No. 19-152

In the Supreme Court of the United States

AMARIN PHARMA, INC., ET AL., PETITIONERS

v.

INTERNATIONAL TRADE COMMISSION, ET AL.

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

BRIEF FOR THE FEDERAL RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether a private party's claim under the Lanham Act, 15 U.S.C. 1051 *et seq.*, presented in a complaint seeking an unfair-trade-practices investigation by the United States International Trade Commission under 19 U.S.C. 1337, is cognizable when that claim is based solely on an alleged violation of the new-drug provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, and the Food and Drug Administration has not determined that the FDCA has been violated.

ADDITIONAL RELATED PROCEEDING

United States Court of Appeals (Fed. Cir.):

Amarin Pharma, Inc. v. *International Trade Comm'n* (*In re Amarin Pharma, Inc.*), No. 18-114 (May 1, 2019)

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-38) is reported at 923 F.3d 959. The decision of the United States International Trade Commission (Pet. App. 39-42) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on May 1, 2019. The petition for a writ of certiorari was filed on July 30, 2019. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. The Tariff Act of 1930, as amended, 19 U.S.C. 1202 *et seq.*, prohibits certain "[u]nfair methods of competition and unfair acts in the importation of articles * * * into the United States, or in the sale of such articles by the owner, importer, or consignee." 19 U.S.C. 1337(a)(1)(A). Congress has directed the United States

International Trade Commission (Commission) to "investigate any alleged violation of [Section 1337] on complaint under oath or upon its initiative," 19 U.S.C. 1337(b)(1), if "one-half of the number of commissioners voting agree that the investigation should be made," 19 U.S.C. 1330(d)(5). See 19 C.F.R. 210.9(a), 210.10(a)(1). Once "an investigation is initiated," the Commission must set a target date for the agency's "final determination." 19 U.S.C. 1337(b)(1).

After completing its investigation, the Commission "shall determine * * * whether or not there is a violation of [Section 1337]" unless the matter is resolved by a consent order or agreement between the private parties. 19 U.S.C. 1337(c). If the Commission finds such a violation, the violation "shall be dealt with, in addition to any other provision of law, as provided in [Section 1337]." 19 U.S.C. 1337(a)(1); see 19 U.S.C. 1337(c). Section 1337 authorizes the Commission to exclude the offending articles "from entry into the United States" and/or to issue a cease-and-desist order, unless the Commission finds that the "effect of such" exclusion or order on certain public interests warrants a different course. 19 U.S.C. 1337(d)(1), (e)(1), (f)(1) and (g)(1). "Any person adversely affected by a final determination of the Commission under [Section 1337](d), (e), (f), or (g)" may obtain judicial review in the Federal Circuit, 19 U.S.C. 1337(c), which possesses corresponding jurisdiction to review "the final determinations of the [Commission] relating to unfair practices in import trade, made under section [1]337," 28 U.S.C. 1295(a)(6).

b. The Commission has long understood the "[u]nfair methods of competition and unfair acts" prohibited by Section 1337, 19 U.S.C. 1337(a)(1)(A), to include the importation of articles that violate 15 U.S.C. 1125(a)(1)(B),

a provision of the Trademark Act of 1946 (Lanham Act), ch. 540, 60 Stat. 427 (15 U.S.C. 1051 *et seq.*). Section 1125(a)(1)(B) makes it unlawful for any person to "use[] in commerce any word, term, name, symbol, or device, or any combination thereof" that "in commercial advertising or promotion, misrepresents the nature, characteristics, [or] qualities * * * of his or her or another person's goods." 15 U.S.C. 1125(a)(1)(B); see, *e.g.*, *Textron, Inc.* v. *U.S. Int'l Trade Comm'n*, 753 F.2d 1019, 1023 (Fed. Cir. 1985). The Commission therefore may investigate, as a possible violation of Section 1337, an allegation of false or misleading representations involving imported articles.

This case concerns the intersection between (1) the Commission's general authority to investigate such Lanham Act violations under Section 1337 and (2) the authority of the Food and Drug Administration (FDA), acting through the United States, to enforce the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq*. As relevant here, the FDCA generally prohibits any person from introducing, or delivering for introduction, into interstate commerce any "new drug," unless an FDA-approved application for that drug is effective. 21 U.S.C. 355(a); see 21 U.S.C. 321(g)(1) and (p) (defining "drug" and "new drug"). Cf. 21 U.S.C. 321(ff) and (3)(A) (defining "dietary supplement," which generally is "deemed to be a food" under the FDCA, to "include an article that is approved as a new drug" in certain contexts). The FDCA also prohibits the "misbranding" of a drug through the use of false or misleading labeling. 21 U.S.C. 331(b); 21 U.S.C. 352(a) (Supp. IV 2016).

