDA retains exclusive jurisdiction over matters it regulates, it is in conflict with decisions of other appellate courts that have allowed Lanham Act claims that included assertions challenging the veracity of claims of government approval.

For example, in *N. Am. Med. Corp. v. Axiom Worldwide, Inc.*, 522 F.3d 1211 (11th Cir. 2008), the court affirmed a Lanham Act claim including an allegation that defendant falsely represented that the product was FDA approved. In doing so, the court was careful to note that the Lanham Act claim was not a collateral attack on the FDA approval process:

> "[T]he district court did not step into the FDA's shoes when it ruled that the DRX 9000 was not approved. The district court was not making a determination whether the device should be approved, it merely noted what the FDA had already determined."

Id. at 1226 n. 15; *see also Alphapharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 939-41 (8th Cir. 2005) (allowing Lanham Act claim asserting that a representation that the FDA had approved a drug was false and deceptive); *Cottrell, Ltd.*, 191 F.3d at 1255-56 (allowing Lanham Act claim that manufacturer misleadingly represented that it had obtained EPA clearance for a surface cleaner); *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990) (Lanham Act claim concerning alleged misrepresentation of the action of a drug regulated by the FDCA).

Conversely, the court *Mylan Laboratories, Inc. v. Matkari* refused to allow a Lanham Act claim to go forward where it amounted to an indirect way to enforce the FDCA. 7 F.3d 1130, 1139 (4th Cir. 1993). In that case, the plaintiff alleged that defendants violated the Lanham Act by falsely stating or implying that their drugs had been "properly approved by the FDA" when the FDA had not done so. *Id.* According to the plaintiff, the acts of putting the drug on the market and using standard package inserts of the type used by approved drugs misled the public into believing that the drug had received FDA approval. *Id.* The defendant was not alleged to have made any affirmative statements of "FDA approval." *Id.*

The court rejected the Lanham Act claim because it would "permit Mylan to use the Lanham Act as a vehicle by which to enforce the Food, Drug, and Cosmetic Act ("FDCA") and the regulations promulgated thereunder." *Id.* This case and the others described above largely strike the right balance in giving full effect to Lanham Act claims concerning misrepresentations of government approval while preventing collateral attack on agency decisions.

The availability of Lanham Act relief with respect to areas not specifically and expressly regulated by the FDA will serve to support the aims of the FDCA and NLEA. This is especially true in light of the alignment of purpose shared by the FDCA and Lanham Act to protect consumers.[5]

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5. *Compare Mut. Pharm. Co., Inc. v Bartlett*, 133 S. Ct. 2466, 2494 (2013) (J. Sotomayor, dissenting) (recognizing "FDCA's core purpose of protecting consumers") *and U.S. v. Lane Labs-USA Inc.*, 427 F.3d 219, 226 (3d Cir. 2005)("protecting consumer health and safety is a primary purpose of the FDCA") *with* S. Rep. No.

Applying the standard urged by AIPLA will give maximum effect to the Lanham Act without impeding the reach of the FDCA and NLEA. Permitting Lanham Act unfair competition claims that do not conflict with FDA regulations poses no threat to the FDA's regulatory authority, and preserves the important rights of consumers and competitors to bring federal false advertising claims under the Lanham Act.

Because the District Court improperly dismissed Petitioner's Lanham Act claim under an improper view of the law, this case should be vacated and remanded for further proceedings.

III. A LANHAM ACT CLAIM CAN BE BASED IN PART ON LACK OF COMPLIANCE WITH FDA REGULATIONS.

Lanham Act false advertising claims can be based upon, *inter alia*, "[s]tatements that are literally true or ambiguous but which nevertheless have a tendency to mislead or deceive the consumer." *United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1182 (8th Cir. 1998).[6] In this respect, a misrepresentation that the government has authorized or approved of the conduct or that it complies

79-1333, at 4-5 (1946), reprinted in 1946 U.S.C.C.A.N. 1274, 1276-77 (purpose of the Lanham Act to "protect[] the public against spurious and falsely marked goods").

