NO. _____

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 U.S. Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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July 30, 2019

QUESTION PRESENTED

The Tariff Act of 1930 grants manufacturers the right to file a complaint with the International Trade Commission alleging Lanham Act violations when an importer engages in unfair trade practices. *See* 19 U.S.C. § 1337. The Tariff Act mandates that the Commission must investigate a complaint and determine whether a violation has occurred, *id.* § 1337(b)(1), (c), requires other agencies to "cooperate fully" with the Commission, *id.* § 1334, and makes clear that the statute's remedies apply "in addition to any other provision of law," *id.* § 1337(a)(1). This Court has held that "Congress did not intend the" Food, Drug and Cosmetic Act to preclude Lanham Act claims alleging false and misleading advertising for products subject to regulation by the Food & Drug Administration. *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 119–21 (2014). But the lower courts have divided over how to apply *POM Wonderful* when a Lanham Act claim requires applying the meaning of terms defined in the Food, Drug and Cosmetic Act. And the Federal Circuit has now held that, in those circumstances, manufacturers are precluded from exercising their rights under the Tariff Act.

The question presented is:

When a manufacturer files a Lanham Act claim under the Tariff Act for competitive injuries caused by unfair trade practices, is the claim barred as a matter of law when the International Trade Commission would need to consider the meaning of terms used in the Food, Drug and Cosmetic Act in order to determine whether the claim has merit?

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

Petitioners in this Court, petitioner-appellants below, are Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

Respondents in this Court, respondent-appellee and intervenors below, are the United States International Trade Commission, 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.

Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. are wholly owned by Amarin Corporation plc., a publicly held corporation. No other publicly held corporation owns 10% or more of the stock of Amarin Pharma, Inc. or Amarin Pharmaceuticals Ireland Ltd.

STATEMENT OF RELATED PROCEEDINGS

– *Amarin Pharma, Inc., et al v. International Trade Commission*, No. 2018-1247 (Fed. Cir.) (opinion and judgment issued May 1, 2019; mandate issued June 24, 2019).

There are no other proceedings in any state and federal trial and appellate courts that are directly related to this case.

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PETITION FOR CERTIORARI

This case offers the Court an opportunity to restore the private rights of action that Congress granted parties under the Tariff Act of 1930 in order to protect domestic industry from unfair trade practices. In its decision below, the Federal Circuit extinguished those rights for large segments of the market. It concluded that the rights of action granted by Congress under the Tariff Act are displaced when investigating and determining a claim would require the International Trade Commission to consider the meaning of terms defined under the Food, Drug and Cosmetic Act ("FDCA"). According to the Federal Circuit, unless and until the Food & Drug Administration ("FDA") exercises discretion to take action under the FDCA against mislabeled and deceptively advertised products, parties are precluded from exercising their rights under the Tariff Act. Because products subject to regulation under the FDCA account for more than $2.5 trillion in consumption—20 cents of every dollar spent by consumers in the United States—the potential impact of the Federal Circuit's decision is enormous, with entire industries left unable to access the trade remedies that Congress intended.

The Federal Circuit's decision cannot be reconciled with the Tariff Act's plain text. It also conflicts with the reasoning and logic of this Court's decision in *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 119–21 (2014). Moreover, because the Federal Circuit has exclusive jurisdiction over appeals from the Commission, its decision represents the final say on the meaning of the

Tariff Act and the availability of the right of action that Congress created. There is no likelihood of further case development and, therefore, no reason this Court should delay granting review.

Beyond the Federal Circuit's serious errors, its decision reflects larger confusion and divisions among the lower courts over the proper interpretation of *POM Wonderful* in cases where adjudicating a Lanham Act claim requires considering the meaning of provisions in the FDCA. By granting certiorari, this Court can provide much-needed guidance on these recurring issues. It can also use this opportunity to clarify an important principle of administrative law—agencies do not have general dispensation and suspension powers. A failure by FDA to enforce the FDCA's requirements is not an affirmative judgment that authorizes companies to engage in unfair trade practices or extinguishes statutory rights of action that Congress has granted under other statutes.

OPINIONS BELOW

The opinion of the court of appeals, reproduced at App. 1–38, is reported at 923 F.3d 959.

The decision of the International Trade Commission, reproduced at App. 39–42, is unreported.

JURISDICTION

The Federal Circuit rendered its decision on May 1, 2019. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The relevant provisions of the Lanham Act, 15 U.S.C. § 1125; the Tariff Act, 19 U.S.C. §§ 1334 and 1337; and the Food, Drug and Cosmetic Act, 21 U.S.C. § 321, are reproduced in the appendix. *See* App. 43–54, 55–73, 74–95.

STATEMENT OF THE CASE

Section 337 of the Tariff Act directs the International Trade Commission to protect the nation's businesses from unfair trade practices by investigating and determining the merits of any complaint alleging that unfair acts or methods of competition in the importation of articles are threatening to destroy or substantially injure a domestic industry. *See* 19 U.S.C. § 1337(a)–(c). Exercising its rights under the Tariff Act, Amarin filed a complaint with the Commission. App. 96–231. Its complaint alleges that certain companies have violated the Lanham Act and other statutory provisions by importing synthetically produced omega-3 products that are falsely labeled, unlawfully marketed, and deceptively advertised as "dietary supplements" when in fact the products are "drugs" that have not been approved for sale in the United States.

The terms "drug" and "dietary supplement" carry well-understood meanings within the market and determining the merits of Amarin's allegations should have been a routine exercise of the Commission's authority under the Tariff Act. Instead of initiating an investigation, however, the Commission concluded that Amarin's claims are

not cognizable as a matter of law, ruling that the claims are precluded by the FDCA.

The Federal Circuit affirmed that conclusion. Relying on precedent from other circuits that pre-date *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014), the Federal Circuit noted that courts have "grappled with the extent to which private parties' claims under ... the Lanham Act are limited by the FDCA." App. 14. The Federal Circuit then concluded that because Amarin's Lanham Act claims depend on the meaning of statutory terms defined in the FDCA, Amarin is precluded as a matter of law from seeking relief under the Tariff Act unless and until FDA exercises its discretion to take action to enforce the FDCA.

