No. 19-152

IN THE

Supreme Court of the United States

AMARIN PHARMA, INC.,
AMARIN PHARMACEUTICALS IRELAND, LTD.,
Petitioners,

v.

INTERNATIONAL TRADE COMMISSION, ET AL.,
Respondents.

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

BRIEF IN OPPOSITION FOR THE PRIVATE RESPONDENTS

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QUESTIONS PRESENTED

1. The Federal Circuit has jurisdiction to review "final determinations of the United States International Trade Commission relating to unfair practices in import trade, made under section 337 of the Tariff Act." 28 U.S.C. § 1295(a)(6). Section 337 in turn specifies that the Federal Circuit may review only "a final determination" made "under subsection (d), (e), (f), or (g)." 19 U.S.C. § 1337(c). Did the Federal Circuit lack jurisdiction to review the Commission's decision under subsection (b) of § 337 not to institute an investigation into Petitioners' allegations of unfair trade practices?

2. Petitioners seek to force the Commission to institute an investigation under the Tariff Act. Their claims are premised entirely on, and seek to enjoin, alleged violations of the Food, Drug and Cosmetic Act (FDCA) that have not been recognized by the Food and Drug Administration (FDA). May the Commission decline to investigate Petitioners' claims because those claims are barred by the FDCA's prohibition (at 21 U.S.C. § 337(a)) on private suits "for the enforcement, or to restrain violations, of" the FDCA?

CORPORATE DISCLOSURE STATEMENT

Parent corporations and publicly held companies that own 10% or more of stock in Royal DSM NV:

Under the Dutch Financial Markets Supervision Act, shareholdings of 3% or more in any Dutch company must be disclosed to the Netherlands Authority for the Financial Markets (AFM). According to the register kept by the AFM, the following shareholders had disclosed that they have a direct or indirect (potential) interest between 3% and 10% in DSM's total share capital on December 31, 2018:

- ASR Nederland N.V.
- BlackRock, Inc.
- Capital Research and Management Company and Capital Group International Inc.
- NN Group N.V.
- Rabobank Nederland Participatie B.V.

Parent corporations and publicly held companies that own 10% or more of stock in DSM Marine Lipids Peru S.A.C.:

DSM Marine Lipids Peru S.A.C. is a subsidiary of Royal DSM N.V.

Parent corporations and publicly held companies that own 10% or more of stock in DSM Nutritional Products, LLC:

DSM Nutritional Products, LLC, is a subsidiary of Royal DSM N.V.

Parent corporations and publicly held companies that own 10% or more of stock in DSM Nutritional Products Canada, Inc.:

DSM Nutritional Products Canada, Inc., is a subsidiary of Royal DSM N.V.

Parent corporations and publicly held companies that own 10% or more of stock in Pharmavite LLC:

Pharmavite LLC is 100% owned by Otsuka America, Inc., a Delaware company. Otsuka America, Inc. is 100% owned by Otsuka Pharmaceutical Co., Ltd., which is 100% owned by Otsuka Holdings Co., Ltd. Otsuka Holdings Co., Ltd., is a publicly traded company.

Parent corporations and publicly held companies that own 10% or more of stock in Nordic Naturals, Inc.:

There are no parent corporations or publicly held companies that own 10% or more of stock in Nordic Naturals, Inc.

Parent corporations and publicly held companies that own 10% or more of stock in Nordic Pharma, Inc.:

Nordic Pharma, Inc., is a subsidiary of Nordic Naturals, Inc.

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INTRODUCTION

The petition should be denied for the simple reason that the Court of Appeals lacked jurisdiction over Petitioners' (Amarin's) question presented. Congress granted the Federal Circuit jurisdiction to review a Commission decision only when it is a "final determination" made "under subsection (d), (e), (f), or (g)" of 19 U.S.C. § 1337—determinations that all *follow* the Commission's decision to institute an investigation. *See* 28 U.S.C. § 1295(a)(6). The decision not to investigate—the decision the Commission made here—is made under subsection (b) and necessarily *before* the investigation. Accordingly, under the plain language of the statute, the Court of Appeals lacked jurisdiction over Amarin's appeal—and, for this reason alone, the petition should be denied.

Beyond that, Amarin attacks a fictional opinion. Amarin criticizes an opinion that supposedly precludes any unfair competition claim concerning any "products subject to regulation under the FDCA." Pet. 1. And it chides the Court of Appeals for purportedly leaving the entire domestic industry of FDA-regulated products—which apparently accounts "for more than $2.5 trillion in consumption" or "20 cents of every dollar spent by consumers in the United States"—wholly "unprotected by the Tariff Act." Pet. 1, 34.

The decision below, however, does no such thing. To the contrary, the Court of Appeals declined to "address [any] broader question" and rendered only the "limited holding" that "a complainant fails to state a cognizable claim" under the Tariff Act when "th[e]

claim is based on proving violations of the FDCA" and "the FDA has not taken the position that the articles at issue do, indeed, violate the FDCA." Pet. App. 19.

On the Court of Appeals' actual holding, there is no division of authority. But there could be: Although Amarin's petition comes from the Federal Circuit, other circuits could be asked to decide whether the Commission must investigate claims like Amarin's—i.e., ones that are premised on alleged violations of the FDCA that the FDA has not recognized. Nor is there any division over whether and when the FDCA precludes Lanham Act claims more generally: Amarin has not pointed to any appellate decision that diverges from the decision below and allows a private plaintiff to litigate Lanham Act claims premised on unrecognized violations of the FDCA.

The decision below is correct on the merits. Amarin asks this Court to create a private right of action under the FDCA. But that statute provides that "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)—a directive that "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with" the FDCA, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Because Amarin's claims are predicated on violations of the FDCA, the Court of Appeals correctly determined that the FDCA precluded them and the Commission had no obligation to investigate them.

Finally, the question presented is of little practical importance. First, cases like Amarin's almost

never arise (Amarin cites just one other instance), so the question presented is unlikely to affect any other parties. Second, the decision below may soon cease to matter, even to Amarin: The FDA—the expert agency charged by Congress with enforcing the FDCA—is poised to decide if Respondents' products violate the FDCA.[1] Third, nothing about the decision below—an ordinary exercise of statutory interpretation—unsettles the separation of powers.

The petition should be denied.