6. *See also Procter & Gamble Co. v. Chesebrough–Pond's Inc.*, 747 F.2d 114, 119 (2d Cir. 1984) (in addition to blatant falsehoods, the Lanham Act "embraces 'innuendo, indirect intimations, and ambiguous suggestions' evidenced by the consuming public's misapprehension of the hard facts underlying an advertisement") (citations omitted).

with government requirements is merely a subset of the variety of misrepresentations of quality, efficacy, safety, approval, authority or affiliation that typically support a claim for unfair competition. Thus, an applicant for FDA approval may well satisfy a labeling regulation with content that is literally true, but that content could be implicitly false or deceptively misleading. A Lanham Act claim, which would not require reexamination of prior agency determinations, should be available to test the veracity or misleading nature of the statement.

Even to the extent that the FDA has specifically regulated conduct, the mere existence of such regulation should not, without more, preclude a Lanham Act suit relating to that conduct. While a private litigant should not be permitted to use the Lanham Act to collaterally attack the decisions of the FDA, or to allege conduct expressly permitted by FDA regulations is a violation, these prohibitions should not be interpreted so broadly as to prevent a Lanham Act plaintiff from pointing to a defendant's clear *non*-compliance with the FDCA as an evidentiary basis for a false advertising claim.[7]

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7. *See N. Am. Med. Corp.*, 522 F.3d at 1225-26; *Alphapharma, Inc.*, 411 F.3d at 939-41; *Cottrell, Ltd.* 191 F.3d at 1255-57; *Mut. Pharm. Co. v. Ivax Pharms., Inc.*, 459 F. Supp. 2d 925, 939 (C.D. Cal. 2006) ("In adjudging this claim the Court need not interpret and then apply any FDA regulation; instead, it need only verify whether defendants' label conforms to what the FDA has already determined is required to be listed for quinine sulfate, something which the Court can do 'without any need to interpret [and then apply] FDA regulations.'") (quoting *Summit Technology, Inc. v. High–Line Medical Instruments Co.*, 933 F. Supp. 918, 933, n.7 (C.D. Cal. 1996)).

To do so does not impinge on the FDA's authority. *See Grove Fresh Distributors, Inc. v. Flavor Fresh Foods, Inc.* 720 F. Supp. 714, 716 (N.D. Ill. 1989) (allowing Lanham Act claim based in part on non-compliance with FDA regulation). In refusing to dismiss plaintiff's Lanham Act claim, the court in *Grove Fresh* sanctioned plaintiff's "reli[ance] on the FDA regulation merely to establish the standard or duty which defendants allegedly failed to meet," distinguishing it from a prohibited private cause of action under the FDCA. *Id.*; *see also Cottrell, Ltd.*, 191 F.3d at 1252 (refusing "to limit the scope of the Lanham Act absent circumstances that inherently require interpretation of FIFRA regulations and/or EPA approvals").

This is necessary because, although the court of appeals expressly noted the possibility that the FDA could take action if it believed a label to be misleading (*Pom Wonderful*, 679 F.3d at 1178), it is unlikely to do so. As Respondent concedes, "FDA lacks the resources to pursue individual actions against each manufacturer that adopts a deceptive label." Brief in Opposition to Petition for Writ of *Certiorari* at 16, *Pom Wonderful, LLC v. The Coca Cola Co.*, No. 12-761 (Feb. 22, 2013); *See* Petition for a Writ of *Certiorari* at 25-27, *Pom Wonderful, LLC v. The Coca Cola Co.*, No. 12-761 (Dec. 2012); *see also Cannon v. Univ. of Chicago*, 441 U.S. 677, 706–08 nn.41–42 (1979) (private right of action under Title IX of the Education Amendments of 1972 would not frustrate the legislative scheme's underlying purpose; Department of Health, Education, and Welfare itself recognized it did not have the resources to redress individual injuries).

Thus, a private Lanham Act challenge will likely be the sole action taken in response to a significant amount of deceptive conduct by food manufacturers, despite the fact that such conduct also violates FDA statutes or regulations. The ability of Lanham Act claimants to base their claims in part on non-compliance with FDA requirements would only serve to give effect to the FDCA and NLEA and other regulations.

CONCLUSION

For the reasons set forth herein, AIPLA respectfully requests the Court to vacate and remand the decision of the court of appeals for further proceedings.

Respectfully submitted,

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