Nos. 2018-1247, 2018-114

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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

Appellants,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

ROYAL DSM NV, et al.,

Intervenors.

On Appeal from the United States International Trade Commission, No. 3247.
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BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING APPELLEE

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In re AMARIN PHARMA, INC., and
AMARIN PHARMACEUTICALS IRELAND LTD.,

Petitioners,

On Petition for Writ of Mandamus to the
United States International Trade Commission

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INTEREST OF THE UNITED STATES

This case presents the question whether private parties may seek to enforce the Federal Food, Drug, and Cosmetic Act (FDCA) through a private proceeding like the complaint that Amarin brought before the International Trade Commission. The United States submits this amicus brief to protect its interest in the proper resolution of that question. *See* 28 U.S.C. § 517; Fed. R. App. P. 29(a)(2).

"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. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Private parties are expressly prohibited from bringing "proceedings for the enforcement, or to restrain violations, of" the FDCA. 21 U.S.C. § 337(a). Yet that is precisely what Amarin seeks to do here. Amarin's claims, though nominally brought under the Tariff Act, attempt to enforce or restrain violations of the FDCA because they seek—as a necessary component of the stated cause of action—to prove FDCA violations and compel obedience to the FDCA through the remedies provided by that statute. For that reason, the International Trade Commission correctly concluded that Amarin's claims are precluded by the FDCA. The United States takes no position on the other issues in this case.

STATEMENT OF THE CASE

A. FDA Regulation of Drugs and Dietary Supplements

1. The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, authorizes the Food and Drug Administration (FDA) to regulate, among other things, drugs and dietary supplements. Determining whether an article is a "drug" or a "dietary supplement" under the FDCA can involve difficult and complex analysis. In general, the term "drug" includes "articles (other than food)" that are "intended to affect the structure or any function of the body of man or other animals," as well as "articles 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 "dietary supplement" is a product that, among other factors, contains a "dietary ingredient[]," which includes, among other things, a vitamin, mineral, herb, or "a dietary substance for use by man to supplement the diet by increasing the total dietary intake." *Id.* § 321(ff)(1).

These general definitions are further refined by other provisions of the FDCA. For example, a "dietary supplement" that otherwise might meet the definition of a "drug" is "not a drug * * * solely because" the label contains certain types of health-related claims. 21 U.S.C. § 321(g)(1). And the term "dietary supplement" excludes "an article authorized for investigation as a new drug," where the investigation has been instituted and made public, unless before such authorization the article was "marketed as a dietary supplement or as a food." *Id.* § 321(ff)(3)(B)(ii).

The FDCA treats "drugs" and "dietary supplements" differently. Unless a drug is "generally recognized" as "safe and effective for use under the conditions prescribed, recommended, or suggested" in its labeling, it is classified as a "new drug." 21 U.S.C. § 321(p)(1). And the FDCA prohibits introducing a new drug into interstate commerce before it has been approved by FDA. *Id.* §§ 331(d), 355. To obtain pre-market approval, the drug sponsor has the burden of proving that a new drug is safe and effective for its intended use. *See Wyeth v. Levine*, 555 U.S. 555, 567 (2009). A sponsor that introduces a new drug into interstate commerce without complying with this requirement is subject to a variety of FDA enforcement measures, including criminal penalties (21 U.S.C. § 333), injunctive relief (*id.* § 332), forfeiture (*id.* § 334(a)(1)), and—most relevant here—exclusion of the drug from importation into the United States (*id.* § 381(a)(3)).

By contrast, "dietary supplements" do not require or receive pre-market approval for safety and efficacy. If FDA determines that a dietary supplement is "adulterated" food—because, for example, it "presents a significant or unreasonable risk of illness or injury," 21 U.S.C. § 342(f)(1)(A)—the manufacturer may be subject to the same range of FDCA enforcement measures applicable to new drugs.

2. "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. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Congress gave the Secretary of Health and Human Services and FDA the authority to execute the

requirements of the FDCA. *See* 21 U.S.C. §§ 355, 393. And Congress prohibited private parties from bringing actions to enforce the FDCA: "[A]ll * * * proceedings for the enforcement, or to restrain violations, of this chapter shall be *by and in the name of the United States*." *Id.* § 337(a) (emphasis added).

B. The International Trade Commission

The Tariff Act of 1930 prohibits "[u]nfair methods of competition and unfair acts in the importation of articles" into the United States, where such 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). Private parties may submit claims under this provision to the International Trade Commission for adjudication. If the Commission finds a violation, it "shall direct that the articles concerned" be "excluded from entry into the United States." *Id.* § 1337(d).

The Tariff Act does not fully define what constitutes an "unfair act" or "unfair method of competition." Through adjudication, the Commission has interpreted those terms to include conduct violating the false-advertising provisions of the Lanham Act, 15 U.S.C. § 1125(a). *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). The Lanham Act prohibits using in commercial advertising any "term" that "misrepresents the nature, characteristics, [or] qualities" of goods. 15 U.S.C. § 1125(a)(1)(B).