A. The Tariff Act

Section 337 of the Tariff Act prohibits "[u]nfair methods of competition and unfair acts in the importation of articles" when those methods or acts have the "threat or effect" of "destroy[ing] or substantially injur[ing] an industry in the United States." 19 U.S.C. § 1337(a)(1)(A)(i). Under this provision, Congress granted parties a private right of action—to have alleged violations investigated and determined on their merits by the Commission—when facing competitive harms caused by unfair trade practices.

The statute specifies that the Commission must initiate an investigation when presented with a complaint under oath and imposes strict deadlines to ensure that the Commission completes its investigation "at the earliest practicable time." *Id.* § 1337(b)(1). The statute mandates that, "with

respect to each investigation," the Commission must "determine" whether a violation has occurred and, in most circumstances, must make its determination "on the record after notice and opportunity for a hearing." *Id.* § 1337(c). When the Commission determines that a violation has occurred, the Tariff Act authorizes a trade-specific remedy not available under other statutes, requiring that the Commission "shall direct that the articles concerned" be "excluded from entry into the United States." *Id.* § 1337(d).

The Tariff Act does not define what constitutes an "unfair act" or "unfair method of competition." But it is well settled that those terms cover conduct that violates the Lanham Act's false-advertising provisions. *See* 15 U.S.C. § 1125(a); *see also* Initial Determination, *In re Certain Insulated Sec. Chests*, USITC Inv. No. 337-TA-244, 1987 WL 451338, at *2 (June 17, 1986). "The Lanham Act creates a cause of action for unfair competition through misleading advertising or labeling." *POM Wonderful*, 573 U.S. at 107. The Lanham Act imposes civil liability on any person who "uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which ... misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1).

Because domestic industries are often subject to regulation under multiple statutory schemes

overseen by different government agencies, the regulatory context in which an imported product is marketed and sold is often relevant to market expectations and whether a product is being falsely or misleadingly advertised. Commission investigations under section 337 cover a wide swathe of unfair trade practices—including patent infringement, trademark infringement, copyright infringement, misappropriation of trade secrets or trade dress, passing off, and antitrust violations—across a wide range of technological areas. *See generally* Neil Chilson, *How the FTC keeps up on technology* (Jan. 4, 2018), https://www.ftc.gov/news-events/blogs/techftc/2018/01/how-ftc-keeps-technology. It is therefore unsurprising that Tariff Act cases often require the Commission to investigate alleged unfair trade practices that might also constitute violations of other provisions of law enforced by other federal and state government agencies. Congress nonetheless structured the Tariff Act's provisions to make clear that, with certain express exceptions not at issue here, the Commission's obligations would not vary depending on regulatory authority granted to other agencies.

The Tariff Act states in mandatory terms that "[t]he Commission *shall* investigate any alleged violation of" section 337 "on complaint under oath," 19 U.S.C. § 1337(b)(1) (emphasis added), and "*shall* determine, with respect to each investigation …, whether or not" a violation has occurred, *id.* § 1337(c); *see also Kingdomware Techns., Inc. v. United States*, 136 S. Ct. 1969, 1977 (2016) (the word "shall" "imposes a mandatory duty"). Those unambiguous directives, which stand in marked

contrast to other provisions in section 337 that use permissive language, *see, e.g.*, 19 U.S.C. § 1337(b)(3) (describing circumstances in which "the Commission may suspend its investigation"); *id.* § 1337(f) (granting the Commission discretion to issue cease and desist orders), leave no general discretion for the Commission to decline to investigate and determine the merits of complaints alleging unfair trade practices. Instead, the statute makes clear that unfair acts and methods of competition "are unlawful, and when found by the Commission to exist *shall* be dealt with, *in addition to any other provision of law*." 19 U.S.C. § 1337(a)(1) (emphases added).

When presented with a complaint, the Commission may decline to investigate the merits only in narrowly defined circumstances. Congress has expressly directed, for example, that the Commission shall not investigate alleged violations that are within the purview of the antidumping laws under 19 U.S.C. § 1673. *See id.* § 1337(b)(3). The Commission is also entitled to dismiss a complaint when its claims are based on allegations that are "wholly insubstantial and frivolous." *Amgen, Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1537 (Fed. Cir. 1990).

Because the Commission's obligations to deal with unfair trade practices might overlap with the work of other government agencies, the Tariff Act includes specific provisions requiring other agencies to assist the Commission in its work. The statute provides that the Commission "shall in appropriate matters act in conjunction and cooperation with ... any other department ... of the

Government." 19 U.S.C. § 1334. The statute also states that, during each investigation, the Commission "shall consult with, and seek advice and information from, the Department of Health and Human Services," which includes FDA, as well as "such other departments and agencies as it considers appropriate." *Id.* § 1337(b)(2). Congress recognized, however, that other agencies might not always be eager to cooperate and, as a result, it chose *not* to leave that decision to the agencies themselves. Instead, the statute mandates that other "departments ... shall cooperate fully with the [C]ommission for the purposes of aiding and assisting in its work …." *Id.* § 1334. Under these provisions, the Commission has developed memorandums of understanding with many agencies to help the Commission "develop cases as well as advance other agencies' missions." Chilson, *supra*.

In circumstances where a Commission decision might ultimately conflict with the prerogatives of another agency under some other statute, Congress established a process to address interagency conflict *after* the Commission completes an investigation. All Commission decisions finding a violation of section 337 are submitted to the President for review. 19 U.S.C. § 1337(j)(1). The President may disapprove of any Commission decision for "policy reasons," draining the decision of force or effect. *Id.* § 1337(j)(2).

B. The Food, Drug and Cosmetic Act

Congress's grant of authority to the Commission under the Tariff Act to protect

domestic industry from competitive injuries is distinct from its grant of authority to FDA under the FDCA to protect and promote public health. With a much different focus, the FDCA grants FDA authority to regulate the nation's food supply, over-the-counter drugs, prescription medications, vaccines, medical devices, cosmetic products, tobacco products, and blood and tissue products. *See* 21 U.S.C. § 393. FDA's reach underscores the significance of the issues raised in this petition: FDA is responsible for overseeing products that account for approximately 20 cents of every dollar spent by consumers in the United States (more than $2.5 trillion in consumption). *See* FDA, Fact Sheet: FDA at a Glance (Aug. 2018), https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance.