STATEMENT

1. The FDCA makes it unlawful to market or sell "new drugs" without approval from the FDA. *See* 21 U.S.C. §§ 331(d), 355. The FDA is responsible for deciding whether products are drugs, which require approval, or instead "dietary supplements," which do not. *See id.* §§ 321(ff), 350b, 355. That decision "implicates complex chemical and pharmacological considerations," *Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645, 654 (1973), and the "determination of technical and scientific questions by experts," *CIBA Corp. v. Weinberger*, 412 U.S. 640, 644 (1973). The FDA is also responsible for "taking appropriate action on the marketing of regulated products" to ensure that such products are "properly labeled." 21 U.S.C. § 393(b).

[1] "Respondents" for purposes of this brief are the intervenors from the Federal Circuit: Royal DSM NV, DSM Marine Lipids Peru S.A.C., DSM Nutritional Products LLC, DSM Nutritional Products Canada, Inc., Pharmavite LLC, Nordic Naturals, Inc., and Nordic Pharma, Inc.

Among the FDA's powers: issuing import alerts to detain violative products at the U.S. border. *Id.* § 381(a); Pet. App. 239 n.6 (FDA letter).

2. Amarin and Respondents import and market synthetic omega-3 fish-oil products. Amarin's products are FDA-approved drugs. Respondents' products are dietary supplements Amarin asserts are actually new drugs that have been mislabeled and marketed in violation of the FDCA. Pet. App. 133, 151.

Amarin, however, cannot sue Respondents under the FDCA because Congress has prohibited private parties from bringing proceedings to "enforce[] or to restrain violations[] of" the FDCA. 21 U.S.C. § 337(a). As this Court explained in *Buckman Co. v. Plaintiffs' Legal Committee*, "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with" the FDCA. 531 U.S. 341, 349 n.4 (2001); *see* Pet. 36 (Amarin conceding that it "has no ability to force the FDA to enforce the FDCA").

Although private parties cannot enforce the FDCA, they may petition the FDA to determine if a product is a dietary supplement or a drug. *See* 21 C.F.R. §§ 10.25, 10.30. Amarin did not do that. The FDA, however, is currently considering a citizen petition (by a non-party) asking the FDA to officially confirm that the types of omega-3 fatty acids in Respondents' products are dietary supplements. *See* Med. Research Collaborative LLC, Citizen Petition, Docket No. FDA-2019-P-3266-0001 (July 8, 2019), https://tinyurl.com/y2o859mf. Amarin has filed an

eight-part response. *See* Amarin Pharma, Inc., Comment, Docket No. FDA-2019-P-3266-0006 (July 26, 2019), https://tinyurl.com/y22k5uag.

Instead of asking the FDA to act, Amarin went to the International Trade Commission. The Commission is authorized under § 337 of the Tariff Act to investigate and remedy certain trade violations. *See* 19 U.S.C. § 1337. The Commission's enforcement agenda is focused primarily on intellectual property protections—patents, in particular. *Id.* § 1337(a)(1)(B)-(E). But the Commission may remedy other "[u]nfair methods of competition and unfair acts in the importation of articles" that threaten to "destroy or substantially injure" the U.S. industry. *Id.* § 1337(a)(1)(A)(i). The Commission considers unfair trade practices to include false advertising under the Lanham Act, 15 U.S.C. § 1125(a)(1). *See, e.g.*, Initial Determination, *In re Certain Insulated Sec. Chests*, USITC Inv. No. 337-TA-244, 1987 WL 451338, at *2 (June 17, 1986).

Like other agencies, the Commission has broad enforcement discretion. That starts with its authority to "determine … whether an investigation should be instituted on the basis of the complaint." 19 C.F.R. § 210.10(a)(1); *see id.* § 210.10(c) (The Commission may "determine[] not to institute an investigation."); *see also* 19 U.S.C. § 1330(d)(5) (An investigation shall occur if "one-half of the number of commissioners voting agree that the investigation should be made"). "[W]hen" the Commission has "found" an unfair act—that is, after it investigates a complaint and determines there is a violation—the Commission can impose its trade-specific remedies "in addition" to other

remedies available under law. 19 U.S.C. § 1337(a)(1). That determination does not become "final" until it is submitted to the President for review and the President does not disapprove the determination. *Id.* § 1337(j)(4).

3. Amarin asked the Commission to investigate its claims against Respondents, to find an unfair trade practice, and to bar Respondents from importing and selling their products in the United States. Pet. App. 227-28.

There is no dispute that Amarin's claims were predicated on violations of the FDCA. Its complaint expressly alleges that Respondents have committed unfair trade practices and methods of competition under § 337 of the Tariff Act by "falsely label[ing] and/or promot[ing] for use" their omega-3 fish oil products as "dietary supplements" when they "are actually unapproved 'new drugs' under the Federal Food, Drug and Cosmetic Act." Pet. App. 105. Because Respondents categorize their products as dietary supplements, not new drugs, Amarin claims Respondents' products "violate … the Lanham Act … and the standards established by the FDCA." Pet. App. 105. Notably, Amarin has conceded that "[i]t is true, of course, that the unfair trade practices that Amarin seeks to remedy also reflect violations of the FDCA that FDA has not targeted with enforcement action." Pet. 27. That includes Amarin's Lanham Act claim. *See* Pet. 28.

Because the FDA had not yet weighed in, Amarin devoted large swaths of its 133-page complaint (Pet. App. 96-228) to arguing that Respondents' products contain chemical structures and molecular forms that

render them unapproved new drugs rather than dietary supplements. Amarin argued, for instance, that a "dietary supplement" must contain a "dietary ingredient," but that Respondents' products contained "re-esterified" forms of omega-3 fatty acids (e.g., "rTG-EPA") that "are not common in conventional food in the United States" and so are not "'dietary ingredients' under … Section 201(ff)(1) of the FDCA." Pet. App. 110, 135, 140; *see, e.g.*, *id.* at 113 (alleging that Respondents' "labeling and/or promoting [of] these products as 'dietary supplements' is false because E-OM3, E-EPA, rTG-OM3, and rTG-EPA [(various molecular forms)] do not meet the definition of 'dietary supplement' in the FDCA, 21 U.S.C. § 321(ff), and these products are actually unapproved 'new drugs' under the FDCA.").

At the request of the Commission, the FDA submitted a letter in response to Amarin's complaint, urging the Commission not to investigate. *See* Pet. App. 232; 19 U.S.C. § 1334 (requiring consultation between the Commission and other agencies "in appropriate matters"). The FDA explained that Amarin's claims "depend" on asserted violations of the FDCA, but the FDA has exclusive authority to enforce that statute. Pet. App. 243. Amarin, in other words, "attempt[s] an unlawful private FDCA enforcement action." Pet. App. 233. The FDA also noted that it has not yet determined whether Respondents' products are dietary supplements or drugs. *Id.* That determination is "complex" and "case-specific" and turns on "small differences in factors such as an ingredient's chemical structure or history of presence in the food supply." Pet. App. 235. And it implicates "open ques-

tions of law and policy" about which the FDA is actively taking comments and developing guidance. Pet. App. 233, 236.