The United States has exclusive authority to bring enforcement actions for violations of the FDCA's new-drug provisions. "Except as provided in [Section 337](b)"—

which authorizes a State to enforce FDCA provisions governing adulterated food within that State—"all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. 337(a); see 21 U.S.C. 337(b). Section 337(a) thus "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [FDCA's] provisions." *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4, 352 (2001); see *POM Wonderful LLC* v. *Coca-Cola Co.*, 573 U.S. 102, 109 (2014) ("Private parties may not bring [FDCA] enforcement suits.").

2. a. Petitioners market Vascepa, an FDA-approved drug that contains eicosapentaenoic acid, a type of Omega-3 fatty acid commonly known as EPA. Pet. App. 4. This case concerns petitioners' complaint (*id.* at 96-229) asking the Commission to "commence an investigation into the [allegedly] unlawful importation or sale" of "synthetically produced" Omega-3 fish oil products. *Id.* at 105. The complaint alleges that such Omega-3 products are "falsely labeled, and/or promoted for use as, or in[,] 'dietary supplements.'" *Ibid.* (citation omitted). Such labeling and promotion, the complaint contends, constitute "an unfair act and/or unfair method of competition under Section [1]337," because the Omega-3 products so marketed are not "'dietary supplements' but [rather] are actually unapproved 'new drugs' under the [FDCA]." *Ibid.*; see *id.* at 106 (stating that other Omega-3 products "comprised of common fish oil" are "not synthetically produced" and are permissibly marketed as "dietary supplements").

The complaint asserts two related claims for investigation. Petitioners' primary claim is that the labeling and promotion of the Omega-3 products as "dietary

supplements" violate the Lanham Act and, hence, Section 1337. Pet. App. 130-161. The complaint recognizes that a Lanham Act claim requires "a false or misleading statement of fact" about a product. *Id.* at 131. It alleges that the "[l]abeling and/or promoti[on]" of the Omega-3 products for use in, or as, "'dietary supplements'" was "literally false," because such products "cannot meet the definition of 'dietary supplement' in Section 201(ff) of the FDCA, 21 U.S.C. § 321(ff)," and "are actually unapproved 'new drugs'" under the FDCA. *Id.* at 133-134; see *id.* at 134-150 (arguing that the products do not satisfy Section 321(ff)'s requirements for "dietary supplements"); *id.* at 151-159 (arguing that the products are "drugs" under 21 U.S.C. 321(g)(1) and are unapproved "new drugs").

Petitioners' secondary claim is that the importation and sale of synthetically produced Omega-3 products "constitute unfair acts or unfair methods of competition under Section [1]337 based upon the standards set forth in the FDCA." Pet. App. 161; see *id.* at 161-165. The complaint argues that the FDCA prohibits the "introduction * * * into interstate commerce of any unapproved 'new drug,'" and that the introduction of the private respondents' products into interstate commerce "violates the standards set forth in Section 505(a) of the FDCA, [21 U.S.C. 355(a)]," because their products "are actually unapproved 'new drugs.'" *Id.* at 161. The complaint further alleges the private respondents' conduct violates other FDCA provisions as well. *Id.* at 162-165; see, *e.g.*, *id.* at 162 (asserting violation of the FDCA's prohibition against false or misleading statements in labeling and promotional materials for drugs, 21 U.S.C. 352(a) (Supp. IV 2016) and (n), because describing the Omega-3 products as "'dietary supplements'" is allegedly "false[]").