As relevant here, the FDCA includes provisions that address when a product qualifies as a "drug" as opposed to a "dietary supplement." 21 U.S.C. §§ 321(f), (g), (ff). A product is a drug if, among other things, it is "intended to affect the structure or any function of the body of man or other animals," or if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." *Id.* § 321(g)(1)(B), (C). A drug is a "new drug" if it is "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested" in its labeling. *Id.* § 321(p)(1). Unless approved by FDA, new drugs

may not be marketed or sold in interstate commerce. *See id.* §§ 331(d), 355.

In contrast, products meeting the definition of dietary supplements are types of "food," not drugs. 21 U.S.C. §§ 321(f), (ff). Consistent with the term's common meaning, a dietary supplement is a product that is intended to supplement the diet and includes one or more dietary ingredients. *See id.* § 321(ff)(1). Under the statute, "dietary ingredients" include (A) vitamins, (B) minerals, (C) herbs or botanicals, (D) amino acids, (E) dietary substances for use by man to supplement the diet by increasing total dietary intake, and (F) "a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)." *See id.* Because they are a type of food (not drugs), dietary supplements may be marketed and sold without undertaking the extensive investments in clinical trials required to obtain FDA approval.

It is well established and understood that "synthetic" substances derived from natural substances that qualify as "dietary ingredients" under subsections 201(ff)(1)(C), (E), and (F) of the FDCA, or synthetic copies of such natural substances, are not themselves "dietary ingredients" unless they were commonly or customarily used in the conventional food supply and in compliance with law. That conclusion follows from the long-recognized distinction between drugs and dietary supplements. For close to 20 years, FDA has acknowledged and explained in draft guidance, in court cases, in citizen-petition responses, in Federal Register notices, in warning

letters, in response to new dietary ingredient notifications, and when providing advice to other federal agencies that, with a rare exception that does not apply here, the FDCA excludes synthetic substances from the definition of "dietary ingredient" and, therefore, those substances cannot be marketed as "dietary supplements." App. 133.

While the law is clear as to what substances do and do not qualify as dietary ingredients, FDA has often failed to take enforcement action even when it is clear that a product is mislabeled. As this Court has recognized, however, there is "'powerful evidence that Congress did not intend FDA oversight to be the exclusive means' of ensuring proper food and beverage labeling." *POM Wonderful*, 573 U.S. at 114 (quoting *Wyeth v. Levine*, 555 U.S. 555, 563 (2009)). In fact, because of the sheer scope of its regulatory mission, FDA has never had the resources to police the proper labeling and advertising of every product available to consumers subject to regulation under the FDCA. Accordingly, although the FDCA does not itself include a private right of action, nothing in the FDCA bars parties from pursuing private rights of action granted under other statutes.

Congress's concerns often extend beyond FDA's mission of protecting public health and safety. *See* 21 U.S.C. § 393(b). Congress has therefore enacted other statutes to protect other important policy objectives, including statutes to protect domestic industry from unfair trade practices. As this Court has concluded, if parties were unable to exercise their rights under these other statutes, merely because the consumer products they use are also

subject to regulation under the FDCA, there would be fewer protections for FDA-regulated products than other products. That would make no sense. *See POM Wonderful*, 573 U.S. at 116 (it is "unlikely that Congress intended the FDCA's protection of health and safety to result in less policing of misleading food and beverage labels than in competitive markets for other products"). FDA has no expertise in protecting industry from unfair trade practices, and there is no indication that Congress intended to anoint FDA a super-regulator to which all other agencies must defer.

That conclusion is particularly compelling in the context of dietary supplements. FDA does not pre-classify products as drugs or dietary supplements, and it does not preapprove the distribution of or labeling for dietary supplements. *See* 21 U.S.C. §§ 343(r)(6)(B), (C). Instead, manufacturers are required to interpret and apply the statutory definitions of "drug" and "dietary supplement" to determine for themselves whether a product qualifies as a drug or a dietary supplement. Nor did Congress grant FDA a monopoly over how the FDCA's terms are interpreted and applied. Actions to enforce the FDCA are brought in district court in the name of the United States by prosecutors. In that enforcement context, it is the trial courts, not FDA, that must interpret and apply the statutory definitions to determine whether a product is or is not mislabeled.

C. Procedural History

Amarin markets Vascepa®, a prescription drug that is synthetically derived from fish oil, with the

active ingredient consisting of 1 gram of eicosapentaenoic acid (the omega-3 acid commonly known as "EPA"). Amarin has invested more than $500 million to develop this innovative product, including undertaking extensive clinical trials to support FDA-approved and planned uses of Vascepa® in the United States. Vascepa® has been hailed as a rare medical breakthrough. Studies have demonstrated that the drug decreases triglyceride blood levels without raising bad cholesterol and reduces the risk of cardiovascular events, like cardiovascular death, heart attack, and stroke.

Unfortunately, there are large quantities of similar synthetic products derived from fish oil that meet the definition of "new drug" that are not of the same manufacturing quality and have not been studied through clinical trials or approved by FDA as safe and effective. Although the law is clear that these products are unapproved "new drugs" that may not be marketed and sold as dietary supplements, FDA has failed to take uniform enforcement action under the FDCA. Whatever the risks to public health might be, the domestic industry faces a serious threat of substantial competitive injury as these mislabeled and deceptively advertised products flood the market.

In August 2017, Amarin filed a complaint with the Commission under section 337 of the Tariff Act seeking a remedy for unfair trade practices. App. 96–231. The complaint asserts that importers of certain synthetically produced omega-3 products are falsely labeling or deceptively advertising their products as (or for use in) "dietary supplements."

App. 133. These imported products are not "dietary supplements," as labeled and advertised; instead, they are "new drugs" that have not been approved for sale or use in the United States. App. 151–161. The complaint further alleges that these unfair acts and methods of competition violate section 43(a) of the Lanham Act, because falsely labeling or deceptively advertising unapproved drugs as dietary supplements deceives consumers and others in the supply chain about the nature of the products. 15 U.S.C. § 1125(a)(1); App. 105, 114, 118, 161, 217.