C. Factual Background and Proceedings Below

1. Amarin obtained approval from FDA to market a new drug to treat severe hypertriglyceridemia. Appx9, Appx14-15. The drug consists of capsules of an ethyl ester form of eicosapentaenoic acid that is synthetically produced from fish oils. Appx9, Appx11, Appx14-15. Amarin alleges that other manufacturers also synthetically derive eicosapentaenoic acid (and close relatives) and import articles "predominantly comprised" of those ingredients into the United States. Appx9. Those manufacturers allegedly label and market those articles as "dietary supplements," and also allegedly market them as suitable for treating various diseases. Appx9, Appx11, Appx14-15, Appx17-18.

Amarin filed a complaint with the International Trade Commission, seeking to exclude these articles from the United States under the Tariff Act. Appx4-114. The complaint alleged that the accused articles do not qualify as "dietary supplements" under the FDCA and instead constitute "new drugs," for which the manufacturers should have, but did not, obtain FDA approval of their safety and efficacy prior to marketing them in the United States, as required by the FDCA. Appx16.

Based on these allegations, Amarin presented two legal claims to the Commission. In one claim, Amarin contended that the importation of the articles violates the Tariff Act "based on the standards set forth in the FDCA." Appx56; *see* Appx56-59. In other words, Amarin alleged that the articles were marketed in violation of the FDCA, and that importation of articles marketed in violation of the

FDCA is an "unfair act" for that reason. In the other claim, Amarin argued that labeling the articles as "dietary supplements" is an "unfair act" in violation of the Tariff Act because it constitutes false advertising under the Lanham Act. Appx16; *see* Appx31-56. Amarin reasoned that labeling the articles as "dietary supplements" is "literally false" because the articles do not qualify as "dietary supplements" under the FDCA, and it also "hides the material fact that the products are actually unapproved 'new drugs.'" Appx55.

2. FDA submitted a letter to the Commission asking it to dismiss the complaint. FDA noted that it had not determined whether the articles were drugs or dietary supplements. Appx627. FDA explained that Congress gave FDA enforcement authority over the FDCA and prohibited private parties from bringing proceedings to enforce the FDCA. Appx630. And, FDA explained, the complaint that Amarin filed with the Commission "attempt[s] an unlawful private FDCA enforcement action." Appx627. Amarin's claims "all depend on the allegation that the products at issue are falsely labeled as 'dietary supplements' because they do not meet the FDCA definition of 'dietary supplements' and instead meet the FDCA definition of 'new drugs.'" Appx631. Accordingly, FDA concluded, "in order to resolve any of [Amarin's] claims, the Commission will necessarily have to step into the shoes of the FDA," but "the FDCA precludes such action." Appx632.

3. The Commission dismissed the complaint. The Commission held that "Amarin's complaint does not allege an unfair method of competition or an unfair act cognizable under" the Tariff Act. Appx1. The Commission explained that "the Lanham Act allegations in this case are precluded by the Food, Drug and Cosmetic Act," and that "the Food and Drug Administration is charged with the administration of the FDCA." *Id.*

SUMMARY OF ARGUMENT

A. The International Trade Commission correctly held that the Federal Food, Drug, and Cosmetic Act precludes Amarin's complaint. The FDCA prohibits private proceedings "for the enforcement, or to restrain violations, of" that statute. 21 U.S.C. § 337(a). The FDCA instead commits enforcement exclusively to the federal government to ensure that complex enforcement decisions are made with the benefit of FDA's scientific and regulatory expertise. As a consequence, private parties, like Amarin, may not initiate proceedings in a court or administrative agency to remedy alleged violations of the FDCA. Nor can private parties circumvent that prohibition by wrapping their FDCA enforcement claims inside some *other* cause of action. The FDCA prohibits "all" private proceedings to enforce or restrain violations of the FDCA, *id.*, including private claims that are nominally brought under another statute but seek to prove violations of the FDCA and compel obedience to that statute—as the courts of appeals have consistently concluded.

B. Amarin's arguments to the contrary are without merit. To be sure, private parties may bring suit to remedy violations of statutes that create private causes of action, so long as those suits are *not* attempts to enforce the FDCA. That is why, for example, false advertising about the content of fruit juice can be remedied in a private action under the Lanham Act, where the claim does not seek to prove or remedy a violation of the FDCA's juice-labeling provisions but instead rests on allegations entirely independent of the FDCA. *See POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014). Nor does the FDCA preempt claims brought under state law that seek to prove and remedy violations of state statutes parallel to but independent of the FDCA. *See Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (Fed. Cir. 2013). But where a private party, like Amarin, seeks to prove and remedy violations of the FDCA itself, as a necessary element of its stated cause of action, its claims are precluded by the FDCA's prohibition on private enforcement proceedings.