Citing regulations that give the Commission discretion to institute investigations, the Commission declined to investigate Amarin's claims and dismissed the complaint. Pet. App. 39-40. It concluded that Amarin failed to "allege an unfair method of competition or an unfair act cognizable under" the Tariff Act because its claims were "precluded by" the FDCA. Pet. App. 40.

4. Amarin then filed a petition for review in the Federal Circuit. It also filed a petition for mandamus and preemptively asked the court to "direct[] the parties to address any issues relating to appellate jurisdiction in their briefs." Ct. App. Dkt. No. 8, at 2.

The Federal Circuit's jurisdiction over Commission decisions is limited to "final determinations … relating to unfair practices in import trade, made under section 337 of the Tariff Act." 28 U.S.C. § 1295(a)(6). Section 337 in turn specifies that the Federal Circuit may review only a "final determination" made "under subsection (d), (e), (f), or (g)" of § 337. 19 U.S.C. § 1337(c). Those subsections cover determinations made *after* an investigation (subsections (d) and (f)), *during* an investigation (subsection (e)), and upon a default *following* notice of an investigation (subsection (g)). *Id.* § 1337(c)-(g). Because the Commission's decision not to institute an investigation was made (by definition) *before* any investigation occurs—and indeed, is not governed by subsections (d)-(g), but rather subsection (b)—the Commission and

Respondents urged the court to dismiss the appeal for lack of jurisdiction. Respondents further contended that the court lacked mandamus jurisdiction for similar reasons.[2]

The court (over Judge Wallach's dissent) held that it had appellate jurisdiction. It described Respondents' focus on the statutory text as "rigid" and concluded that the Commission's decision not to open an investigation was "intrinsically a final determination" because it was a "determination on the merits." Pet. App. 7 (quoting *Amgen, Inc. v. ITC*, 902 F.2d 1532, 1535 (Fed. Cir. 1990)).

On the merits, the court rejected Amarin's argument that the Commission had a mandatory, non-discretionary duty to investigate its complaint. The court expressly reserved the question "whether the Commission has discretion *generally* not to institute an investigation" because it was clear the Commission "may decline to institute an investigation where a complaint fails to state a cognizable claim under § 337." Pet. App. 13.

The court concluded (unanimously) that the complaint failed to state a claim because Amarin's "allegations are based entirely on violations of the FDCA" and "claims based on such allegations are precluded by the FDCA, at least where the FDA has not yet provided guidance as to whether violations of the FDCA

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[2] The United States appeared as amicus in the Federal Circuit. Although it did not take a position on the jurisdictional issue, it agreed with the Commission and Respondents on the merits that Amarin's claims were precluded by the FDCA.

have occurred." Pet. App. 13; *see* Pet. App. 23 (Wallach, J., dissenting) ("I agree with the majority's conclusion that the ITC did not err in declining to institute an investigation into the complaint under [19 U.S.C.] § 1337 brought by Appellants-Petitioners ...."). That conclusion followed from the relevant statutory text and this Court's precedent, including *Buckman* and *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014). *E.g.*, Pet. App. 14. And it accorded with decisions of the Third, Eighth, and Ninth Circuits. Pet. App. 14-16, 18-19.

The court stressed that its holding was "limited." Pet. App. 19. Because the FDA had not weighed in, the court "s[aw] no need to go further" and address the "broader question" whether *all* claims predicated on FDCA violations are precluded "*regardless* of whether the FDA has provided guidance." *Id.* Instead, the court held that "Amarin's claims are precluded *at least* until the FDA has provided guidance as to whether the products at issue are dietary supplements." *Id.*

Judge Wallach dissented. He agreed with the majority's preclusion conclusion but would have dismissed Amarin's appeal for lack of jurisdiction. Pet. App. 23. As to the latter, he explained that Congress did not include decisions not to investigate among the § 337 determinations it expressly authorized the Federal Circuit to review. That stood in stark contrast to Congress's decision "elsewhere in the Tariff Act" to authorize appellate review of other "administrative decisions not to institute an investigation." Pet. App. 29-30 (citing 19 U.S.C. § 1516a(a)(1)). Judge Wallach also found that the majority's conclusion was at odds

with other aspects of the statutory text and the legislative history. Pet. App. 30-31. He thus determined that review in the Federal Circuit was available only via mandamus petition but agreed with the majority that Amarin was not entitled to the "extraordinary relief of mandamus." Pet. App. 37; *see* Pet. App. 11 n.3 (majority op.) ("Amarin has failed to explain how it would satisfy the traditional mandamus requirements.").

Amarin did not request rehearing.

REASONS FOR DENYING CERTIORARI

Amarin's petition should be denied because the Court of Appeals lacked jurisdiction.

Beyond that, each of Amarin's reasons for granting review rests on a fundamental misunderstanding of the decision below. Amarin asserts that the Court of Appeals broadly held that any claim involving a product regulated by the FDA or touching on a term that appears in the FDCA is precluded. Pet. 1, 19-20, 31-32. The Court of Appeals' "limited holding" said no such thing. Pet. App. 19. Rather, the court held only that a private party cannot force the Commission to investigate a claim that a competitor has violated the FDCA when the FDA itself has not recognized such a violation, no matter how that party dresses up its claim. Pet. App. 13, 19.

That modest holding does not warrant this Court's review. First, although the question presented (unlike in the typical Federal Circuit case) can arise in other circuits, Amarin identifies no court of

appeals that would allow its claims to go forward. Second, the decision below is correct, as it flows directly from the FDCA's plain text and this Court's precedents, *Buckman* and *POM Wonderful*. Third, the question presented has few practical consequences, as cases like this hardly ever arise.

This Court should deny certiorari.

I. The Federal Circuit Lacked Jurisdiction.

Even if the Court were inclined to address Amarin's question presented, it could not: The Court of Appeals lacked jurisdiction, and this Court therefore cannot reach the merits.

