No. 17-_____

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

IN RE AMARIN PHARMA, INC. AND
AMARIN PHARMACEUTICALS IRELAND LTD.,

Petitioners.

On Petition for a Writ of Mandamus to the
United States International Trade Commission,
In the Matter of Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form,
ITC Docket No. 3247.

PETITION FOR A WRIT OF MANDAMUS

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December 1, 2017

**Admission Pending*

CERTIFICATE OF INTEREST

Counsel for Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. certify the following:

1. The full name of every party or amicus represented herein:

Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented us:

Not applicable.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented herein:

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.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented herein in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

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5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. See Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

Petitioners Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. are simultaneously filing both a petition for review and a petition for writ of mandamus, and have asked that the two cases be consolidated. Petitioners are not aware of any other cases that will be directly affected by this court's decision.

December 1, 2017

Respectfully submitted,

/s/ *Ashley C. Parrish*
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STATEMENT OF RELIEF SOUGHT

Petitioners Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. ("Amarin") filed a complaint requesting the International Trade Commission to institute an investigation into Amarin's allegations that the false labeling and deceptive description of certain imported products — synthetically produced, predominantly eicosapentaenoic acid ("EPA") omega-3 products in ethyl ester or re-esterified form ("synthetically produced omega-3 products") — marketed and sold as (or for use in) "dietary supplements" is an unfair act or unfair method of competition under Section 337 of the Tariff Act of 1930. Despite Congress's mandate that the Commission institute an investigation of complaints under Section 337, the Commission refused to institute the requested investigation. Amarin seeks a writ of mandamus that reverses the Commission's decision and directs the Commission to institute the requested investigation.

ISSUE PRESENTED

The Tariff Act imposes a mandatory obligation on the Commission to investigate allegations of unfair trade practices and unfair methods of competition, directing 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). The Supreme Court has held that "Congress did not intend the" Federal Food, Drug and Cosmetic Act ("FDCA") "to preclude Lanham Act suits" alleging false and misleading advertising. *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2241 (2014). The issue presented is:

Did the Commission clearly abuse its discretion, and/or fail to exercise authority that it has a duty to exercise, in refusing to institute an investigation into allegations raising cognizable claims of unfair trade practices under Section 337 of the Tariff Act, based in part on violations of Section 43(a) of the Lanham Act, on the view that "the Lanham Act allegations in this case are precluded by the Food, Drug and Cosmetic Act"?

STATEMENT OF JURISDICTION

Amarin has filed a petition for review of the Commission's decision refusing to institute an investigation. This Court has jurisdiction over the appeal under 28 U.S.C. § 1295(a)(6) because the decision constitutes a final determination under 19 U.S.C. § 1337(c). *See Amgen, Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1535 (Fed. Cir. 1990).

Out of an abundance of caution, and to avoid any impediment to this Court's exercise of jurisdiction, Amarin is also filing this petition for writ of mandamus. The Court may issue a writ as "necessary or appropriate in aid of [its] jurisdiction." *Miss. Chem. Corp. v. Swift Agric. Chems. Corp.*, 717 F.2d 1374, 1379 (Fed. Cir. 1983) (quoting 28 U.S.C. § 1651(a) (1976) (internal quotation marks omitted)). A writ of mandamus is necessary and appropriate when an administrative agency or lower court has committed a "demonstrable abuse of discretion" or failed to exercise "authority when it is its duty to do so." *Gulfstream Aerospace Corp. v. Mayacamas Corp.*, 485 U.S. 271, 289 (1988) (quoting *Roche v. Evaporated Milk Ass'n*, 319 U.S. 21, 26 (1943)); *see also In re Halliburton Co.*, 991 F.2d 810, 1993 WL 118929, at *1–2

(Fed. Cir. Mar. 12, 1993) (unpublished) (providing examples). The Court has jurisdiction to grant mandamus relief under the All Writs Act. *See* 28 U.S.C. § 1651; s*ee also, e.g.*, *In re Link_A_Media Devices Corp.*, 662 F.3d 1221 (Fed. Cir. 2011) (granting mandamus).