b. While petitioners' investigation request was pending, FDA submitted to the Commission a letter (Pet. App. 232-245) "request[ing] that the Commission decline to initiate the requested investigation," *id.* at 244. FDA stated that "Congress has authorized only FDA to initiate FDCA enforcement actions." *Id.* at 233. FDA also stated that, under the FDCA's "complex statutory scheme, determinations of whether a product is a dietary supplement require case-specific analysis," and that "very small differences in factors such as an ingredient's chemical structure or history of presence in the food supply can mean the difference between dietary-ingredient status and non-dietary-ingredient status." *Id.* at 235. FDA further stated that it was "in the process of developing a guidance document for industry on when a dietary supplement ingredient is [a new dietary ingredient]" that requires pre-marketing regulatory compliance, *id.* at 235-236, and was contemplating the development of "an authoritative list of pre-October 15, 1994, dietary ingredients [exempt from that requirement] based on independent and verifiable data," *id.* at 237. FDA cautioned that a "Commission finding on issues raised in [petitioners'] Complaint here could conflict" with such FDA guidance. *Ibid.*

c. The Commission declined to institute an investigation and dismissed petitioners' complaint. Pet. App. 39-42. The agency determined that petitioners' "complaint does not allege an unfair method of competition or an unfair act" that is "cognizable" under Section 1337. *Id.* at 40. The Commission stated that "the Lanham Act allegations in this case are precluded by the [FDCA]," which "the [FDA] is charged with * * * administ[ering]." *Ibid.*

3. Petitioners filed a petition for review and a separate mandamus petition in the court of appeals, which the court consolidated for its review. Pet. App. 5.

The Commission, as respondent, defended its decision not to institute an investigation. The Commission explained that "[petitioners'] claims are entirely predicated on a violation of the FDCA"; that "Congress [has] expressly and exclusively assigned to the FDA" the authority to "interpret[] and appl[y]" the FDCA "in the first instance"; and that, "[w]ithout sufficient guidance from the FDA," petitioners' claims before the Commission were not cognizable. Commission C.A. Br. 16-17, 20. The Commission stated that petitioners would later be "free to file a new complaint" if "FDA issues sufficient guidance with respect to the accused products such that the Commission is not required to interpret the FDCA in the first instance and [petitioners'] claims are otherwise no longer precluded by the FDCA." *Id.* at 58.[1]

The United States, as amicus curiae, argued that the United States' exclusive authority to "enforce[], or to restrain violations, of [the FDCA]," 21 U.S.C. 337(a), precludes private parties from asserting a claim nominally based on another statute if, "as a necessary element" of that claim, the party must establish (and thus seek redress for) a "violation[] of the FDCA itself." U.S. Corrected C.A. Amicus Br. 7-8.

4. The court of appeals denied petitioners' petition for review and petition for mandamus. Pet. App. 1-38.

a. i. The court of appeals held that it possessed jurisdiction to review the Commission's decision not to institute a Section 1337(b) investigation. Pet. App. 6-11.

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[1] In the court of appeals, the Commission appeared through its own attorneys as authorized by 19 U.S.C. 1333(g).

The court stated that its statutory jurisdiction to review "final determinations of the [Commission] relating to unfair practices in import trade, made under section [1]337," 28 U.S.C. 1295(a)(6), requires a "final determination decision *on the merits*." Pet. App. 6-7 (citation omitted). The court concluded, however, that the Commission's decision not to investigate here was "'intrinsically'" a "'determination *on the merits*'" because that decision reflected the agency's view that petitioners' claims "were precluded by the FDCA." *Id.* at 8 (citation omitted).

ii. Petitioners contended that the Tariff Act imposes a "mandatory duty to institute an investigation in this case" by directing that the Commission "'shall investigate any alleged violation of [Section 1337].'" Pet. App. 11 (quoting 19 U.S.C. 1337(b)(1)). The court of appeals rejected that argument. *Id.* at 11-13. It read the Tariff Act to provide that "the Commission may decline to institute an investigation where a complaint fails to state a cognizable claim under [Section] [1]337." *Id.* at 13.

iii. The court of appeals upheld the Commission's determination that petitioners' Section 1337 claims were not cognizable because the FDCA precludes those claims. Pet. App. 13-21. The court thus denied petitioners' petition for review, *id.* at 22, and, to the extent petitioners continued to seek mandamus, denied mandamus relief, *id.* at 11 n.3, 22.