1. "Federal courts are not courts of general jurisdiction; they have only the power that is authorized by Article III of the Constitution and the statutes enacted by Congress pursuant thereto." *Bender v. Williamsport Area Sch. Dist.*, 475 U.S. 534, 541 (1986). Here, Congress deliberately declined to grant the Federal Circuit jurisdiction over the Commission's decision not to investigate a complaint.

a. Congress granted the Federal Circuit jurisdiction over only "final determinations" of the Commission made "under subsection (d), (e), (f), or (g)"—determinations that all *presuppose* an investigation. 19 U.S.C. § 1337(c); 28 U.S.C. § 1295(a)(6). The Commission's decision not to investigate, by contrast, is made under subsection (b). *See* 19 U.S.C. § 1337(b). And it is one that, by definition, cannot follow or occur during an investigation. Were there any doubt, sub-

section (b) itself confirms that a decision is a "final determination" only if it is made "after an investigation is initiated."[3] "In the context of the statute's precisely drawn provisions, th[e] omission" of non-investigation decisions from the Federal Circuit's jurisdiction "provides persuasive evidence that Congress deliberately intended to foreclose further review of such claims." *United States v. Erika, Inc.*, 456 U.S. 201, 208 (1982).

b. That omission is all the more striking because the Tariff Act expressly authorizes appellate review of *other* decisions not to investigate. *See KP Permanent Make-Up, Inc. v. Lasting Impression I, Inc.*, 543 U.S. 111, 118 (2004) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."). Congress, for instance, has permitted an interested party to seek review in the Court of International Trade of a decision of the Secretary of Commerce "not to initiate an investigation" involving countervailing duties and antidumping proceedings. 19 U.S.C. § 1516a(a)(1)(A); *see* 28 U.S.C. § 1581(c).

That is not all. As Judge Wallach explained, several other aspects of the statutory context, including

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[3] What is more, other statutory provisions make clear when an investigation has begun—it is after the commissioners vote to institute an investigation, 19 U.S.C. § 1330(d)(5), and is marked by the publication of a notice of investigation, 19 C.F.R. § 210.10(b)(1). Neither of those events occurred here, confirming that the Commission's decision was made before (not during or following) any investigation.

the legislative history, further confirm the absence of appellate jurisdiction. *See* Pet. App. 28-31.

c. The majority below reached the contrary conclusion by dismissing Respondents' focus on the statutory text as too "rigid." Pet. App. 7, 10. It reasoned that, although the Commission's decision did not fall "under subsection (d), (e), (f), or (g)," the court nonetheless had jurisdiction because the Commission's decision was "intrinsically a final determination on the merits." Pet. App. 8-10 & n.2. But Congress means what it says, and courts "must enforce plain and unambiguous statutory language according to its terms." *Hardt v. Reliance Standard Life Ins. Co.*, 560 U.S. 242, 251 (2010). And by going beyond the statute's plain text (and the other clear indicia of Congress's intent), the majority "fail[ed] to give due respect to Congress's choice to limit [its] appellate jurisdiction." Pet. App. 23 (Wallach, J., dissenting).

In any event, the Commission's decision was not *on the merits*. After all, the Commission did not decide whether Respondents' products violated the FDCA. Nor was the decision *final*: As the Commission itself explained, if circumstances changed—i.e., the FDA concluded there was a violation—Amarin could return to the Commission and seek to have its claims investigated. *See* Pet. App. 19 (quoting Commission's C.A. Br. 58 stating that "Amarin is free to file a new complaint once the FDA issues sufficient guidance"); Pet. App. 34 (Wallach, J., dissenting) (same).

2. The Court of Appeals did not have mandamus jurisdiction, either. Mandamus jurisdiction is availa-

ble under the All Writs Act only as "necessary or appropriate in aid" of the court's appellate jurisdiction. 28 U.S.C. § 1651(a). But Congress deliberately chose not to grant the Court of Appeals appellate jurisdiction over cases like this one, and the court cannot use mandamus to circumvent that limit. Additionally, as the decision below found, Amarin "failed to explain how it would satisfy the traditional mandamus requirements." Pet. App. 11 n.3.[4]

3. Because the Court of Appeals lacked jurisdiction, this Court cannot reach the merits. *See Adarand Constructors, Inc. v. Mineta*, 534 U.S. 103, 110 (2001) (dismissing writ as improvidently granted where appellate court lacked jurisdiction over question pressed); *Swint v. Chambers Cty. Comm'n*, 514 U.S. 35, 37-38 (1995) (declining to address merits question because court of appeals lacked jurisdiction). At the very least, the Court would have to answer this jurisdictional question before it could decide Amarin's question presented. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 95 (1998).

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[4] Amarin suggested below that the mandamus jurisdiction could be created by a supposed "mandatory duty" on the part of the Commission to investigate any complaint presented to it. *See* Pet. App. 11. But that argument fails in light of 19 C.F.R. § 210.10, which provides that the Commission has authority to "determine … whether an investigation should be instituted on the basis of [a] complaint," and thus contemplates that the Commission may "determine[] not to institute an investigation." *See also* 49 Fed. Reg. 46,123, 46,124 (Nov. 23, 1984) (explaining that this language reflects the Commission's "discretion in the area of institution" of investigations); *infra* pp. 28-29.

II. The Lower Courts Are Not Divided.

Amarin contends that this case warrants review both because it raises an issue unique to the Federal Circuit such that "no further development of the caselaw is likely to occur," and because the circuits are divided over the broader issue of when the FDCA precludes Lanham Act claims. Pet. 18; *see* Pet. 1-2. Amarin is wrong about both.

A. The question presented could be considered by other courts of appeals, but has not been yet.

Amarin correctly acknowledges that there is no division in the lower courts as to whether a Lanham Act claim brought under the Tariff Act is precluded when it is premised on a novel FDCA violation. But Amarin is wrong to say that "no further development of the caselaw is likely to occur." Pet. 18; *see* Pet. 19-21.

The Federal Circuit in this case was the first appellate court to answer that question. But it may not be the last. The next competitor that wants the Commission to investigate an FDCA violation could avoid the Federal Circuit and bring a district court action under the Administrative Procedure Act (APA) to "compel agency action unlawfully withheld." 5 U.S.C. § 706(1); *see* 28 U.S.C. § 1361. The dissenting judge suggested this possibility, without pushback from the majority. Pet. App. 37-38 n.8 (Wallach, J., dissenting) ("Amarin may be able to raise an APA challenge in district court."). The district court could then decide

whether, for such a claim, the Commission is obligated to investigate—or instead, whether it is precluded from investigating or may otherwise decline to investigate. And an appeal to the regional circuit court, such as the D.C. Circuit, would follow.