Shortly after Amarin filed its complaint, FDA submitted a letter, before the Commission instituted an investigation, urging the Commission to dismiss the complaint without considering its merits. App. 232–245. The letter did not take a position on the merits of Amarin's complaint. Instead, according to FDA, because there is no private right of action to enforce the FDCA, the Commission should not investigate Amarin's claims under the Tariff Act because the acts of false and deceptive advertising depend on applying terms that are defined under the FDCA. *See id.* FDA did not identify any provision in the FDCA that displaces the Commission's obligations under the Tariff Act. Nor did it deny that it has no obligation to police unfair trade practices, and that the Tariff Act provides specific trade remedies that are not available under the FDCA. Nonetheless, FDA asserted that it has exclusive authority over all fields of regulation when it comes to FDA-regulated products. App. 232–245. In FDA's view, because Amarin's claims "require the Commission to

directly apply, enforce, or interpret" terms that appear in the FDCA, the claims are not cognizable under the Tariff Act. App. 241.

Accepting FDA's position, the Commission dismissed Amarin's complaint, asserting that Amarin's Lanham Act allegations "are precluded" by the FDCA. App. 39–42. On appeal to the Federal Circuit, and underscoring the importance of the issues, the United States filed an amicus brief, and seven intervenors joined the case alongside two other amici.

The United States, the Commission, and the intervenors and amici advanced different views on if and when a party may take advantage of the private right of action that Congress created in the Tariff Act. The United States maintained that "private parties, like Amarin, may not initiate proceedings in a court or administrative agency" to protect "competitive interests related to violations of the FDCA." Br. of the United States as *Amicus Curiae*, at 7, No. 18-1247, Dkt. 79 (Mar. 27, 2018). In contrast, the Commission asserted that, "[w]ithout sufficient guidance from the FDA, the Commission cannot adjudicate Amarin's claims." Br. for Appellee ITC at 17, No. 18-1247, Dkt. 62 (Mar. 19, 2018). The Commission had no answer to the fact that the FDCA requires manufacturers to determine for themselves whether a product qualifies as a drug or a dietary supplement and, as a result, the law is designed to allow parties to make that determination without FDA involvement. Nor did it address the Tariff Act's provisions that require agencies, like FDA, to cooperate with the Commission and allow the

Commission to obtain guidance by consulting with FDA in the course of an investigation.

D. The Decision Below

The Federal Circuit affirmed in a 2-1 decision, concluding that "Amarin's claims are precluded *at least* until the FDA has provided guidance as to whether the products at issue are dietary supplements." App. 19 (emphasis in original). Relying on cases that predate *POM Wonderful*—in particular, the Ninth Circuit's discredited decision in *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010)—the Federal Circuit concluded that Amarin's Lanham Act claims under the Tariff Act are precluded by the FDCA as a matter of law. *Cf. ThermoLife Int'l, LLC v. Gaspari Nutrition Inc.*, 648 F. App'x 609, 612 (9th Cir. 2016) (questioning "the precedential value of the *PhotoMedex* rule after *POM Wonderful*").

The Federal Circuit did not ground its decision in any express statutory text precluding Lanham Act claims under the Tariff Act. Instead, the court reasoned that, because FDA had not announced whether in its view the imported products were mislabeled, the private rights of action that Congress granted under the Tariff Act would not be recognized unless and until FDA exercised its discretion to take enforcement action. According to the court of appeals, "Amarin's complaint may not be precluded in the future, under a different set of facts (*i.e.*, where FDA has provided guidance as to whether these particular articles violate the FDCA)." App. 9.

In concluding that the rights granted under the Tariff Act are displaced by the FDCA, the Federal Circuit attempted to distinguish *POM Wonderful*:

> Although *POM Wonderful* held that the FDCA does not categorically preclude a Lanham Act claim based on a product (*e.g.*, a label) that is regulated by the FDCA, the court did not open the door to Lanham Act claims that are based on proving FDCA violations. The allegations underlying the Lanham Act claim in *POM Wonderful* did not require proving a violation of the FDCA itself.

App. 20. The Federal Circuit did not address language in *POM Wonderful* rejecting the view that Congress's decision to deny parties a right of action under the FDCA reflects an intent to displace private rights of action granted under other federal statutes. *See POM Wonderful*, 573 U.S. at 117. It also did not address the investigative role that the Commission is supposed to perform when presented with a complaint. Nor did it identify any language in the Tariff Act, the FDCA, or any other statute suggesting that Congress intended FDA to be able to block parties from exercising their rights under the Tariff Act when faced with competitive injuries caused by unfair trade practices.

Judge Wallach dissented. He would have found jurisdiction proper under mandamus review, but he would have concluded that Amarin did not satisfy the standards for obtaining mandamus relief. *See* App. 23, 37 (Wallach, J., dissenting).

REASONS FOR GRANTING THE PETITION

The Court should grant review for three reasons. *First*, the Federal Circuit's decision extinguishes private rights of action under the Tariff Act that Congress designed to protect domestic industry from unfair trade practices. The decision conflicts with the logic and reasoning of *POM Wonderful* and, because the Federal Circuit has exclusive authority over appeals from the Commission, no further development of the caselaw is likely to occur. *Second*, the Federal Circuit's decision deepens an existing split in lower court authority over whether claims under the Lanham Act are cognizable when they require considering the meaning of terms defined in the FDCA. *Third,* granting the petition would allow this Court to address important principles of separation of powers and recurring issues of administrative law, including the Federal Circuit's conclusion that FDA's failure to take enforcement action exempts companies from other legal requirements and displaces remedies provided under other statutes that FDA does not administer.

I. The Court Should Grant Review to Restore the Private Right of Action that Congress Created Under the Tariff Act.

When a federal court of appeals decision invalidates a federal statute or adopts an interpretation that renders substantial portions inoperative, this Court has not hesitated to grant certiorari in light of the decision's obvious importance and out of respect for a coordinate branch of government. *See*, *e.g.*, *Dep't of Transp. v.*

Ass'n of Am. R.R., 134 S. Ct. 2865 (2014) (granting review when a federal statute was held unconstitutional, notwithstanding absence of a circuit split). Review is especially warranted when the question presented raises a pure legal issue, no further development in the case law is likely, and the decision conflicts with relevant decisions of this Court. *See* S. Ct. R. 10(a), (c). All of these considerations apply here.