The court of appeals held that petitioners' Section 1337 claims ultimately rest on alleged "violations of the FDCA." Pet. App. 16-17. The court reasoned that petitioners' Lanham Act claim alleging false or misleading marketing of "products as 'dietary supplements,'" when the products allegedly are "'unapproved "new drugs" under the FDCA,'" necessarily requires "proving violations

of the FDCA." *Ibid.* (quoting petitioners' complaint). "Every allegation" supporting petitioners' separate unfair-competition claim "based on the standards set forth in the FDCA" similarly "rests on an alleged violation of the FDCA." *Id.* at 17. The court further observed that "FDA has not provided guidance as to whether the products at issue in this case should be considered 'new drugs' that require approval." *Id.* at 18-19. The court concluded that "a complainant fails to state a cognizable claim under [Section] [1]337 where that claim is based on proving violations of the FDCA and where the FDA has not taken the position that the articles at issue do, indeed, violate the FDCA." *Id.* at 19.

The court of appeals explained that its holding was consistent with *POM Wonderful*, *supra*. Pet. App. 19-20. The court observed that *POM Wonderful* did not involve a Lanham Act claim that "require[d] proving a violation of the FDCA." *Id.* at 20. The court viewed this Court's decision as holding only that regulation of a particular product under the FDCA does "not categorically preclude a Lanham Act claim based on [that] product." *Ibid.* The court explained that *POM Wonderful* does not address the distinct question whether a claim "based solely on alleged violations of the FDCA's requirements" would be precluded. *Ibid.*

The court of appeals observed that its "limited holding" concerning Section 1337 claims based solely on violations of the FDCA, in circumstances where FDA has not provided guidance about the status of disputed products, was "consistent with the Commission's arguments" that such "claims are precluded *at least* until the FDA has provided guidance as to whether the products at issue are dietary supplements." Pet. App. 19. The

court stated that, although "the United States, as amicus, appears to seek a broader ruling—that all such claims are precluded *regardless* of whether the FDA has provided guidance"—the court did "not [need to] address that broader question here," because no relevant FDA guidance yet exists. *Ibid.*

b. Judge Wallach dissented. Pet. App. 22-38. Although he "agree[d] with the majority's conclusion that the [Commission] did not err in declining to institute an investigation," he would have ruled for the Commission under a different jurisdictional "approach." *Id.* at 23. Judge Wallach would have held that the court of appeals lacked jurisdiction over the petition for review because the Commission's decision not to investigate is not a "final determination" reviewable under 19 U.S.C. 1337(c) and 28 U.S.C. 1295(a)(6). Pet. App. 22-35. Judge Wallach concluded that the court instead possessed only mandamus jurisdiction, and he "agree[d] with the majority's conclusion that [petitioners] ha[ve] failed to demonstrate that [they are] entitled to the extraordinary relief of mandamus." *Id.* at 35, 37; see *id.* at 23, 35-37.

ARGUMENT

Petitioners challenge the court of appeals' holding that the FDCA precludes their Lanham Act claim. Pet. 22-28. Petitioners further contend that the decision below conflicts with this Court's decision in *POM Wonderful LLC* v. *Coca-Cola Co.*, 573 U.S. 102 (2014), see Pet. 22-25, and with the Second Circuit's application of *POM Wonderful* in *Church & Dwight Co.* v. *SPD Swiss Precision Diagnostics, GmbH*, 843 F.3d 48 (2016), see Pet. 28-33. The decision of the court of appeals is correct, does not conflict with *POM Wonderful* or *Church & Dwight Co.*, and does not independently warrant

review absent a relevant conflict of authority. Furthermore, this case would be a poor vehicle for review, because the court of appeals lacked jurisdiction under 19 U.S.C. 1337(c) and 28 U.S.C. 1295(a)(6) to review the Commission's refusal to institute an investigation. Although the court of appeals did possess mandamus jurisdiction, petitioners do not present their arguments through the limited lens of mandamus, which requires a "clear and indisputable" right to relief, *Cheney* v. *United States Dist. Court*, 542 U.S. 367, 381 (2004) (citation omitted).