In other words, the question presented does not lie exclusively in the Federal Circuit's jurisdiction. (Indeed, it does not lie within that court's jurisdiction *at all*. *See supra* § I.) Amarin does not disagree, contending just that the Federal Circuit "is the only court with *direct* appellate jurisdiction over final" Commission decisions—an implicit acknowledgment that other courts of appeals could review appeals from collateral challenges under the APA. Pet. 20 (emphasis added).

If the question presented is as recurring as Amarin claims, then the Court should "follow [its] ordinary practice of denying petitions insofar as they raise legal issues that have not been considered by additional Courts of Appeals." *Box v. Planned Parenthood of Ind. & Ky., Inc.*, 139 S. Ct. 1780, 1782 (2019) (citing S. Ct. R. 10). And if the question is idiosyncratic, then denying the petition is appropriate for that reason alone. *See infra* § IV.A.1.

B. There is no broader division in the courts of appeals.

Amarin is also wrong that there is "larger confusion and divisions among the lower courts" about whether and when the FDCA precludes Lanham Act claims predicated on FDCA violations. Pet. 2.

a. Amarin's various articulations of the division in the lower courts reflect its mischaracterization of the decision below. Amarin asserts that the courts "have divided over how to apply *POM Wonderful* when a Lanham Act claim requires applying the meaning of terms defined in the [FDCA]," Pet. i, "whether claims under the Lanham Act are cognizable when they require considering the meaning of terms defined in the FDCA," Pet. 18, and whether a Lanham Act claim is "precluded by FDA regulation," Pet. 28-29. But the decision below did not hold that claims are precluded when they include terms that also appear in the FDCA or involve products the FDA regulates. Rather, it held that Amarin's claims were precluded because they alleged *violations* of the FDCA that the FDA had not yet acknowledged. Pet. App. 13, 19.

There is no split on that score, for Amarin has not identified *any* court that allows a Lanham Act claim to proceed when it is based on a supposed FDCA violation that has not been recognized by the FDA.

b. Indeed, in holding that a claim is precluded only where it depends on an alleged violation of the FDCA not recognized by the FDA, the Federal Circuit follows every other circuit that has addressed the question, including the Third, Eighth, Ninth, and Eleventh Circuits. *See Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990) (Lanham Act claim fails where "[plaintiff's] position would require us to usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous [FDA] regulations."); *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 940 (8th Cir. 2005)

(allowing claim to proceed because it "does not require" the court "to 'determine preemptively how a federal administrative agency will interpret and enforce its own regulation'") (quoting and comparing *Sandoz*, 902 F.2d at 231); *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010) ("Because the FDCA forbids private rights of action under that statute, a private action brought under the Lanham Act may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation."); *id.* at 928-30 (identifying its approach as "consistent" with *Sandoz* and *Alpharma*); *Hi-Tech Pharm., Inc. v. HBS Int'l Corp.*, 910 F.3d 1186, 1192-93, 1199 (11th Cir. 2018) (concluding claim not precluded because the court would not have to decide whether the label violated the FDCA and citing *PhotoMedex* and *Sandoz*).

c. *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmBH*, 843 F.3d 48 (2d Cir. 2016), is the only circuit decision Amarin asserts diverges. Pet. 29-31. But that decision is perfectly consistent with the others because the plaintiff there never claimed that the supposedly misleading label violated the FDCA—much less premised its claim on such an alleged violation—and it was clear that resolving the case would not "require[] the Court to interpret, apply, or enforce the FDCA, the FDA's regulations, or the [FDA's] Clearance Letter." *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH,* No. 14 CIV. 00585 AJN, 2014 WL 2526965, at *11 (S.D.N.Y. June 3, 2014); *id.* (Plaintiff's "claim is independent of the FDCA and FDA regulations and would exist even in their absence"). Said otherwise, *Church* did not even

present the question considered by the decision below—whether a Lanham Act claim premised on an alleged FDCA violation not recognized by the FDA is precluded—and so cannot create any division of authority on that issue.

Instead, the *Church* plaintiff alleged that a pregnancy test label was misleading under the Lanham Act because it used an unconventional metric to date a pregnancy. The defendant argued that the claim was precluded because the FDA had approved the label. 843 F.3d at 63. The Second Circuit rejected that argument as squarely foreclosed by *POM Wonderful*, holding that *compliance* with the FDCA does not preclude Lanham Act liability. *Id.* at 63-64; Pet. 30 (acknowledging this holding). The Second Circuit had no reason to decide whether the FDCA precludes a Lanham Act claim for *non-compliance* with the FDCA. And there is no reason to think it would answer that question differently than the other circuits have. To the contrary, the Second Circuit has recognized that an "insistence that [defendant's] products are sold without proper FDA approval suggests … that [plaintiff's] true goal is to privately enforce alleged violations of the FDCA. However, no such private right of action exists." *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) (citing 21 U.S.C. § 337(a); other citations omitted).

d. Amarin is wrong to say these cases "cannot be reconciled" (Pet. 32). A simple principle explains them: Claims are precluded when they are premised on an alleged violation of the FDCA not recognized by the FDA (here, *Sandoz*, and *PhotoMedex*) and are al-

lowed to proceed when they do not (*Church*, *Alpharma*, and *Hi-Tech*). That follows from the FDCA's text, which precludes private actions "for the enforcement, or to restrain violations, of [the FDCA]." 21 U.S.C. § 337(a). It also makes sense. When products comply with the FDCA, plaintiffs are not seeking to enforce the FDCA, and therefore do not encroach the FDA's enforcement authority or upset the uniformity of the law. By contrast, when Lanham Act claims can succeed only by proving FDCA violations, plaintiffs *are* seeking to usurp the FDA's enforcement discretion and thus *do* risk creating conflicting regulatory regimes. *See infra* § III.A.

e. Amarin is similarly incorrect to assert that the lower courts are divided "over how *POM Wonderful* applies in cases like this one." Pet. 28. The only two courts of appeals to discuss *POM Wonderful* in a case like this one—i.e., one involving a Lanham Act claim predicated on an alleged FDCA violation not recognized by the FDA—are the Federal Circuit and Eleventh Circuit. And both applied the same rule: The FDCA bars "private actions under the Lanham Act premised on [FDCA] enforcement determinations that the FDA … did not [itself] make, such as an action that would require an original determination whether a drug is 'new.'" *Hi-Tech*, 910 F.3d at 1199; *see also* Pet. App. 19. That makes sense. *POM Wonderful* held that the mere fact that FDA regulates a product—or even approves it—does not preclude a Lanham Act claim. 573 U.S. at 106, 118-19. This Court did not—and indeed, could not—allow private enforcement of claims predicated on FDCA violations (much less violations not recognized by the FDA). *See*

infra § III. That is why no court of appeals has understood *POM Wonderful* to permit a claim like Amarin's to go forward.