This Court's review is warranted because the Federal Circuit's decision extinguishes a private right of action under the Tariff Act. Congress designed that statute to protect domestic industries from unfair trade practices by providing private parties with a right to have their complaints investigated and determined by the Commission. The Tariff Act requires the Commission to investigate unfair trade practices when presented with a complaint and to determine on the merits whether a violation has occurred. The statute, and the remedies it authorizes, are expressly "in addition to any other provision of law." 19 U.S.C. § 1337(a)(1). Moreover, because unfair trade practices often violate other statutory requirements overseen by other agencies, the Tariff Act includes specific provisions requiring other agencies, including FDA, to cooperate with the Commission. *See id*. §§ 1334, 1337(b)(2).

The Federal Circuit's decision eviscerates these provisions, effectively eliminating the trade-specific remedies that Congress created, for any domestic industry threatened by unfair competition as a result of imported products also subject to regulation under the FDCA. For these domestic

industries, the Federal Circuit's decision renders the Tariff Act's provisions inoperative unless and until FDA chooses to exercise its enforcement discretion and determines that the specific imported products at issue are mislabeled under the FDCA—an exercise of discretion that FDA may never decide to take. In the Federal Circuit's view, Congress's decision not to grant a private right of action under the FDCA displaces the affirmative right of action that Congress granted under the Tariff Act. App. 8–9, 18. Accordingly, although Amarin's complaint alleges that, under well-established law, the imported products do not qualify as dietary supplements, the Federal Circuit concluded that because FDA has not taken action against the specific imported products, the Commission is precluded from investigating and resolving the merits of Amarin's complaint.

In addition to extinguishing a private right of action created by Congress, the Federal Circuit's decision overlooks key provisions in the Tariff Act that are designed to prevent any intrusion on FDA's proper prerogatives. It also relies on an approach to reconciling statutory provisions that *POM Wonderful* rejected, and it misunderstands FDA's role as matter of administrative law.

First, the question presented is ripe for this Court's review and no further caselaw development is likely to occur. The Federal Circuit is the only court with direct appellate jurisdiction over final decisions and determinations by the Commission. *See* 19 U.S.C. § 1337(c). Moreover, the Commission has indicated that it intends to buckle to FDA's demand that it decline to investigate and remedy

unfair trade practices when the unfair acts or methods of competition involve mislabeling and deceptively advertising products that are also subject to regulation under the FDCA. In these circumstances, the Federal Circuit's decision is the final say on the meaning of the Tariff Act and the Commission's obligations to remedy trade violations when FDA-regulated products are involved. If this Court does not grant review, parties will be denied the right to bring claims under the Tariff Act as Congress intended, and the well-being of domestic industries threatened by unfair trade practices will depend on the exercise of FDA's enforcement discretion and priorities.

Significantly, in concluding that the FDCA precludes claims under the Tariff Act, the Federal Circuit did not attempt to reconcile its decision with the Tariff Act's plain text. Instead, the Federal Circuit's decision appears to be driven out of misguided deference to FDA and the odd notion that the rights and remedies granted under the Tariff Act must remain dormant unless and until FDA takes action under the FDCA (action that FDA has no obligation to ever take). The Federal Circuit's decision does not address the Tariff Act provisions discussed above that require other agencies, like FDA, to "cooperate fully" with the Commission. *Id.* § 1334. Nor does it address the statutory provisions making clear that the Tariff Act's remedies apply "in addition to any other provision of law." *Id.* § 1337(a)(1). Nor does it mention the Tariff Act provisions that grant the President authority to resolve potential conflicts

between the Commission's determinations and the interests of other agencies. *Id.* § 1337(j)(1).

The separation-of-power concerns are significant. The approach applied by the court of appeals is governed not by the terms of the statutes that Congress enacted but out of a misguided sense of deference to FDA. And the private rights of action that Congress designed to protect domestic industry are available not as directed in the Tariff Act but only if and when FDA chooses to exercise enforcement discretion under a separate statutory scheme. Out of respect for Congress, if these provisions are to be written out of the Tariff Act and made subservient to FDA, that decision should be made by this Court, not by the Federal Circuit. *See POM Wonderful*, 573 U.S. at 120 ("An agency may not reorder federal statutory rights without congressional authorization."); *see also Nat'l Mining Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 629 (2018) (courts are not free to "rewrite" statutes "to the Government's liking").

Second, the Federal Circuit's decision conflicts with *POM Wonderful*. This Court concluded in *POM Wonderful* that "neither the Lanham Act nor the FDCA, in express terms, forbids or limits Lanham Act claims challenging labels that are regulated by the FDCA." 573 U.S. at 113. In reaching that conclusion, the Court observed that "the Lanham Act subjects to suit any person who 'misrepresents the nature, characteristics, qualities, or geographic origin' of goods or services" and that "this comprehensive imposition of liability extends, by its own terms, to misrepresentations on labels, including food and beverage labels." *Id.*

POM Wonderful could not have been clearer that "the FDCA, by its terms, does not preclude Lanham Act suits," which means, "[i]n consequence, food and beverage labels regulated by the FDCA are not, under the terms of either statute, off limits to Lanham Act claims." *Id.*

A private party seeking relief under the Lanham Act based on labeling falsity has no obligation to obtain FDA's views as a prerequisite to filing suit even if the mislabeled products are subject to regulation under the FDCA. *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, noting that the different statutes have "separate scopes and purposes." *Id.* at 118. A straightforward application of *POM Wonderful* should have required honoring Amarin's right to bring Lanham Act claims before the Commission under the Tariff Act. If Congress had concluded that Lanham Act suits improperly interfere with the FDCA, it surely would have enacted a provision addressing the issue since the Lanham Act's passage in 1946 and the Tariff Act's passage in 1930. *Id*. at 113. Indeed, having directed that the Commission does not have authority to investigate violations within the purview of the antidumping laws, *see* 21 U.S.C. § 1337(b)(3), the only sensible inference is that Congress did not intend other unmentioned exceptions to apply. *Cf. United States v. Brockamp*, 519 U.S. 347, 352 (1997) (applying *expressio unius* principle).