INTRODUCTION AND SUMMARY OF ARGUMENT

This petition asks the Court to direct the Commission to institute an investigation into the merits of Amarin's claims under Section 337 of the Tariff Act challenging the unlawful importation and sale of certain synthetically produced omega-3 products that are falsely labeled and deceptively described as (or for use in) "dietary supplements." The marketing and sale of these products, which do not meet the definition of "dietary supplement" and are therefore unapproved drugs, is an unfair trade practice that is causing substantial harm to the domestic industry and for which Congress intended to provide a remedy under Section 337. The statute imposes a mandatory, non-discretionary duty on the Commission to institute an investigation where, as here, it is presented with a complaint under oath. Nonetheless, the Commission declined to investigate on the erroneous view that Amarin's allegations are precluded by the FDCA, which is administered by the Food & Drug

Administration ("FDA"). That decision reflects a clear abuse of discretion.

First, the Commission has no discretion not to institute an investigation where, as here, it is presented with a complaint that properly invokes its jurisdiction. Section 337 unequivocally states that "[t]he Commission *shall* investigate any alleged violation . . . on complaint under oath." 19 U.S.C. § 1337(b)(1) (emphasis added). The Commission's refusal to institute an investigation violates that clear statutory mandate.

Second, the Commission's reason for not instituting an investigation — that Amarin's allegations under the Lanham Act are precluded by the FDCA — cannot be reconciled with controlling Supreme Court precedent. The Supreme Court has rejected the view that FDA has exclusive authority over the labeling of FDCA-regulated products, holding that "Congress did not intend the" FDCA "to preclude Lanham Act suits" alleging false and misleading advertising. *POM Wonderful*, 134 S. Ct. 2241. Nor is the Commission stripped of jurisdiction merely because it is asked to apply the well-settled meaning of statutory terms, like "dietary supplement" and "drug." This Court's

decision in *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (Fed. Cir. 2013), rejected the view that only FDA had authority to interpret and apply the FDCA's statutory terms and determine whether a manufacturer engaged in an unfair trade practice by improperly marketing an unapproved "drug" as a "cosmetic." *Cf.* 21 U.S.C. § 321(g)(1) (defining "drug"); *id.* § 321(i) (defining "cosmetic").

Third, the Commission erred in deferring to FDA. Nothing in Amarin's complaint requires the Commission to enforce the FDCA or resolve any issue that would require scientific expertise. The remedies Amarin seeks are unique to Section 337. And the statutory terms "drug" and "dietary supplement" carry meanings that are well understood in the market, and applying them to the facts is a straightforward exercise within the Commission's authority under Section 337, not a complicated scientific inquiry. In any event, when an agency's special expertise is required, the Tariff Act sets out a specific process by which the agency may participate in an investigation. Congress directed agencies to "cooperate fully with the [C]ommission for the purposes of aiding and assisting in its work," 19 U.S.C. § 1334 (emphasis added) — not to block the Commission from instituting the

investigation. The Commission cannot avoid its statutory obligation to enforce Section 337 of the Tariff Act when presented with a complaint merely because FDA has separate authority to enforce the FDCA.

STATEMENT OF FACTS AND PROCEDURAL HISTORY

Amarin markets Vascepa® capsules, a prescription drug that consists of 1 gram of eicosapentaenoic acid (the omega-3 acid commonly known as "EPA") in a 1-gram capsule. The EPA in Vascepa® is in ethyl ester form and is synthetically produced from common fish oil. When it developed Vascepa®, Amarin took care to comply with all applicable laws, including making the extensive investments necessary to obtain FDA approval to market and sell Vascepa® in the United States as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Appx32, Appx82–83, Appx117 ¶¶ 16, 131, 213. Vascepa® is the only purified ethyl ester E-EPA ("E-EPA") product sold in the United States as an FDA-approved drug. Appx32 ¶ 16.

Amarin's Complaint. In August 2017, Amarin filed a complaint with the Commission alleging that certain competitors are falsely labeling or deceptively describing synthetically produced omega-3 products as (or for use in) "dietary supplements" when the products are

in fact "drugs" that have not been approved for sale or use in the United States. Appx19–29. (Amarin's complaint applied only to a small group of synthetically modified products, not to the majority of fish oil dietary supplements.) Amarin alleged that those acts constitute unfair acts or unfair methods of competition under Section 337 of the Tariff Act. Appx24 ¶ 1; *see* 19 U.S.C. § 1337. Amarin also asserted that those unfair acts violate Section 43(a) of the Lanham Act because falsely labeling or deceptively describing drugs as (or for use in) dietary supplements deceives consumers and others in the supply chain regarding the nature of the product. Appx24 ¶ 1; *see* 15 U.S.C. § 1125(a)(1). Amarin alleged that its domestic-industry commercial interests were being injured as a result of certain competitors' false and deceptive representations concerning the nature and characteristics of their imported products. Appx115–126.