ARGUMENT

THE FEDERAL FOOD, DRUG, AND COSMETIC ACT PRECLUDES PRIVATE ENFORCEMENT PROCEEDINGS LIKE AMARIN'S.

A. Amarin's Claims Are Private Attempts to Enforce the FDCA, and Are Therefore Prohibited.

1. "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. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Congress gave the Secretary of Health and Human Services and FDA the authority to execute the

requirements of the FDCA. *See* 21 U.S.C. §§ 355, 393. And Congress expressly provided that "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be *by and in the name of the United States*"—not private parties. *Id.* § 337(a) (emphasis added); *see* H.R. Rep. No. 2139, at 5 (April 14, 1938).

The only exception to this rule is that "[a] State may bring in its own name and within its jurisdiction proceedings for the civil enforcement" of specific provisions of the FDCA related to food. 21 U.S.C. § 337(b). In narrowly drawing that lone exception, Congress underscored that, otherwise, only the United States may bring "proceedings for the enforcement, or to restrain violations, of" the FDCA. *Id.* § 337(a); *see Ventas, Inc. v. United States*, 381 F.3d 1156, 1161 (Fed. Cir. 2004) ("[T]he maxim *expressio unius est exclusio alterius* presumes that [enumerated exceptions] are the only exceptions Congress intended."). For that reason, this Court has correctly noted that, outside this single exception, "[t]he FDA—and the FDA alone—has the power and the discretion to enforce the FDCA." *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1359 (Fed. Cir. 2013).

Centralizing FDCA enforcement authority within FDA ensures that FDA's expertise will inform often-difficult factual and legal determinations, such as which requirements apply to particular articles and whether an article is being distributed in violation of the FDCA. *See* Appellee Br. 27-37 (illustrating the technical issues that would arise in adjudicating Amarin's claims). It also ensures that discretionary determinations—like whether enforcement measures should be pursued for a

violation, and if so, which remedies are appropriate—will be made by policymakers, not private parties. And it promotes uniformity. Private parties, of course, must reach their own determinations about what the FDCA requires in the first instance, and courts may need to determine if the FDCA has been violated when the federal government brings FDCA enforcement proceedings. But Congress deliberately chose to centralize within FDA the crucial decision whether to seek to prove and redress alleged violations of the FDCA. Doing so maximizes the benefits of centralized enforcement. *Cf. Heckler v. Chaney*, 470 U.S. 821, 832 (1985) (discussing those benefits).

2. The FDCA's prohibition on private "proceedings for the enforcement, or to restrain violations, of" the Act, 21 U.S.C. § 337(a), means that private parties may not bring suit under the FDCA itself to remedy what they allege to be violations of the Act. It also means that private parties may not circumvent this straightforward prohibition by invoking some *other* cause of action, under another federal statute, in order to bring what is, at bottom, still an action "for the enforcement" or "to restrain violations" of the FDCA. *See Buckman*, 531 U.S. at 353 (preempting state fraud claims that "exist solely by virtue of the FDCA").

A proceeding "for the enforcement" of the FDCA is one that seeks "[t]o give force or effect" and "compel obedience to" the FDCA. *Black's Law Dictionary* (10th ed. 2014) (defining "to enforce"). Similarly, a proceeding to "restrain violations" of the FDCA seeks to prove and redress such violations. In order to give meaningful

effect to Congress's mandate that "*all*" such proceedings to enforce or restrain violations of the FDCA "shall be by and in the name of the United States," 21 U.S.C. § 337(a) (emphasis added), the FDCA precludes those private proceedings that rely on alleged violations of the FDCA as a necessary component of their cause of action and that seek to redress or restrain those FDCA violations. That is particularly clear where the private proceeding seeks remedies like those available under the FDCA, such as injunctive relief, *id.* § 332, or refusal of admission of articles into the United States, *id.* § 381(a).

That conclusion is reinforced by traditional principles of statutory construction. Where "Congress has enacted a comprehensive scheme and has deliberately targeted specific problems with specific solutions," and where one such specific solution contradicts a more-general statute, the "specific provision is construed as an exception to the general one" in order to "eliminate the contradiction." *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012). Here, the FDCA is a highly reticulated regime of requirements for very specific articles—including drugs and dietary supplements—and, as part of that comprehensive scheme to solve particular problems, the FDCA prohibits private proceedings to enforce or restrain violations of the FDCA. By contrast, the Tariff Act states general requirements—no "unfair acts" in the "importation of articles"—that are applicable to a far larger universe of articles, and it creates a private cause of action to enforce those general requirements. The FDCA's careful prohibition on private enforcement proceedings cannot be fully

implemented if a private party may use the Tariff Act to enforce or restrain violations of the FDCA. Accordingly, the more-specific provisions of the FDCA control.