One might have expected the Federal Circuit to begin its analysis with this Court's on-point precedent in *POM Wonderful*. Instead, near the end of its decision, the Federal Circuit attempts to distinguish *POM Wonderful*, noting that the Lanham Act claims in *POM Wonderful* did not depend on proving unfair acts that would also constitute violations of the FDCA. No one disputes that *POM Wonderful* did not address the specific question presented here. But the Federal Circuit provides no reason why the factual circumstances here should change the mode of analysis that *POM Wonderful* requires. After all, the lower courts are bound not only by this Court's case-specific holdings but also by the logic and reasoning of its decisions. *See Seminole Tribe of Fla. v. Fla.*, 517 U.S. 44, 67 (1996). The Federal Circuit has an obligation to faithfully apply this Court's precedents, for narrowing them improperly poses risks of "creating doctrinal fragmentation." Richard M. Re, *Narrowing Precedent in the Supreme Court*, 114 Col. L. Rev. 1861, 1910 (2014). That duty is especially important where, as here, the government attempts to resurrect arguments and positions that it has previously presented to the Court and this Court has already rejected. *See POM* Wonderful, 573 U.S. at 118–20.

Instead of faithfully applying *POM Wonderful*'s reasoning, the Federal Circuit relied heavily on the Ninth Circuit's decision in *PhotoMedex*. App. 18–19. Almost four years before *POM Wonderful*, the Ninth Circuit concluded in *PhotoMedex* that "[b]ecause 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." 601 F.3d at 924. But *POM Wonderful* repudiated that binary reasoning—rejecting the view that the possibility of FDA enforcing the FDCA precludes a lawsuit seeking different remedies under the Lanham Act. Instead, as the Court explained, the "[c]entralization of FDCA enforcement authority in the Federal Government does not indicate that Congress intended to foreclose private enforcement of other federal statutes." *POM Wonderful*, 573 U.S. at 117. That makes sense because FDA "does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess," *id.* at 115, and the "Lanham Act suits draw upon this market expertise by empowering private parties to sue competitors to protect their interests on a case-by-case basis," *id.*

That logic applies with particular force in the trade context. Congress designed the Tariff Act to allow companies to bring suit and to have their Lanham Act claims investigated and determined by the Commission when unfair trade practices are threatening a domestic industry with substantial competitive harm. *See* 19 U.S.C. § 1337(a). FDA does not have any expertise in enforcing the nation's trade laws. Nor does it have any commitment or obligation to protect domestic industry from competitive harm.

Third, the Federal Circuit's decision relies on a misconception of administrative law and is

inconsistent with the principle that regulated parties are supposed to have "fair warning about what the law demands of them." *United States v. Davis*, 139 S. Ct. 2319, 2323 (2019). The requirements for labeling products under the FDCA are not supposed to be secret, unspoken obligations that do not exist unless and until FDA affirmatively takes a position with respect to a specific product. Instead, the law imposes clear and generally applicable requirements, so that manufacturers can self-police and understand when they are required to undertake the burdensome process of having their products approved as new drugs. *See* App. 18. That is precisely the determination that Amarin was required to make when, with FDA's support, it determined that FDA approval was required before it could market and sell Vascepa®. There is no reason the Commission should not be able to determine whether other manufacturers have complied with applicable legal requirements when labeling and importing their products into the United States. The judgment that the Commission will need to make is the same judgment that manufacturers are expected to make under the law when determining whether their products qualify as drugs or dietary supplements.

If Amarin's allegations turn out to be incorrect, then the Commission will be entitled to reject Amarin's claims on their merits. To prevail on its claims, Amarin must satisfy the requirements of the Tariff Act and prove the merits of its Lanham Act claims, including showing that importers are falsely labeling and deceptively advertising their

drug products as dietary supplements. But under the Tariff Act those determinations must be made on their merits, by the Commission, and after a proper investigation. They should not be dismissed as legally non-cognizable based on the mistaken notion that, because the FDCA does not include a private right of action, the FDCA extinguishes the separate rights that Congress granted private parties under the Tariff Act unless and until FDA elects to take action to enforce the FDCA.

The Federal Circuit's suggestion that Amarin is trying to enforce the FDCA is wrong. Amarin is not asking the Commission to grant remedies under the FDCA to protect public health and safety. Nor does its complaint require FDA to take any enforcement action under the FDCA. It merely seeks the trade-specific remedies that Congress authorized under the Tariff Act for the separate and distinct purpose of protecting domestic industry from unfair trade practices.

It 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. But that does not change the Commission's obligations under the Tariff Act. Because the terms "drugs" and "dietary supplements" are defined in the FDCA, and have been addressed in regulations, guidance, and other pronouncements issued by FDA, nothing prevents the Commission from investigating the facts alleged in Amarin's complaint and applying the relevant law to determine whether imported articles are being mislabeled and deceptively advertised. That traditional investigative function

requires an understanding of the trade laws and an assessment of applicable legal requirements, not some unpublished statement of expertise held in secret by FDA that is unavailable to the Commission.

As Amarin has alleged, the law is clear as to what products do or do not qualify as dietary supplements, and manufacturers are supposed to apply that law when determining whether their products must be approved by FDA for sale in the United States. If there is any doubt, however, the Tariff Act ensures that the Commission will have the benefit of FDA's expertise, as it entitles the Commission to consult with FDA and requires FDA to cooperate with the Commission. There is accordingly no need to contort the Tariff Act in order to protect FDA's legitimate prerogatives.

II. The Federal Circuit's Decision Deepens Confusion Among the Lower Courts Over How to Apply *POM Wonderful*.

In addition to allowing the Court to restore the rights of action that Congress created in the Tariff Act, granting certiorari would also allow the Court to provide guidance to the lower courts over how *POM Wonderful* applies in cases like this one, where addressing a claim under the Lanham Act might also require considering whether the product is being labeled or advertised in violation of the FDCA. Despite the importance of this issue, the courts of appeals remain split over how to interpret and apply *POM Wonderful*.