FDA's Letter. After Amarin filed its complaint, FDA submitted a letter urging the Commission not to institute an investigation. FDA did not claim any authority to enforce either the Tariff Act or the Lanham Act. Nor did it dispute that the Commission is tasked by Congress to protect the domestic industry from unfair trade practices. It also did

not dispute that, as set forth in Amarin's complaint, the terms "dietary supplement" and "drug" have unambiguous, well-accepted meanings that are understood in the market and reflected in definitions set forth in the FDCA and decades of administrative precedent. Appx163–165.

Nonetheless, FDA asserted that because Amarin has no private right of action to enforce the FDCA, and because "FDA is the expert agency responsible for determining whether products comply with the FDCA," the Commission should not consider Amarin's Section 337 claims. According to FDA, the FDCA "preclude[s]" any claim that "require[s] the Commission to directly apply, enforce, or interpret the FDCA." Appx167. FDA also stated that "the Commission should decline to initiate an investigation under principles of comity to FDA — the federal agency that has the congressionally-delegated authority to determine the status of the products at issue." Appx165.

But Amarin's complaint does not seek any relief under the FDCA. Nor does it require FDA (or the Commission) to take action to enforce the FDCA. *See* Appx34, Appx51–53, Appx106–107 ¶ 18, 67, 185 (describing FDA's enforcement tools). Nor does anything in the FDCA give FDA a monopoly over the "appl[ication]" or "interpret[ation]" of

statutory terms, like "dietary supplement" or "drug." Appx49, Appx53–54, Appx63–64, Appx71–72, Appx126–128 ¶ 1, 62, 68, 86, 107, § XII. FDA does not pre-approve dietary supplements, so these statutory terms are interpreted and applied on a daily basis by manufacturers as they self-police by ensuring that products they wish to sell as dietary supplements qualify as dietary supplements and are not unapproved drugs. Moreover, FDA cannot take an enforcement action to restrain a company from selling an unapproved drug as a dietary supplement without a court interpreting those terms for itself and deciding *de novo* the status of the product. *See* 21 U.S.C. § 332. Accordingly, in response to FDA's letter, Amarin urged the Commission to institute its investigation, as required by statute, and not to defer to FDA's request under principles of comity.

As Amarin explained, FDA's letter attempts to resurrect the same field-preclusion arguments that the Supreme Court rejected in *POM Wonderful*. *See* 134 S. Ct. at 2241. FDA's letter also contradicts and disregards positions taken by the United States in briefing before the Supreme Court. In *POM Wonderful*, the Solicitor General argued that Lanham Act claims are barred by the FDCA "only to the extent the

FDCA or FDA regulations specifically *require* or *authorize* the challenged aspects of respondent's . . . label" — circumstances that are not present here. Br. of United States, *POM Wonderful LLC v. The Coca Cola Co.*, No. 12-761, 2014 WL 827980, at *9 (U.S. Mar. 3, 2014) (emphasis added). In taking that position, the Solicitor General recognized that "[c]ourts are called upon to interpret FDA regulations in various contexts." *Id.* at *10. The Solicitor General also made clear that "categorical preclusion [is not] warranted to prevent courts from interpreting the FDCA or FDA regulations[] to protect against 'backdoor' private FDCA enforcement actions, or to preserve FDA's regulatory authority." *Id.*; *see also* Br. of United States, *Athena Cosmetics, Inc. v. Allergan*, No. 13-1379, 2015 WL 2457643 (May 26, 2015); Br. of United States, *Albertson's v. Kanter*, No. 07-1327, 2008 WL 5151069 (Dec. 5, 2008).