That conclusion is reinforced by the timeline. When Congress enacted the Tariff Act in 1930, it allowed private parties to file complaints with the Commission alleging "unfair acts" in the importation of articles and seeking to exclude those articles from the United States. *See* 46 Stat. 590, 703. The question whether private parties could use that mechanism to exclude articles alleged to violate the FDCA first arose in 1938, when the FDCA was enacted. And, at that first available opportunity, Congress made clear that its new and specific regulatory regime could not be enforced through private enforcement proceedings of any stripe. *See* 52 Stat. 1040, 1046 (prohibiting "all" private enforcement). Congress thus did not extend the Tariff Act to cover violations of the FDCA; it preferred instead to leave FDCA enforcement to the comprehensive framework it created in that more-specific statute.

The Supreme Court and this Court applied similar reasoning when limiting the scope of the Lanham Act in order to give full force to the Copyright and Patent Acts. These courts held that claims alleging false statements about the authorship of a written work, or origin of an innovation, are not cognizable under the false-advertising provision of the Lanham Act because, among other reasons, entertaining such claims under the Lanham Act would avoid the more-specific regulation of those subjects under the Copyright and Patent Acts. *See Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23, 33-35 (2003); *Baden Sports, Inc. v. Molten USA, Inc.*, 556 F.3d

1300, 1307 (Fed. Cir. 2009); *see also TianRui Grp. Co. v. Int'l Trade Comm'n*, 661 F.3d 1322, 1333 (Fed. Cir. 2011) (The Tariff Act "cannot be used to circumvent express congressional limitations on the scope of substantive U.S. patent law.").

Similarly, this Court held in *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323, 1332-33 (Fed. Cir. 2001), *superseded by statute on other grounds as recognized in Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408 (2012), that a claim nominally seeking declaratory judgment regarding non-liability for patent infringement was actually an improper attempt to privately enforce the FDCA. The plaintiff argued that it should be declared to not be liable for infringement because the defendant had violated a provision of the FDCA. *Id.* Because no cause of action existed to challenge that type of FDCA violation, this Court held that the prohibition on private FDCA enforcement proceedings precluded entertaining the plaintiff's suit under the Declaratory Judgment and Patent Acts. *Id.*

For these reasons, permitting private parties to enforce and restrain violations of the FDCA using the Tariff Act would permit what Congress prohibited. The specific provisions of the FDCA govern, and they preclude extending the provisions of the earlier and more-general Tariff Act to enforce the FDCA.

3. Both of the claims that Amarin submitted to the International Trade Commission constitute private efforts to enforce or restrain violations of the FDCA, and both are therefore precluded.

a. One of Amarin's claims contends that the Commission should exclude articles from entry into the United States because those articles allegedly violate several provisions of the FDCA. Amarin claims that the importation of the accused articles is an "unfair act," within the meaning of the Tariff Act, "*based upon the standards set forth in the FDCA*." Appx56 (emphasis added). Amarin elaborates that the accused articles are allegedly "misbranded drugs in violation of the standards set forth in Section 502 of the FDCA, [21 U.S.C.] § 352, and adulterated drugs, in violation of Section 501 of the FDCA, *id.* § 351." Appx57; *see also* Appx57-59 (alleging other violations). Amarin further contends that the introduction of these allegedly adulterated and misbranded drugs "is prohibited by Section 301(d) and (a) of the FDCA[,] [21 U.S.C.] § 331(a), (d)." Appx59. Amarin also explains that "the FDCA prohibits unapproved 'new drugs,' and adulterated and misbranded 'drugs,' from entering the United States under Section 801(a) of the FDCA, 21 U.S.C. § 381(a)," and argues that, under that provision of the FDCA, FDA "must refuse * * * admission to the United States" of unapproved, adulterated, and misbranded drugs. *Id.*

In sum, Amarin seeks to prove a series of alleged FDCA violations and to remedy those violations by excluding unapproved, adulterated, and misbranded drugs from importation into the United States. In advancing this claim, Amarin provides no reason, other than the alleged violations of the FDCA, to conclude that the importation of the accused articles constitutes an "unfair act" within the meaning of

the Tariff Act. Instead, Amarin candidly admits that this claim seeks relief "based upon the standards set forth in the FDCA." Appx56. For these reasons, Amarin's claim is a private proceeding "for the enforcement, or to restrain violations, of" the FDCA, 21 U.S.C. § 337(a), and Amarin is therefore prohibited from pursuing that claim.

b. Amarin's false-advertising claim is no different. In that claim, Amarin contends that the accused articles should be excluded from entry into the United States because labeling on, or advertisements about, those articles is allegedly false or misleading, in violation of the false-advertising provision of the Lanham Act, such that importation of those articles would constitute an "unfair act" under the Tariff Act. Appx31-56. But this claim, too, is expressly predicated on proving, and seeks remedies for, alleged violations of the FDCA.