1. Petitioners' Section 1337 claims are "based entirely on—and could not exist without—the FDCA," because each "rests on an alleged violation of the FDCA" and "requires proving violations of the FDCA." Pet. App. 17-18. The court of appeals correctly held that those claims were not cognizable under Section 1337 because the FDCA "preclude[s]" private enforcement through such purely derivative claims, at least where "FDA has not taken the position that the articles at issue do, indeed, violate the FDCA." *Id.* at 19; see *id.* at 14 (citing 21 U.S.C. 337(a)).

a. Petitioners do not dispute that their Section 1337 claims are ultimately premised on allegations that the FDCA was violated. As construed by the Commission, Section 1337's ban on "[u]nfair methods of competition and unfair acts in the importation of articles * * * into the United States" that threaten certain adverse effects on industry or commerce, 19 U.S.C. 1337(a)(1)(A), includes Lanham Act violations involving the use in commercial advertising or promotion of a word or term that "misrepresents the nature, characteristics, [or] qualities" of relevant goods, 15 U.S.C. 1125(a)(1)(B). See

pp. 2-3, *supra*. The Lanham Act misrepresentation alleged here is the purported mislabeling as "'dietary supplements'" of certain products that petitioners assert "are actually unapproved 'new drugs'" under the FDCA. Pet. App. 134, 156-160; see pp. 4-5, *supra*.

Subject to an exception that is not implicated here, however, "all * * * proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. 337(a). That provision "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [FDCA's] provisions." *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4, 352 (2001). Section 337(a) thus precludes a private party from pursuing a claim that requires proof of a "violation of FDCA requirements" and thus exists "solely by virtue of the FDCA." *Id.* at 352-353. Allowing private litigants to bring claims that are purely derivative of FDCA requirements would displace the complex scientific and administrative judgments that actions to restrain FDCA violations require, and that Congress has vested exclusively in an expert federal agency (*i.e.*, FDA) exercising its authority through the United States.

The court of appeals thus correctly held that, at least if FDA has not already determined that an FDCA violation has occurred, a derivative Section 1337 claim "based entirely" on an alleged FDCA violation is precluded. Pet. App. 18-19. The court emphasized that its "limited holding" did not resolve whether such a claim would continue to be precluded even after FDA has made that determination, because that "broader question" was not presented in this case. *Id.* at 19.

b. Petitioners do not squarely join issue with the court of appeals' rationale. Instead, they argue that the court's decision "conflicts with *POM Wonderful*," Pet. 22-25, and fails to account for the Commission's independent unfair-trade-practices authority under Section 1337, Pet. 26-28. Petitioners are wrong.

i. *POM Wonderful* did not involve a Lanham Act claim that was purely derivative of the FDCA. *POM Wonderful* instead addressed whether the FDCA precluded a traditional Lanham Act claim alleging that "misleading product descriptions" on beverage labeling had caused consumer "confusion" diminishing POM's beverage sales. *POM Wonderful*, 573 U.S. at 106, 110. That claim did not depend on any showing that the labeling violated the FDCA. See *ibid.*; *id.* at 118-119 (name of juice blend was affirmatively authorized by FDA). The Court's conclusion that "Congress did not intend the FDCA to preclude Lanham Act suits like POM's," *id.* at 121; see *id.* at 106 (addressing "suits like the one brought by POM"), thus does not speak to claims like petitioners'.

Central to the Court's decision was its conclusion that the FDCA and the Lanham Act are designed to "complement each other with respect to food and beverage labeling," so that "the FDCA and its regulations are * * * [not] a ceiling on the regulation of [that] labeling." *POM Wonderful*, 573 U.S. at 119; see *id.* at 106, 115, 118. The Court explained that "Lanham Act suits draw upon th[e] market expertise" of competitors that "manufacture or distribute products," that have "detailed knowledge regarding how consumers rely upon certain sales and marketing strategies," and whose "awareness of unfair competition practices may be far more

* * * accurate than that of agency rulemakers and regulators." *Id.* at 115 (citation omitted). The Court acknowledged that Congress intended FDA to be responsible for actions based on "the FDCA and the detailed prescriptions of its implementing regulations." *Ibid.*; see *id.* at 109 ("Private parties may not bring [FDCA] enforcement suits."); cf. 21 U.S.C. 337(b) (vesting States with some authority over adulterated food). But the Court viewed FDA's technical expertise and authority over the FDCA in the food context as addressing considerations different from those relevant to the typical Lanham Act claim before it, because FDA does not have "the same perspective or expertise in assessing market dynamics that day-to-day competitors possess." 573 U.S. at 115; cf. *id.* at 109 (noting "the less extensive role the FDA plays in the regulation of food than in the regulation of drugs").