Significantly, although the Solicitor General's position was not nearly as extreme as the position advanced by FDA's letter in this case, the Supreme Court rejected it as *too preclusive* and as "reorder[ing] federal statutory rights without congressional authorization." *POM Wonderful*, 134 S. Ct. at 2241. As the Court explained, the Solicitor

General's argument improperly assumed that "the FDCA and its regulations" are a "ceiling on the regulation" of labeling, when "Congress intended the Lanham Act and the FDCA to complement each other" with respect to labeling. *Id.* at 2240.

The Commission's Final Determination. On October 27, 2017, deferring to FDA, the Commission declined to institute an investigation. Appx1–2. The entirety of the Commission's determination reads:

> Under Commission Rules 210.9, 210.10 and 210.12(a)(2), (3) and (8), 19 C.F.R. §§ 210.9, 210.10, 210.12(a)(2), (3) and (8), the Commission has determined not to institute an investigation based on the complaint filed on behalf of Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (collectively "Amarin") concerning Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form, and has dismissed the complaint.
>
> Amarin's complaint does not allege an unfair method of competition or an unfair act cognizable under 19 U.S.C. § 1337(a)(1)(A), as required by the statute and the Commission's rules. The Commission notes that the Lanham Act allegations in this case are precluded by the Food, Drug and Cosmetic Act ("FDCA"). The Commission also notes that the Food and Drug Administration is charged with the administration of the FDCA.

Appx1; *see also* Appx3 (Comm'r Broadbent, concurring).

STANDARD OF REVIEW

A writ of mandamus should issue if (1) "no other adequate means [exists] to attain the relief" sought; (2) the right to mandamus is "clear and indisputable"; and (3) the court is "satisfied that the writ is appropriate under the circumstances." *Cheney v. United States Dist. Ct. for the Dist. of Columbia*, 542 U.S. 367, 380–81 (2004). As the Supreme Court has made clear, mandamus may be used to decide "basic [and] undecided" legal issues that a lower court has abused its discretion in deciding. *Schlagenhauf v. Holder*, 379 U.S. 104, 110 (1964); *see also In re Cray Inc.*, 871 F.3d 1355, 1359 (Fed. Cir. 2017) (granting mandamus because "the district court misunderstood the scope and effect of our decision in *Cordis*," which "led the court to deny the motion to transfer, which we find to have been an abuse of discretion"). Mandamus also may be used to compel a lower court or agency to "exercise its authority when it is its duty to do so." *Roche*, 319 U.S. at 26.

REASONS TO GRANT THE WRIT

Amarin is entitled to appeal the Commission's non-institution decision for reasons it will address in more detail in its opening brief on appeal. This mandamus petition is filed as a protective measure to avoid any impediment to the exercise of this Court's jurisdiction. If for

any reason the Court determines that Amarin is not entitled to appeal, then Amarin's only avenue for review is to seek mandamus relief. The Commission's non-institution decision is final and, if it is not reversed, Amarin will be improperly denied the remedies that Congress provided under the Tariff Act.

For reasons set forth below, the Commission's non-institution decision constitutes a clear abuse of discretion. Mandamus is warranted because (1) the Tariff Act mandates that the Commission institute an investigation where, as here, a complaint's properly pleaded allegations raise claims within the Commission's jurisdiction, and (2) the Commission's reasons for not instituting an investigation rest on a clear misunderstanding and violation of controlling precedent. The Court should therefore grant the writ and direct the Commission to exercise the jurisdiction that it has a duty to exercise and institute an investigation into the merits of Amarin's complaint.

I. The Commission Has A Non-Discretionary Obligation To Institute An Investigation When Presented With A Properly Pleaded Complaint.

The Tariff Act imposes a non-discretionary duty on the Commission to institute investigations into alleged unfair trade

practices and methods of competition. The statute directs that "[t]he Commission *shall* investigate any alleged violation of this section on complaint under oath . . . ." 19 U.S.C. § 1337(b)(1) (emphasis added). That mandatory command reinforces the statute's unequivocal requirement that unfair trade practices and unfair 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 . . . ." *Id.* § 1337(a)(1) (emphasis added).