Amarin contends that labeling on the accused articles "falsely asserts that the products are 'dietary supplements,'" where the articles "cannot meet the definition of 'dietary supplement' in Section 201(ff) of the FDCA, 21 U.S.C. § 321(ff)." Appx33. Amarin's complaint devotes over twelve pages to identifying provisions of the FDCA that govern what is and is not a "dietary supplement," alleging facts about the articles, and explaining why, in Amarin's view, the articles do not meet the FDCA's definition of "dietary supplement." Appx34-47. Amarin further alleges that the articles "are actually unapproved 'new drugs' under the FDCA," within the meaning of "Section

201(g)(1) of the FDCA," 21 U.S.C. § 321(g)(1). Appx47. The complaint devotes another eight pages to identifying the provisions of the FDCA that govern what constitutes a "drug" and a "new drug," alleging facts about the articles, and explaining why, in Amarin's view, the articles qualify as unapproved "new drugs" under the FDCA. Appx47-55. Amarin also identifies warning letters and other statements by FDA regarding what Amarin alleges are similar articles presenting similar violations of the FDCA. Appx37-38, Appx50-51.

Amarin relies on these alleged FDCA violations to establish the central element of Amarin's false-advertising claim. Appx55-56. The Lanham Act makes it unlawful to use in commercial advertising any "term" that "misrepresents the nature, characteristics, [or] qualities" of goods. 15 U.S.C. § 1125(a)(1)(B). Amarin's only argument for why the accused articles' labeling is false or misleading is that it is "literally false" to call the articles "dietary supplements" when they allegedly do not meet the FDCA's definition of that term and instead are unapproved "new drugs." Appx55. Amarin provides no reason, other than these alleged FDCA violations, to conclude that the labeling or advertising makes a false or misleading statement. Amarin also relies on these alleged FDCA violations for another element of its false-advertising claim—materiality—alleging that "[i]f consumers knew that the products were illegally marketed unapproved 'new drugs' and that, as such, it was unclear whether the products were safe and effective, it would influence the consumers' purchasing decisions." *Id.* Amarin's false-advertising claim, like Amarin's other claim,

is thus expressly predicated on alleging, proving, and restraining a series of FDCA violations.

It makes no difference that Amarin's claims require proof of additional matters beyond the alleged violations of the FDCA. To prevail on either of its two claims, for example, Amarin will need to prove that importation of the articles that violate the FDCA will harm Amarin's business. *See Clock Spring, LP v. Wrapmaster, Inc.*, 560 F.3d 1317, 1329 n.10 (Fed. Cir. 2009) (a false-advertising plaintiff must show that it "has been or is likely to be injured as a result of the [false] statement"); 19 U.S.C. § 1337(a)(1)(A)(i) (a Tariff Act complainant must show a "threat or effect" of "destroy[ing] or substantially injur[ing] an industry in the United States"). But the existence of these additional elements in Amarin's claims does not change the fact that Amarin's claim to relief ultimately requires that it prove what are alleged to be violations of the FDCA; nor does it change the fact that Amarin seeks to redress and restrain those FDCA violations. Indeed, Amarin seeks remedies like those that are available to the government—and only to the government—in an FDCA enforcement proceeding. Accordingly, Amarin's claims are private actions "for the enforcement, or to restrain violations, of" the FDCA, and they are prohibited for that reason. 21 U.S.C. § 337(a).

4. That conclusion is consistent with the consensus of the courts of appeals that have addressed this issue. For example, in *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010), a medical-device manufacturer brought a false-advertising claim under

the Lanham Act against a competitor who allegedly advertised its device as "FDA approved" when, the plaintiff contended, the competitor's device was different enough from a previously-approved device that the competitor was required by the FDCA to make a further filing with FDA, but had not done so. *Id.* at 923-28. The Ninth Circuit held 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." *Id.* at 924. The court explained that to permit adjudication of the false-advertising claim "would, in effect, permit [the plaintiff] to assume enforcement power which the [FDCA] does not allow and require the finder of fact to make a decision that the FDA itself did not make." *Id.* at 930.

The Third Circuit reached the same conclusion in *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990), where a drug manufacturer brought a false-advertising claim under the Lanham Act against a competitor, alleging that the labeling on the competitor's drug lists an ingredient as "inactive" when the FDCA allegedly required that the ingredient be labeled as "active." *Id.* at 230. The court noted that the plaintiff had provided no reason to think that the labeling was false or misleading other than the contention that the labeling violated the FDCA, and the court noted that FDA had not concluded whether the ingredient at issue was active or inactive or taken enforcement action accordingly. *Id.* at 230-31. The court held that

adjudication of the claim would improperly "usurp" FDA's exclusive authority, emphasizing that the FDCA does not "create[] an express or implied private right of action," and concluding that what the FDCA "do[es] not create directly, the Lanham Act does not create indirectly, at least not in cases requiring original interpretation" of the FDCA. *Id.* at 231.