In this case, by contrast, the court of appeals did not rely on the mere existence of FDCA regulation to preclude petitioners' claim. Unlike the claims in *POM Wonderful*, petitioners' Lanham Act claim is wholly derivative of the FDCA's distinct requirements for "'drugs'" and "'dietary supplements'" and ultimately "requires proving violations of the FDCA." Pet. App. 17-18. Rather than draw upon the Lanham Act's "complement[ary]" regulatory provisions that "impose 'different requirements and protections,'" *POM Wonderful*, 573 U.S. at 115 (citation omitted), petitioners seek to restrain a violation of the FDCA itself. See Pet. App. 20 (concluding that petitioners' claim "stands in stark contrast to" the "Lanham Act claim in *POM Wonderful*," which "did not require proving a violation of the FDCA").

ii. Petitioners argue (Pet. 26-28) that their complaint to the Commission sought to assert "separate rights"

under Section 1337 and did not seek "remedies under the FDCA." They acknowledge, however, that "the unfair trade practices" that they challenge "reflect violations of the FDCA," Pet. 27, and they do not assert any Section 1337 claim that could be proved *without* establishing an FDCA violation.

Petitioners appear to suggest that their Lanham Act claim is a freestanding claim because it relies on the Lanham Act's independent prohibition against the misleading use of terms in commerical labeling. But the only basis for their misleading-labeling claim is that the Omega-3 fish oil labeling at issue is inconsistent with the FDCA's definitions of "drug," "new drug," and "dietary supplement," 21 U.S.C. 321(g)(1), (p), and (ff). See Pet. App. 113, 133-141, 151-159 (complaint relying on those definitions). Like all of the definitions in Section 321, those definitions apply only "[f]or the purposes of [the FDCA]." 21 U.S.C. 321. Because petitioners assert a wholly derivative claim that relies solely upon alleged violations of the FDCA, in a circumstance where FDA has not found any such violation, their claim impermissibly intrudes on FDA's exclusive authority to "restrain [FDCA] violations." 21 U.S.C. 337(a).

iii. Petitioners suggest (Pet. 20) that the court of appeals' analysis "overlooks key provisions in the Tariff Act that are designed to prevent any intrusion on FDA's proper prerogatives." The provisions petitioners invoke (Pet. 21) are inapposite.

One such provision states that the Commission shall "in appropriate matters" act in "cooperation" with other federal agencies, which "shall cooperate fully with the commission for the purposes of aiding and assisting in its work." 19 U.S.C. 1334. That textual reference to "appropriate matters" involving the "[Commission']s

work" is fully consistent with the court of appeals' determination that petitioners cannot bring to the Commission matters that the FDCA reserves for FDA. Section 1337(a) is similarly unhelpful to petitioners' argument. It states that unlawful acts violating that provision, "when found by the Commission to exist[,] shall be dealt with, in addition to any other provision of law, as provided in [Section 1337]." 19 U.S.C. 1337(a)(1). That provision makes clear that the exclusion and cease-and-desist orders specified in Section 1337 supplement other statutory remedies *if* the Commission has found a violation. It does not define the circumstances in which the Commission must or should determine whether a violation has occurred.

2. a. Petitioners contend (Pet. 28-30) that the decision below conflicts with the Second Circuit's decision in *Church & Dwight Co.*, *supra*. Petitioners' reliance on *Church & Dwight Co.* is misplaced.

Church & Dwight Co. involved a Lanham Act claim that, like the claim in *POM Wonderful*, did not depend on proof of an FDCA violation. The false-advertising claim in *Church & Dwight Co.* alleged that the defendant's pregnancy test, which was the first to estimate the number of weeks that its user had been pregnant, was misleading because it communicated the number of weeks since a woman's ovulation, rather than the more standard estimate of the number of weeks "since the woman's last menstrual period." 843 F.3d at 53. Although FDA had determined that the product's labeling satisfied FDCA requirements, the court held that the Lanham Act challenge could go forward because the FDCA's labeling requirements did not displace the Lanham Act's distinct provisions governing "the capacity of the representations to mislead." *Id.* at 63. The

plaintiff therefore could attempt to prove its claim without impinging on FDA's exclusive authority "to restrain [FDCA] violations." 21 U.S.C. 337(a). Thus, like this Court in *POM Wonderful*, the Second Circuit had no occasion to address the distinct situation presented here, where a plaintiff presents a Lanham Act claim that is wholly derivative of an alleged FDCA violation.

b. Petitioners also contend (Pet. 20-21) that review is warranted because "[t]he Federal Circuit is the only court with direct appellate jurisdiction over final decisions and determinations by the Commission," such that "no further caselaw development is likely to occur," Pet. 20. But questions concerning the interplay between the Lanham Act and the FDCA—and, in particular, the question whether a Lanham Act claim can go forward if it is premised on an allegation that the defendant's labeling violates the FDCA—can arise in district court litigation and can be decided by the regional courts of appeals. If a decision in such a case produces a conflict of authority, the Court can then consider whether its review is warranted.