In short, Amarin's attempt to cast the circuits as irreconcilably divided (Pet. 32) ignores the pivotal role FDCA violations play in the analysis. *See* Pet. 30-31, 33 (omitting from its description of the Eleventh Circuit's *Hi-Tech* decision that no FDCA violation was alleged). It is only when an FDCA violation forms the basis of the claim that the plaintiff seeks to enjoin or restrain violation of the FDCA in contravention of Congress's ban on private enforcement actions. *See* 21 U.S.C. § 337(a).[5]

Because there is no lower court disagreement over any issue in this case (though there could be), the Court should deny the petition.

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[5] In the absence of a genuine circuit split, Amarin is left to argue that a handful of district courts are confused. Pet. 31-32. They are not, but in any event, it is for the courts of appeals, not this Court, to resolve any district court confusion. *See* S. Ct. R. 10. Further percolation is also warranted to allow the circuit courts to grapple with whether a *broader* preclusion rule is appropriate—one that would bar any claim predicated on a violation of the FDCA, even if the FDA has confirmed the violation. *See, e.g.*, Pet. App. 19 ("[W]e need not address that broader question"—whether all claims predicated on FDCA violations are precluded, "*regardless* of whether the FDA has provided guidance").

III. The Decision Below Is Correct And Consistent With This Court's Precedents.

A. The Court of Appeals correctly held that the Commission could decline to investigate Amarin's claims because they were predicated on unrecognized violations of the FDCA. That "limited holding," Pet. App. 19, flows directly from this Court's decision in *Buckman*. *See* Pet. App. 14. That case—which appears nowhere in Amarin's petition—held that the FDCA's prohibition on private suits, 21 U.S.C. § 337(a), bars not only actions brought under the FDCA itself, but also claims brought under other laws that seek to enforce FDCA provisions (in that case, state-law fraud claims attempting to enforce the FDCA's disclosure provisions). 531 U.S. at 353. The Court gave two reasons for that holding, each of which applies here and precludes Amarin's claims. Additionally, even if Amarin's claims are not precluded, the Commission had discretion to decline to investigate them.

1. As *Buckman* explained, the text of the FDCA "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [FDCA]." 531 U.S. at 349 n.4. Specifically, the FDCA directs that "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).

With that language, Congress did more than just decline "to grant a private right of action under the FDCA," Pet. 20; it affirmatively prohibited private actions predicated on violations of the FDCA. As this

Court recently explained, quoting a dictionary published not too long before the FDCA's enactment in 1938, "'enforce' means 'give force [or] effect to.'" *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Manning*, 136 S. Ct. 1562, 1568 (2016) (quoting 1 Webster's New International Dictionary of the English Language 725 (1927)). So an action is one for the enforcement of a statute if it "is commenced in order to give effect to a[] [statute's] requirement"—i.e., where "the claim's very success depends on" showing a violation of the statute. *Id.* at 1568, 1570. (Or, to use *Buckman*'s words, where an FDCA violation "is a critical element" of the plaintiff's claim. 531 U.S. at 353.) Similarly, a suit is one to "restrain a violation of" a statute whenever it seeks to "to prohibit or forbid" an action that allegedly violates the FDCA. *Restrain*, Oxford English Dictionary, https://tinyurl.com/y4l52v2k.

And so, per *Buckman*, a state-law fraud suit based on a violation of the FDCA is precluded because it is just as much an action to enforce and restrain violations of the FDCA as a claim brought directly under that statute. So is Amarin's complaint. For one thing, Amarin's claims seek to "enforce[]" the FDCA because they depend entirely on proving violations of the FDCA. *See* Pet. App. 17. Amarin's complaint, for instance, asks the Commission to "[f]ind that" Respondents' products "violat[e] Section 337 of the Tariff Act … in that they are sold as 'dietary supplements' … without meeting the definition of 'dietary supplement' in the FDCA." Pet. App. 227. As Amarin now concedes, "[t]o prevail on its claims, Amarin must … prove" that Respondents' products are not "dietary supplements," but instead "drug[s]," under the FDCA.

Pet. 26-27. Additionally, Amarin also attempts to "restrain violations" of the FDCA. Amarin says outright that it "seeks to remedy … violations of the FDCA." Pet. 27. And it asked the Commission to stop those violations by barring the importation of all allegedly violative articles. Pet. App. 227-28.

Amarin nevertheless insists that its claims are not brought to enforce the FDCA (it ignores the "restrain violations" language) because it does "not ask[] the Commission to grant remedies under the FDCA to protect public health and safety" or "require FDA to take any enforcement action under the FDCA." Pet. 27. This Court says otherwise: A suit seeking remedies under one statute is still "enforc[ing]" another if the suit's success turns on proving a violation of the second statute. *See Merrill Lynch*, 136 S. Ct. at 1569-70 (addressing the Securities Exchange Act). That is true even if (as in *Merrill Lynch*) the suit does not seek remedies under the second statute or attempt to compel action by the agency charged with enforcing it. *See id.*

Amarin next criticizes the Court of Appeals for "not attempt[ing] to reconcile its decision with the Tariff Act's plain text," Pet. 21, namely the requirement that other agencies "cooperate fully with the [C]ommission," 19 U.S.C. § 1334, the provision stating that the Tariff Act's remedies apply "in addition to any other provision of law," *id.* § 1337(a)(1), and the provision authorizing the President to review the Commission's determination that a violation of the Tariff Act has occurred, *id.* § 1337(j). *See* Pet. 21-22. But none of those provisions displaces the FDCA's bar on private suits. Neither the requirement that other

agencies "cooperate" with the Commission nor the grant of presidential review authority says anything about how the Tariff Act interacts with any other statute—much less upends the normal rules of preclusion. Similarly, the "in addition" provision merely indicates that "when" the Commission determines that a plaintiff has prevailed on its claim, the Tariff Act's remedies shall be "in addition" to any others. 19 U.S.C. § 1337(a)(1). That provision does not, as Amarin suggests, direct the nonsensical result that claims which would be precluded if brought in a district court are somehow un-precluded if brought in the Commission. Accordingly, nothing in the Tariff Act disturbs the normal, preclusive operation of FDCA § 337(a).[6]

2. *Buckman*'s second rationale applies here, too, precluding Amarin's claims. The Court reasoned that the private lawsuits would interfere with the FDA's ability to execute its "statutorily required judgment" to interpret and enforce the FDCA. 531 U.S. at 348-49. The FDA's regulatory tasks are already "difficult," not least because it must act carefully "to achieve a somewhat delicate balance" of "competing" "statutory objectives." *Id.* at 348-50. Allowing private parties to enforce the FDCA could "skew[]" that balance. *Id.* at 348. *Buckman*'s concurrence recognized the risk was heightened when the FDCA violation underlying the

[6] In any event, if Amarin is right that the preclusion analysis turns on these idiosyncratic features of the Tariff Act, then that is further reason not to grant its petition, for that means that a decision in this case will not resolve whatever confusion Amarin thinks exists as to the broader question (outside of the Tariff Act context) of when the FDCA precludes Lanham Act claims.

plaintiffs' claims had not been recognized by the FDA. *Id.* at 353-54 (Stevens, J., joined by Thomas, J., concurring).