Similarly, in *Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993), a drug manufacturer brought a false-advertising claim under the Lanham Act against competitors who implicitly represented that their generic drugs were "properly approved by the FDA" by placing those drugs on the market in alleged violation of the FDCA. The Fourth Circuit recognized that a false-advertising claim might proceed if the plaintiff could identify representations in the drug's packaging or labeling that misled consumers in a way independent of the FDCA. *Id.* But the Fourth Circuit held that "permitting [the plaintiff] to proceed on the theory that the defendants violated [the Lanham Act] merely by placing their drugs on the market would, in effect, permit [the plaintiff] to use the Lanham Act as a vehicle by which to enforce" the FDCA, which, the court noted, the plaintiff "is not empowered" to do. *Id.* This Court quoted this passage with approval in another case, also called *Mylan*, 268 F.3d at 1332, to support this Court's holding that a claim brought as a declaratory judgment action was actually an improper attempt to enforce the FDCA through a private enforcement proceeding.

Finally, the Second Circuit held in *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997), that an inventor developing a weight-loss product had no standing to bring a false-advertising claim against a competitor under the Lanham Act. In support of that holding, the court concluded that the plaintiff's "dogged insistence that [the defendant's] products are sold without proper FDA approval suggests" that the plaintiff's "true goal is to privately enforce alleged violations of the FDCA," but "no such private right of action exists." *Id.*[1]

The courts of appeals have applied the same principle consistently in contexts involving other statutory schemes that also prohibit private enforcement actions. For example, in *IQ Products Co. v. Pennzoil Products Co.*, 305 F.3d 368, 374 (5th Cir. 2002), the Fifth Circuit held that the Federal Hazardous Substances Act's prohibition on private enforcement actions precluded adjudication of a false-advertising claim that was predicated on the allegation that a product's labeling violated the Act and was false or misleading for that reason. Similarly, in *Dial A Car, Inc. v. Transportation, Inc.*,

[1] *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934 (8th Cir. 2005), is not to the contrary. There, an antibiotic manufacturer brought a false-advertising claim against a competitor whose product was approved by FDA for certain uses but who allegedly falsely advertised additional, unapproved uses. *Id.* at 935-37. The Eighth Circuit held that this claim was cognizable, distinguishing the cases above. It was undisputed in *Alpharma* that the product was a "drug" and that FDA approval was required for each intended use. The court explained that there was thus no need to make a "preemptive determination" about how FDA would categorize the article at issue. *Id.* at 940. The claim rested on whether FDA had approved the competitor's drug for additional uses —a factual issue that FDA had partially addressed. *Id.* at 939. By contrast, Amarin's claims rest on disputed allegations about the proper FDCA classification of certain articles, a determination at the heart of FDCA enforcement that FDA has not made.

82 F.3d 484, 489-90 (D.C. Cir. 1996), the D.C. Circuit held that a false-advertising claim was not a proper vehicle by which a taxi company could sue a competitor for advertising itself to be lawfully permitted to operate in the District of Columbia. The Lanham Act could not be used "to interpret and *enforce* municipal regulations" (emphasis in original), at least where the Taxicab Commission had not clearly addressed the issue already. *Id.* at 490; *see also Cottrell, Ltd. v. Biotrol Int'l, Inc.*, 191 F.3d 1248, 1255 (10th Cir. 1999) (holding that plaintiff could not bring a claim seeking enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act "dressed up as a Lanham Act claim").

B. Amarin's Arguments Are Without Merit.

1. Amarin chiefly contends that the Supreme Court's decision in *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014), has already settled the question presented in this case. Br. 2, 4, 18, 44-54. But Amarin's reliance on *POM Wonderful* is fundamentally misplaced.

In *POM Wonderful*, a juice manufacturer brought a false-advertising claim under the Lanham Act against the manufacturer of a competing juice product. 134 S. Ct. at 2233. The plaintiff alleged that the competitor's labeling misled consumers by prominently featuring the words "pomegranate" and "blueberry" in large type on the product's label, even though the juice contained only small amounts of each, *id.* at 2233, 2235—allegations entirely independent of the FDCA. Indeed, the plaintiff in *POM Wonderful* did not cite the FDCA, allege that the competitor's labeling violated

the FDCA, or allege that any such violation was the reason that the labeling was false or misleading. *See* First Am. Compl., *POM Wonderful LLC v. The Coca Cola Co.*, No. 08-cv-6237 (C.D. Cal., filed July 27, 2009) (Dkt. No. 53).