To the extent that petitioners contend (Pet. 22) that their assertion of a Lanham Act claim under Section 1337 of the Tariff Act separately warrants review, that contention is misplaced. Petitioners argue (*ibid.*) that their Section 1337 claim reflects a special "private right[] of action" designed to "protect domestic industry." But petitioners misapprehend the nature of the Tariff Act provisions at issue.

Unlike a traditional private right of action (like a direct Lanham Act claim) that allows a plaintiff to sue to enforce its own rights in court, the procedure that petitioners invoked is a mechanism for seeking administrative action by the Commission. 19 U.S.C. 1337(b)(1); see

19 U.S.C. 1330(d)(5) (investigation proceeds if "one-half of the number of commissioners voting agree that the investigation should be made"). The Commission may decline to exclude articles from the United States or to issue a cease-and-desist order, even when it has found a Section 1337 violation "as a result of [its] investigation," if the Commission concludes that the articles should not be excluded or the order should not issue in light of various public-policy considerations. 19 U.S.C. 1337(d)(1); see 19 U.S.C. 1337(e)(1), (f)(1) and (g)(1). And even if the Commission determines such action is warranted, the President may disapprove that determination "for policy reasons" and thus deprive the determination of any "force or effect." 19 U.S.C. 1337(j)(2).[2]

3. Even if review were otherwise warranted, this case would be a poor vehicle for the Court's consideration of the question presented. The court of appeals held that it had jurisdiction to hear petitioners' petition for review under 19 U.S.C. 1337(c) and 28 U.S.C. 1295(a)(6). See Pet. App. 6-10. As the dissenting judge below explained, however, the court lacked jurisdiction under

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[2] Petitioners appear to dispute (Pet. 6-7) the court of appeals' holding that the Commission may decline to investigate allegations in a private complaint under Section 1337 if, *inter alia*, the "complaint fails to state a cognizable claim," Pet. App. 13; see *id.* at 11-13. But "the fact that [petitioners have] discussed this issue in the text of [their] petition for certiorari does not bring it before" this Court, because "Rule 14.1(a) requires that a subsidiary question be fairly included in the *question presented* for our review." *Wood* v. *Allen*, 558 U.S. 290, 304 (2010) (quoting *Izumi Seimitsu Kogyo Kabushiki Kaisha* v. *United States Philips Corp.*, 510 U.S. 27, 31 n.5 (1993) (per curiam)). The only question on which petitioners seek review is the logically distinct question whether a litigant asserts a cognizable Lanham Act claim under Section 1337 when that claim depends on an alleged FDCA violation. Pet. i.

those provisions, and it was authorized to consider only petitioners' separate petition for mandamus. See *id.* at 23-37 (Wallach, J.) (agreeing that the Commission "did not err in declining to institute an investigation," but finding that review is limited to mandamus).

a. The Federal Circuit possesses jurisdiction to review a "final determination of the Commission under [Section 1337](d), (e), (f), or (g)," using standards for judicial review set forth in the Administrative Procedure Act (APA), 5 U.S.C. 701 *et seq*. See 19 U.S.C. 1337(c); accord 28 U.S.C. 1295(a)(6) ("final determinations of the [Commission] relating to unfair practices in import trade, made under section [1]337"). But the Tariff Act makes clear that a "final determination" under Section 1337 occurs only *after* the Commission has initiated an investigation. The agency's decision not to conduct an investigation is not a reviewable "final determination."

i. Section 1337(b) directs the Commission to "establish a target date for its final determination" "within 45 days after an investigation is initiated." 19 U.S.C. 1337(b)(1). That final determination is governed by Section 1337(c), which provides that the "Commission shall determine, with respect to each investigation conducted by it under [Section 1337], whether or not there is a violation of [Section 1337]." 19 U.S.C. 1337(c) (emphasis added). If the Commission finds a violation after such investigation and decides to take action under subsections (d)-(g) of Section 1337—which authorize it to exclude articles from the United States, see 19 U.S.C. 1337(d), (e), and (g), and to order a person to cease and desist violations of Section 1337, see 19 U.S.C. 1337(f) and (g)—the Commission must then transmit its determination to the President, who may disapprove that determination and thus strip it of any "force or effect,"