The Second Circuit has interpreted *POM Wonderful* broadly to conclude that "a Lanham Act

claim is not precluded by FDA regulation under the FDCA because the two statutes serve distinct and complementary purposes," even if the Lanham Act claim directly conflicts with an affirmative judgment made by FDA. *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH*, 843 F.3d 48, 65 (2d Cir. 2016). In *Church & Dwight Co.*, the Second Circuit considered whether a defendant's labeling of an over-the-counter pregnancy test could be challenged under the Lanham Act as false or misleading, even though the product was cleared by FDA and the labeling mandated by the agency. The Second Circuit explained:

> We see no reason why the subjugation of Defendant's Product labeling to FDA regulation through the § 510(k) process should categorically immunize it from Lanham Act claims by competitors regarding the regulated labeling. As the *POM Wonderful* opinion noted, regardless of the fact that the FDCA and Lanham Act sometimes overlap in scope and effect, each statute nonetheless has a distinct purpose, and in carrying out its FDCA duties, the FDA is not charged with protecting the interests of its subject's competitors.

Id. at 63.

In direct conflict with the Federal Circuit's reasoning here, the Second Circuit concluded that whether FDA has taken action is not the right question after *POM Wonderful*:

> The fact that the FDA has satisfied itself that a product's labeling is sufficiently accurate to secure FDA [clearance] gives no assurance that the intervention of a competitor would not reveal problematic misleading messaging that is harmful to the competitor's interests, which the federal agency either overlooked or failed to appreciate as important.

Id.

According to the Second Circuit, it makes no difference whether FDA has taken a position—or even taken action directly contrary to the basis of a lawsuit—because "FDA approval of the accuracy of a subject's representations does not create a ceiling that bars still better protections against the capacity of the representations to mislead." *Id.* Compliance with the FDCA does not preclude liability under the Lanham Act.

In contrast, the Eleventh Circuit has concluded that a Lanham Act claim is permissible if the court does not have to interpret or apply the FDCA in determining whether a label is deceptive. *See*, *e.g.*, *Hi-Tech Pharms., Inc. v. HBS Int'l Corp.*, 910 F.3d 1186 (11th Cir. 2018). In *Hi-Tech*, the Eleventh Circuit considered whether a manufacturer could pursue a Lanham Act claim against a competitor who was allegedly misleading consumers about the quantity and source of protein in a dietary supplement. Relying on *PhotoMedex,* the court concluded that the Lanham Act claims were not barred because the claims did not require the court to interpret and apply the FDCA. In the Eleventh

Circuit's view, because the claims "would not require a court 'to interpret or apply the FDCA to determine whether or not the marketing of the supplement was deceptive,' resolving Hi-Tech's claim under the Lanham Act would not 'step on the FDCA's toes.'" *Id.* at 1199 (citation omitted)).

This split in authority—between the Second Circuit, on one hand, and the Eleventh and Federal Circuits, on the other—also extends to the district courts. "Following *POM Wonderful*, many district courts have navigated 'the tightrope between permitted and precluded Lanham Act claims.'" *Frompovicz v. Niagara Bottling, LLC*, 313 F. Supp. 3d 603, 616 (E.D. Pa. 2018) (citations omitted). In tension with the Federal Circuit's approach, many of these courts have recognized that, after *POM Wonderful*, the precedential value of *PhotoMedex* "may be limited." *JHP Pharms., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 999 (C.D. Cal. 2014); *see also ThermoLife*, 648 F. App'x at 612 (questioning "the precedential value of the *PhotoMedex* rule after *POM Wonderful*"). They have concluded that "Lanham Act claims (even with regard to FDA approval) are not, as a general matter, precluded or barred by the FDCA." 52 F. Supp. 3d at 999. "The general presumption following *POM Wonderful* ... is that Lanham Act claims with regard to FDCA-regulated products are permissible and, indeed, desirable." *Id.* at 1000; *see also Youngevity Int'l v. Smith*, No. 16-CV-704-BTM-JLB, 2019 WL 2918161, at *5 (S.D. Cal. July 5, 2019).

Many courts have rejected the view that the FDCA precludes courts from adjudicating Lanham Act claims requiring the consideration of terms

defined in the FDCA or an FDA regulation. In the Third Circuit, for instance, the Eastern District of Pennsylvania has permitted a spring-water extractor to sue competitors who allegedly labeled their drinking water as "spring water" when in fact it was only "well water." *Frompovicz*, 313 F. Supp. 3d at 607. Although the complaint alleged that the competitors had deceptively advertised their products because their water did not satisfy FDA's regulatory definition of "spring water," the court concluded that the claim was not barred under the FDCA. Noting that there was "no allegation that the FDA has made an affirmative judgment as to whether [defendants'] water falls within its definition of spring water," the court ruled that the fact that FDA had not taken action could not be used to prevent the plaintiff from exercising its rights under the Lanham Act. *Id.* at 617. Taking a different approach, district courts in the Ninth Circuit have concluded that Lanham Act claims are precluded only if they "require the expertise of the FDA to resolve," *JHP Pharms.*, 52 F. Supp. 3d at 999—in circumstances, for example, where a question "directly implicates the FDA's rulemaking authority" and turns on the content of "a drug label … preapproved by the FDA," *id.* at 998, 1004.

These divisions in lower court authority cannot be reconciled. Although most FDA-regulated products are sold and marketed nationwide, in some parts of the country, a Lanham Act claim for false and misleading advertising is not precluded even if it directly conflicts with an affirmative judgment made by FDA, *see Church & Dwight*, 843 F.3d at 65; in other parts, a Lanham Act claim is

precluded only if FDA has made an affirmative judgment with respect to the product at issue and adjudicating the claim would directly conflict with that judgment, *see Frompovicz*, 313 F. Supp. 3d at 617; and still in other parts, the Lanham Act claim is precluded even if FDA has not made an affirmative judgment but adjudicating the claim would require interpreting and applying terms defined in the FDCA, *see Hi-Tech*, 910 F.3d at 1199. By granting review, this Court can help resolve this confusion within the lower courts.