Amarin's case fits *Buckman*'s bill: It usurps the FDA's statutorily prescribed duty to determine whether products are "drugs," "new drugs," and/or "dietary supplements." 21 U.S.C. §§ 350b, 355. As this Court has noted, the FDA "cannot administer the [FDCA] intelligently and rationally unless it has authority to determine what drugs are 'new drugs' under" the FDCA. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 624 (1973). That determination requires difficult judgment calls, turning on (among other things) the product's intended effect, risks, chemical components, and historical presence in the food supply. Pet. App. 235. For instance, the FDA has indicated that the dispositive feature may be a product's "active moiety"—i.e., "the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt, … or other noncovalent derivative … of the molecule, responsible for the physiological or pharmacological action." 21 C.F.R. § 316.3(b)(2). Amarin's suit, however, would snatch those judgments out of the FDA's hands and foist them upon the Commission—an agency whose expertise is "traditionally focused" on "imports which infringe U.S. patents," 5 McCarthy on Trademarks and Unfair Competition § 29:55 (5th ed. 2017).

Amarin's suit also interferes with the FDA's "flexibility" to determine the appropriate response to a suspected FDCA violation. *Buckman*, 531 U.S. at 349. Congress granted the FDA "a variety of enforcement

options": It may respond to a violation by "seeking injunctive relief" and "civil penalties;" "seizing the [violative products];" "pursuing criminal prosecutions," *id.* (citing 21 U.S.C. §§ 332-334); or issuing import alerts to detain violative products at the border, 21 U.S.C. § 381(a). A "critical component" of the FDCA's "statutory and regulatory framework" is the ability to choose among them to ensure a "measured response." *Buckman*, 531 U.S. at 349. Amarin's suit, however, would deprive the FDA of the ability to carefully select an appropriate remedy by instead having the Commission jump straight to an import ban.

Amarin says there is no problem taking those decisions away from the FDA because the Commission can "obtain guidance by consulting with FDA," per the Tariff Act. Pet. 15-16. But the provisions of the Tariff Act requiring "expeditious adjudication" and conclusion of investigations "at the earliest practical time" after initiation, 19 U.S.C. § 1337(b)(1), guarantee that the FDA could not undertake its ordinary—and important—technical review and public comment processes. C*f.* C.A. Appx. 628-29 (detailing the years of FDA deliberation over the subject matter of Amarin's complaint). In any event, "consultat[ion]" does not mean agreement or even deference. The Commission, in other words, could disregard the FDA's recommendation, leading to inter-agency conflict and disparate treatment of imported and domestically manufactured products.

3. Even if Amarin's claims were not precluded, the Court of Appeals' decision would still be correct because the Commission has discretion to decide whether it will initiate an investigation. Amarin's

question presented assumes that "[t]he Tariff Act mandates that the Commission must investigate a complaint and determine whether a violation has occurred." Pet. i. But in fact, the Commission has broad discretion to decline an investigation. 19 C.F.R. § 210.10(a)(1); *id.* § 210.10(c) (the Commission may "determine[] not to institute [such] an investigation."); *see* 19 U.S.C. § 1330(d)(5) (An investigation shall occur if "one-half of the number of commissioners voting agree that the investigation should be made"); *Certain Hydroxyprogesterone Caproate & Products Containing the Same (HPC)*, Inv. No. 337-TA-2919 (Dec. 21, 2012) (declining an investigation and citing § 210.10); *see also Heckler v. Chaney*, 470 U.S. 821 (1985). Accordingly, even if the Commission *could have* investigated Amarin's claim, it was not *required* to do so. Amarin's argument that the Commission erred in declining to investigate thus fails for this independent reason.

B. In response to all of that, Amarin contends that this Court has already held that the FDCA does not preclude *any* claims under the Lanham Act or Tariff Act—that "*POM Wonderful* rejected any suggestion that the FDCA impliedly bars causes of action that Congress has granted parties in 'complementary' statutes, such as the Lanham Act." Pet. 23.

Even Amarin, however, cannot maintain that position, admitting—just sentences after criticizing the Court of Appeals for not "begin[ning] its analysis with this Court's on-point precedent in *POM Wonderful*"—that "*POM Wonderful* did not address the specific

question presented here." Pet. 24.[7] In fact, *POM Wonderful*'s holding (like that of the decision below) is far more modest than Amarin's characterization. *POM Wonderful* merely rejected the all-or-nothing position advanced by the defendant in that case, that the FDCA categorically precludes *all* Lanham Act claims concerning products that are *regulated by* the FDCA—which would have meant no Lanham Act claim could ever be brought for unfair marketing or mislabeling of any food or beverage. *See* 573 U.S. at 116. *POM Wonderful* permitted the claims in that case to go forward because—unlike Amarin's—they neither "s[ought] to enforce … the FDCA or its regulations," nor posed any danger of "undermining an [FDA] judgment." *Id.* at 117, 120. Thus, far from retreating from *Buckman*, *POM Wonderful* reaffirmed it, stating that "[e]nforcement of the FDCA and the detailed prescriptions of its implementing regulations is largely committed to the FDA." *Id*. at 115.[8]

Amarin's complaint that the court below "provide[d] no reason why the factual circumstances here should change the mode of analysis that *POM Wonderful* requires" thus misses the mark. Pet. 24. As discussed, the Court of Appeals did just what Amarin says it did not: It noted that a key premise of *POM*

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[7] Contrary to Amarin's contention, the Court of Appeals *did* begin its preclusion analysis with *POM Wonderful*. Pet. App. 14. It also ended the analysis there. Pet. App. 19-20.