19 U.S.C. 1337(j)(1)(B) and (2). If the President approves the determination or declines to disapprove it within 60 days, the Commission's determination "shall become final" "for purposes of * * * [Section 1337](c)." 19 U.S.C. 1337(j)(4). Under Section 1337(c), the Federal Circuit then has jurisdiction to review the "final determination of the Commission under [Section 1337](d), (e), (f), or (g)." 19 U.S.C. 1337(c).

Those provisions demonstrate that the "final determination" for which the Tariff Act authorizes judicial review is the Commission's determination "after an investigation is initiated," 19 U.S.C. 1337(b)(1), that the Commission must make "with respect to each investigation conducted by it," 19 U.S.C. 1337(c). In addition, Congress has authorized review only of a "final determination of the Commission under [Section 1337](d), (e), (f), or (g)," *ibid.*, and those subsections govern the Commission's consideration of an exclusion or cease-and-desist order "during" or "as a result of an investigation." 19 U.S.C. 1337(d)(1) and (e)(1); see 19 U.S.C. 1337(f)(1) (action "[i]n addition to, or in lieu of," action under Section 1337(d) and (e)); 19 U.S.C. 1337(g)(1)(B) (action after issuing "notice of investigation"). The Commission's decision not to institute an investigation thus is not a "final determination" reviewable under Section 1337.

That statutory framework is consistent with the normal "presumption that agency decisions not to institute proceedings" "for investigating possible [statutory] violations" are "unreviewable" under the APA. *Heckler* v. *Chaney*, 470 U.S. 821, 837 (1985) (emphasis omitted). The Court in *Heckler* v. *Chaney* applied that principle in holding that courts could not review FDA's refusal to take enforcement actions under the FDCA. *Id.* at 828. The Tariff Act does not suggest that the Federal Circuit

has broader authority to review the Commission's refusal to commence an investigation here.

ii. The court of appeals largely ignored the governing statutory text. See Pet. App. 6-10; cf. *id.* at 24-31 (dissenting opinion analyzing the statutory text). The court instead deemed Section 1337(c)'s use of the term "final determination" to refer to a "'final determination decision *on the merits*'" and then concluded that the Commission's decision not to initiate an investigation in this case "is 'intrinsically a final determination, i.e., a determination *on the merits*,'" because the Commission based its decision on its view that petitioners' "complaint failed to state a cognizable claim under [Section 1]337." *Id.* at 7-8 (citation omitted). As explained above, however, the Commission declined to decide whether the challenged product label violated the Lanham Act, because resolution of that issue would have required the agency to decide an FDCA question that is reserved for FDA. In any event, whether or not the Commission's refusal to commence an investigation is properly deemed a "merits" decision, it is not the sort of "final determination" for which Section 1337(c) authorizes review.

b. Because the Federal Circuit lacked appellate jurisdiction, the Court could review only the court of appeals' denial of petitioners' separate petition for mandamus. See Pet. App. 11 n.3, 22. For two reasons, review of that mandamus decision would not provide the Court a suitable opportunity to resolve the question petitioners present.

First, the court of appeals stated that petitioners had "failed to explain how [they] would satisfy the traditional mandamus requirements" reflected in *Cheney* v. *United States District Court*, *supra*, see Pet. App. 11 n.3, and the court appears to have denied mandamus as

"moot" in light of its rejection of petitioners' contentions under normal APA review, Pet. App. 22. Cf. *id.* at 35-37 (dissenting opinion concluding that mandamus standard was not met). That limited analysis makes this case a poor vehicle to resolve the mandamus question.

Second, the mandamus standard requires that petitioners establish not only error but a "clear and indisputable" right to relief. *Cheney*, 542 U.S. at 381 (citation omitted). A determination that petitioners failed to establish a clear and indisputable right to proceed before the Commission would not definitively resolve whether the Commission correctly declined to institute an investigation based on petitioners' complaint. Perhaps for that reason, petitioners do not appear to seek this Court's review of the court of appeals' denial of their mandamus petition.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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