The district court and court of appeals in *POM Wonderful* held that the FDCA nonetheless precluded the plaintiff's false-advertising claim because regulations under the FDCA, which contain detailed provisions governing juice labeling, occupied the field, permitting some features of the defendant's label and prohibiting none of the features alleged to be misleading. 134 S. Ct. at 2236. But the Supreme Court reversed, holding that there was no conflict in fully enforcing both the FDCA and the Lanham Act in that case, where the plaintiff's claims were predicated on statements made on labeling regulated by the FDCA, but were not predicated on proving and remedying violations of the FDCA.

POM Wonderful thus stands for the proposition that the FDCA does not occupy the field of food labeling. False-advertising claims are not precluded by the FDCA simply because the FDCA independently regulates food labeling. As the Court characterized its holding in *POM Wonderful*, "Congress did not intend the FDCA to preclude Lanham Act suits *like POM's*." 134 S. Ct. at 2241 (emphasis added). And POM, as the Court emphasized, sought "to enforce the Lanham Act, not the FDCA or its regulations." *Id.* at 2239.

POM Wonderful therefore did not decide the question presented here: whether the FDCA's prohibition on private proceedings to enforce or restrain violations of the FDCA precludes a private party's claims that seek to prove and stop violations of the FDCA by invoking a private cause of action under another statute. Amarin alleges that the labeling on the accused articles constitutes an "unfair act" under the Tariff Act, and "false" advertising under the Lanham Act, solely *because* the articles allegedly violate the FDCA's requirements. Amarin's claims thus come into direct conflict with the government's exclusive enforcement authority under the FDCA. And *POM Wonderful* expressly left open the question whether the FDCA precludes private causes of action brought under other statutes where those statutes and the FDCA "cannot be implemented in full at the same time." 134 S. Ct. at 2240.

In the wake of *POM Wonderful*, courts have recognized this distinction between false-advertising claims that rest on FDCA violations and those that do not. Courts have permitted adjudication of false-advertising claims involving allegations not predicated on proving FDCA violations, like claims that a dietary supplement was falsely advertised as "safe" and "natural" when it was neither, under the common meaning of those words. *See ThermoLife Int'l, LLC v. Gaspari Nutrition Inc.*, 648 F. App'x 609, 612 (9th Cir. 2016) (unpublished). But they have properly continued to hold that Lanham Act claims predicated on proving and restraining FDCA violations are precluded, consistent with the consensus among the courts of appeals on that

issue before *POM Wonderful*. *See, e.g.*, *Hi-Tech Pharm., Inc. v. Hodges Consulting, Inc.*, 230 F. Supp. 3d 1323, 1331 (N.D. Ga. 2016); Appellee Br. 24-25 (collecting cases).

2. Taking a different tack, Amarin argues (Br. 54-56) that the Commission's conclusion that the FDCA precludes Amarin's claims "cannot be reconciled" with this Court's opinion in *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (Fed. Cir. 2013). But *Allergan* is fully consistent with the Commission's conclusion.

The plaintiff in *Allergan* sold an eyelash-growth product and sued a competitor for alleged violations of California's Sherman Food, Drug, and Cosmetic Law, *see* Cal. Health & Safety Code § 109875 *et seq.*, which parallels the FDCA. The plaintiff alleged that the competitor was wrongly marketing an eyelash-growth product as a "cosmetic" when it was actually an unapproved "new drug," under California law. *Allergan*, 738 F.3d at 1353. The plaintiff brought the action under California's Unfair Competition Law, which creates a cause of action to remedy violations of state business laws like the Sherman Law. Cal. Bus. & Prof. Code § 17203.

This Court held in *Allergan* that the FDCA did not impliedly preempt the plaintiff's state-law claim. 738 F.3d at 1355. The Court reasoned that California's Sherman Law regulated in areas—health and safety—that "implicate an historic state power that may be vindicated under state law tort principles" absent a "clear and manifest purpose of Congress" to preempt such state law. *Id.* Applying this presumption against preemption, the Court "d[id] not find a clear purpose by Congress to preempt the state law claim at issue." *Id.* And the Court concluded that

the Sherman Law "is not an obstacle to realizing federal goals" because "it contains provisions that parallel the FDCA, such that the statutes have consistent goals." *Id.* at 1355-56. The Court distinguished *Buckman*, 531 U.S. 341, which held that the FDCA preempted a state tort claim predicated on alleged fraud against FDA. The *Allergan* Court reasoned that the tort action in *Buckman* "existed—unlike [the *Allergan* plaintiff's] claim—'solely by virtue of the FDCA disclosure requirements.'" 738 F.3d at 1356 (quoting *Buckman*, 531 U.S. at 352-53). The claim in *Allergan* existed solely by virtue of independent state law.