III. The Court Should Grant Review Because the Question Presented Is Recurring and Important.

This case is an ideal vehicle for considering the question presented. The administrative record on appeal is minimal because the Commission dismissed without considering the merits of Amarin's complaint. Moreover, as noted above, because the Federal Circuit is the only court with direct appellate jurisdiction over the Commission's final decisions, *see* 19 U.S.C. § 1337(c), there will be no further legal development on whether Congress intended the FDCA to preclude parties from bringing claims under the Tariff Act. Indeed, that is another reason for this Court's intervention. This Court has had few opportunities to review the scope of the Commission's jurisdiction and, as a result, the Federal Circuit has been left to define how and when the Commission operates without this Court's guidance.

The petition also implicates important U.S. trade interests. If the Federal Circuit's decision is

left uncorrected, a substantial portion of the domestic industry—responsible for manufacturing products worth billions of dollars in annual sales—will be left unprotected by the Tariff Act merely because the false and deceptively advertised products are subject to regulation under the FDCA and FDA has not taken discretionary enforcement action. Indeed, the dietary supplement industry on its own is a $40 billion industry with "more than 50,000—and possibly as many as 80,000 or even more—different products available to consumers." FDA, Statement from FDA Commissioner Scott Gottlieb, M.D. (Feb. 11, 2019). And, yet, FDA has only approximately 25 employees responsible for policing the labeling and promotion of these products. *See Jan. 19: FRONTLINE and The New York Times Investigate "Supplements and Safety,"* Frontline (Jan 11, 2016).

Because it is infeasible for FDA to take enforcement action against all products that may be evading the drug approval process, and because FDA has no expertise in protecting competitive trade interests, it is important that companies have the protections against unfair trade practices that Congress granted under the Tariff Act. Without those protections, an entire industry could be significantly harmed by unlawful trade practices that FDA has no practical ability, obligation, or commitment to address. Indeed, FDA's Center for Drug Evaluation and Research Director, Janet Woodcock, M.D., has made clear that FDA is unlikely to take enforcement action against companies committing violations that FDA does not view as threatening public health, directing the

companies to "duke it out" among themselves. Derrick Gingery, *Advertising Enforcement: US FDA to Let Competitors 'Duke it Out', Woodcock Says*, Pink Sheet (Sept. 23, 2018).

More broadly, this case raises important issues of administrative and constitutional law. It is well established that there is no executive authority of dispensation or suspension—no power for an agency to free individuals or groups of individuals from the obligations of law. *See* 5 U.S.C. §§ 551(8), 553(d)(1) (requiring agencies to undertake rulemaking when granting a "license" exempting a party from generally applicable requirements of law). Nonetheless, agencies are often tempted to speak out of both sides of their mouth—interpreting statutory requirements to prohibit certain conduct and then selectively allowing large-scale violations to occur. *See OSG Bulk Ships, Inc. v. United States*, 132 F.3d 808, 811–12 (D.C. Cir. 1998) (discussing difference between general policy of refusing to enforce a provision of substantive law and a "*single-shot* non-enforcement decision" (citation omitted)). Sometimes the failure to enforce is a result of limited resources and case-by-case non-enforcement determinations that are not subject to judicial review. *See Heckler v. Chaney*, 470 U.S. 821 (1985). But it also can be a way for an agency to avoid accountability and can result in significant commercial inequities.

The Tariff Act offers an elegant solution to these concerns. By requiring FDA to cooperate with the Commission, the Tariff Act provides private parties with a remedy for unfair trade practices regardless of whether and when FDA

might decide to exercise its enforcement authority under the FDCA against particular products. Acting responsibly, Amarin followed the law when undertaking the significant investments and clinical studies required to have Vascepa® approved by FDA so it can lawfully market and sell Vascepa® in the United States. Several of its competitors have not complied and instead have falsely labeled and deceptively advertised their products as dietary supplements. In these circumstances, Amarin has no ability to force FDA to enforce the FDCA. But it does have the ability to obtain the more limited trade remedies that Congress provided under the Tariff Act to protect domestic industry from competitive harm—an injunction preventing the products from being sold in the United States when unfair acts or methods of competition are threatening substantial injury to a domestic industry. *See* 19 U.S.C. § 1337(d).

Properly interpreted, the statutory scheme avoids any intrusion on FDA's prerogatives. In the course of the investigative process called for under the Tariff Act, FDA is entitled to express its views on how the law should be applied to the facts as it understands them. But what it cannot do is what the Federal Circuit has allowed: put itself in a blocking position so that its failure to enforce to has the effect of suspending other requirements of law. Put differently, while FDA is entitled to provide guidance to the Commission on whether Amarin's claims should succeed on their merits, it cannot prevent the Commission from investigating the merits based on the view that FDA's failure to enforce the FDCA to protect public health

extinguishes private parties' separate rights to pursue remedies under the Tariff Act to address competitive trade injuries. *Cf. Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 67 (D.D.C. 1998) ("In asserting that any and all scientific claims about the safety, effectiveness, … and the like regarding prescription drugs are presumptively untruthful or misleading until the FDA has had the opportunity to evaluate them, FDA exaggerates its overall place in the universe."). Where, as here, the FDCA imposes requirements on domestic industry, foreign competitors should not be allowed to skirt those requirements when doing so results in unfair trade. *See* Bryan A. Liang, *A Dose of Reality: Promoting Access to Pharms.*, 8 Wake Forest Intell. Prop. L.J. 301, 355, 368 (2008) (noting that FDA often declines to enforce "requirements on foreign entities"). At the very least, those issues should be decided on their merits by the Commission with input from FDA through the carefully structured process that the Tariff Act provides.

The Federal Circuit's decision disrupts the statutory scheme that Congress created to protect domestic industry from unfair trade practices. And it renders rights of action that Congress provided under the Tariff Act hostage to FDA's enforcement priorities under the FDCA. This affront to principles of administrative law and separation of powers should not be allowed to stand. The Court can and should grant review.

CONCLUSION

The Court should grant the petition.

Respectfully submitted,

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July 30, 2019