[8] The word "largely" in this quote reflects the fact that, under limited circumstances, the FDCA permits States to bring enforcement actions against certain violations. 21 U.S.C. § 337(b). That sole exception to the general rule of exclusive federal enforcement is not relevant here.

Wonderful's holding was that the Lanham Act claim in that case "did not require proving a violation of the FDCA itself." Pet. App. 20 (citing *POM Wonderful*, 573 U.S. at 117). And it explained that Amarin's claims, by contrast, were "based solely on alleged violations of the FDCA's requirements" and accordingly were not covered by *POM Wonderful*. *Id.*

IV. The Question Presented Is Not Of Broad Importance.

As with the rest of its arguments for certiorari, Amarin's assertion of importance is based on a significant distortion of the opinion below. In reality, the question resolved by the court below hardly ever arises and may soon not even continue to bar Amarin's suit. Nor does the decision below represent a threat to the separation of powers; rather, it reflects only a routine exercise of judicial statutory interpretation.

A. Amarin overstates the practical significance of the decision below.

1. Cases like this one hardly ever arise.

Amarin is wrong to claim that the Court of Appeals' decision will cause the Commission to abandon all Tariff Act investigations of all products regulated in any way by the FDCA. Pet. 19-20. As explained above, the Court of Appeals' holding is far narrower: The Commission may decline to investigate a complaint that is premised on a purported violation of the FDCA that the FDA has not recognized. Pet. App. 19.

That holding will have little practical effect, for there are almost no cases presenting those unusual circumstances. As Amarin recognized in its filings below, cases like this one—in which the Commission declined to investigate a claim because of FDCA preclusion—are few and far between. Amarin C.A. Opening Br. 41-42. Indeed, Respondents are aware of only one case other than this one in which the Commission has declined an investigation for that reason. *See HPC*, Inv. No. 337-TA-2919. Nor is there any reason to believe that this dearth is due to plaintiffs forgoing such complaints in light of the Commission's position on preclusion. After all, in the 74 years between the passage of the FDCA and the Commission's decision in *HPC*, the Commission received no other complaints alleging violations of the FDCA.

The Commission, however, has investigated complaints about products regulated by the FDA that are not alleging violations of the FDCA, further belying Amarin's assertion (at 19-20) that the Commission will leave the entire industry unprotected from unfair trade practices. *See, e.g.*, *Certain Potassium Chloride Powder Products*, Inv. No. 337-TA-1013 (July 21, 2016); *Certain Periodontal Laser Devices & Components Thereof*, Inv. No. 337-TA-1070 (Sept. 11, 2017). Indeed, even Amarin does not seriously contend that the Commission will cease Tariff Act investigations of patent-infringement claims against, say, all medical devices because they are regulated by the FDCA. And if (as Amarin claims) the decision below really did obliterate all Tariff Act protections for any FDCA-regulated product, one would expect amici to be pouring in to support Amarin's petition. It is noteworthy that not a one has stepped forward.

If the decision below is not literally a one-off, it is about as close as you can get. There is no reason to deploy this Court's limited resources to address a question that has arisen only twice.

2. The decision below may soon not matter even to Amarin.

Not only is the decision below unlikely to affect other parties, it may not even continue to matter to Amarin itself. As explained above, the decision below held only that Amarin may not force a Tariff Act investigation so long as two things are true: (1) the claim is to enforce an alleged violation of the FDCA and (2) the FDA has not decided that a violation has occurred. Indeed, both the Commission and the Court of Appeals went out of their way to state that if that second condition falls away—i.e., if "the 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"—the result may be different. Pet. App. 19 (quoting Commission's C.A. Br. 58). In other words, when the FDCA "provide[s] guidance as to whether these particular articles violate the FDCA," Amarin may be "'free to file a new complaint,'" which will not be covered by the decision below (and thus may not be precluded). Pet. App. 9 n.1, 19 (quoting Commission's C.A. Br. 58).

That may soon happen. The FDA is currently "in the process of developing a guidance document for industry on when a dietary supplement ingredient is [a new dietary ingredient (NDI)], when the manufacturer of a dietary ingredient or supplement should submit an NDI notification, the evidence needed to

document the safety of an NDI, appropriate methods for establishing the identity of an NDI, and related issues." Pet App. 236. Specifically, the FDA has already published two rounds of draft guidance documents, each of which received hundreds of public comments, including ones addressing the issues raised in Amarin's complaint. Pet. App. 236-37; *see also* Development of a List of Pre-Dietary Supplement Health and Education Act Dietary Ingredients; Public Meeting; Request for Comments, 82 Fed. Reg. 42,098 (Sept. 6, 2017). Additionally, the FDA is currently reviewing a citizen petition (along with a related filing from Amarin itself) that raises the question of whether "four 'synthetic' chemical forms of omega-3 ... can be characterized as '*dietary ingredients*' under [the FDCA]" and whether "the same substances are not excluded from the definition of 'dietary supplement.'" Amarin Pharma Inc, Comment, Part 1 at 1-2, Docket No. FDA-2019-P-3266-0006 (July 26, 2019), https://tinyurl.com/y22k5uag; *see supra* p. 5.

As soon as the FDA concludes either of those processes and issues its guidance, the decision below may no longer cover Amarin's claims. *See* Pet. App. 13 (explaining that the decision below applies only "where the FDA has not yet provided guidance as to whether violations of the FDCA have occurred"). Thus, even to these parties (and others similarly situated), the decision below could soon have little practical import.

B. This case does not raise any special or significant concerns about the separation of powers.

Contrary to Amarin's contention, certiorari is not necessary to vindicate the separation of powers and to show "respect" for Congress. Pet. 19, 22. Amarin disagrees with the appellate court's reading of the statute, but it cannot deny that interpreting and applying statutes is an appropriate and common function of federal courts, and one that rarely warrants review in the absence of a circuit split.

It may be true that "this Court has not hesitated to grant certiorari … notwithstanding [the] absence of a circuit split" when a lower court "invalidates a federal statute." Pet. 18-19 (citing *Dep't of Transp. v. Ass'n of Am. R.R.*, 134 S. Ct. 2865 (2014)). But the court below did not strike down a statute. Nor did it "extinguish[] private rights of action" Congress granted. Pet. 18. The court merely interpreted statutory language to find no such right existed, at least not in the circumstances presented here. *See* Pet. App. 14-21. In other words, the court engaged in the routine and unremarkable business of interpreting a statute and applying it to the facts. That hardly justifies this Court's intervention—especially where there is no split, little practical impact, and a serious jurisdictional defect at the threshold.

CONCLUSION

The petition for a writ of certiorari should be denied.

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