Allergan does not support Amarin's argument that private parties may use the Tariff Act to enforce or restrain violations of the FDCA. The *Allergan* claim did not run afoul of the FDCA's prohibition on private enforcement proceedings because the claim did not attempt to enforce the FDCA. Rather, the claim sought to enforce compliance with an independent state statute—the Sherman Law—using a state cause of action that permits private enforcement of the Sherman Law. To be sure, the contents of the Sherman Law paralleled the FDCA. But the Sherman Law was not dependent on the FDCA for its existence. And it was this independent state law, not the FDCA, that the *Allergan* plaintiff sought to enforce in a private action for unfair competition under state law.

Amarin, by contrast, seeks to prove and remedy violations of the FDCA itself through the claims brought under the Tariff Act, and the FDCA prohibits such private enforcement proceedings. *Accord* U.S. Amicus Br., *Athena Cosmetics, Inc. v.*

Allergan, Inc., No. 13-1379, 2015 WL 2457643, at *18 (U.S. May 26, 2015) (distinguishing *Allergan* from cases, like *PDK Labs*, that are "essentially efforts to enforce the FDCA itself, rather than parallel state law"); U.S. Amicus Br., *Albertson's, Inc. v. Kanter*, No. 07-1327, 2008 WL 5151069, at *8 (U.S. Dec. 5, 2008) ("Although 21 U.S.C. 337 precludes private actions to enforce the FDCA itself, Section 337 does not prohibit private actions to enforce parallel state requirements.").

That distinction—between suits to enforce the independent Sherman Law and impermissible suits to enforce the FDCA—is bolstered by the federalism interests at issue in *Allergan*, which are absent here. This Court noted in *Allergan* that California's Sherman Law was enacted pursuant to the state's "historic police powers," and the Court therefore applied a presumption against preemption, which, it held, the FDCA did not overcome. 738 F.3d at 1355; *accord* U.S. Amicus Br., *Athena*, 2015 WL 2457643, at *11-17 (relying on the presumption against preemption). In so holding, this Court left for state law the interpretation and enforcement of state law within California. And it did so secure in the knowledge that private actions under state law to enforce state law would have no necessary consequence for the proper interpretation and enforcement of the FDCA itself.

Not so, here. Amarin's claims seek to enforce and restrain violations of the FDCA—a federal statute. Adjudication of those claims would directly enforce the FDCA, with nationwide effect. Worse, nothing in Amarin's theory would seem to prevent other private commercial competitors from bringing claims under the

Lanham Act in federal courts across the country seeking to prove and remedy alleged FDCA violations, with potentially precedential effect. That would effectively circumvent FDA's exclusive control over how products are regulated under the FDCA and which products warrant enforcement proceedings. And it would significantly diminish the benefits that Congress secured in centralizing "all" decisions to bring FDCA enforcement proceedings. 21 U.S.C. § 337(a). As discussed above, Amarin's claims are precluded by the FDCA under the normal tools of statutory construction. And, unlike in *Allergan*, there is no extra thumb on the scale in analyzing that question—no presumption against preemption to protect independent state law—because there are no federalism interests are at stake. *See* 738 F.3d at 1356 (applying the presumption against preemption and distinguishing preclusion cases like *PhotoMedex*).

3. Finally, Amarin appears to argue (Br. 5, 18, 51, 63) that two provisions of the Tariff Act override the FDCA's express prohibition on private enforcement proceedings. Amarin notes that the Commission's remedies are "in addition to any other provision of law," 19 U.S.C. § 1337(a)(1), and that the Tariff Act generally requires that other parts of the Executive Branch "shall cooperate fully" with the Commission "for the purposes of aiding and assisting its work," *id.* § 1334.

Neither provision qualifies the FDCA's flat prohibition on "all" private proceedings "for the enforcement, or to restrain violations, of" the FDCA. 21 U.S.C. § 337(a). The "in addition" provision does not address when a complainant's claim is

cognizable (the question here); it conditionally indicates that "when" the Commission finds an "unfair act" in a claim properly before it, the Tariff Act's remedies shall be "in addition" to any others. 19 U.S.C. § 1337(a)(1). Moreover, the "in addition" provision preserves other remedies—an issue unrelated to whether the later-enacted *FDCA* displaces an application of the *Tariff Act* that is incompatible with the FDCA's specific prohibition on private enforcement proceedings. The "shall cooperate" provision speaks to how agencies assist the Commission where the Commission has jurisdiction. It does not blithely require all other federal agencies to make regulatory enforcement determinations that are exclusively reserved to those agencies in their organic acts, much less override the clear language of 21 U.S.C. § 337(a).

CONCLUSION

For the foregoing reasons, this Court should hold that the FDCA precludes Amarin's claims.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rules of Appellate Procedure 29 and 32(a). This brief was prepared using Microsoft Word 2013 in Garamond 14-point font, a proportionally spaced typeface. This brief contains 6,995 words.

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CERTIFICATE OF SERVICE

I hereby certify that on March 26, 2018, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

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