In describing the Commission's statutory duties, this Court has noted that the Commission has both "the authority *and obligation* to investigate and prohibit importation based on unfair competition." *Amgen, Inc. v. Int'l Trade Comm'n*, 565 F.3d 846, 849 (Fed. Cir. 2009) (emphasis added). The Court has likened "shall" in this context to "the language of command," necessitating "strict compliance" and permitting termination of an investigation only in statutorily defined circumstances, "interpreted narrowly." *Farrel Corp. v. U.S. Int'l Trade Comm'n*, 949 F.2d 1147, 1153 (Fed. Cir. 1991); *see also Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998) ("The mandatory 'shall' . . . normally creates an obligation impervious to

judicial discretion"). Accordingly, this Court has recognized that when a complaint "on its face . . . [comes] within the jurisdiction of the Commission," the Commission "should assume jurisdiction" and address the complaint on its merits. *Amgen*, 902 F.2d at 1536.

In another area within this Court's exclusive jurisdiction, the Supreme Court recently emphasized that when a statute uses "may" and "shall" in different provisions, the word "shall" denotes a "requirement" and "imposes a mandatory duty" on the agency. *Kingdomware Techs., Inc. v. United States*, 136 S. Ct. 1969, 1977 (2016) (holding that the Small Business Act imposes a mandatory obligation that the Department of Veterans Affairs "shall award" contracts to veteran-owned small businesses). It is therefore significant that several of Section 337's subsections use permissive language. *See, e.g.*, 19 U.S.C. § 1337(b)(3) (stating that "the Commission *may* suspend its investigation" in certain circumstances); *id.* § 1337(f) (granting the Commission discretion to issue cease and desist orders). These permissive grants of authority highlight that Congress made a deliberate decision to use "shall" in Section 1337(b)(1), directing that the Commission must initiate an investigation when presented with a

complaint under oath. The statute provides no room for administrative leeway.

The Commission's historic practice confirms that the statute means what it says. Although the Commission does not keep public statistics on which cases it has declined to investigate, independent research suggests that in the last twenty years well over a thousand Section 337 cases were filed. The Commission declined to institute an investigation in only a small handful. *See, e.g.*, *Compl. of Prospera Corp. Concerning Certain Elec. Hand Held Pulse Massagers and Components Thereof* (ITC Docket No. 2997), issued Jan. 28, 2014; *Compl. of KV Pharm. Co. Concerning Hydroxyprogesterone Caproate and Prods. Containing Same* (ITC Docket No. 2919), issued Dec. 21, 2014; *see also L.A. Biomedical Research Inst. at Harbor-UCLA Med. Ctr. v. Eli Lilly & Co.*, 849 F.3d 1049, 1061 n.6 (Fed. Cir. 2017) ("We can properly take judicial notice of the records of related court proceedings."). As the Commission's public representations confirm, "[d]ecisions not to institute an investigation are rare." *Section 337 Investigations Answers to Frequently Asked Questions* 16 (Mar. 2009), https://www.usitc.gov/intellectual_property/documents/337_faqs.pdf.

The ITC Trial Lawyers Association offers the same assessment: "Only in extremely rare circumstances does the ITC decide not to institute an investigation." *FAQs*, http://www.itctla.org/resources/faqs.

There are only a few specifically enumerated and narrowly drawn exceptions to the Commission's mandatory obligation to institute an investigation. For example, in cases within the purview of the antidumping and countervailing laws, Congress has expressly directed that the Commission *shall not* institute an investigation. *See* 19 U.S.C. § 1337(b) ("the Commission shall terminate, or not institute, any investigation" into acts that constitute dumping and are solely within the purview of 19 U.S.C. § 1673). Congress's decision to enact an express provision that exempts antidumping and countervailing duty claims is strong evidence that it did not intend to carve out other categories of claims, such as those involving FDA-regulated products, from Section 337's requirements. *See Ventas, Inc. v. United States*, 381 F.3d 1156, 1161 (Fed. Cir. 2004) ("Where Congress includes certain exceptions in a statute, the maxim *expressio unius est exclusio alterius* presumes that those are the only exceptions Congress intended.").

Courts have also recognized a narrow exception to the Commission's obligation to institute an investigation in "unique circumstances" when a complaint's allegations are so inadequate that they do not provide a sufficient factual basis for the Commission to take action. *See Union Mfg. Co. v. U.S. Int'l Trade Comm'n*, 826 F.2d 1071, 1987 WL 37901, at *3 (Fed. Cir. July 2, 1987) (finding that Commission could decline to institute a second investigation when presented with no new material allegations that had not already been investigated). In *Syntex*, for instance, the Court of Customs and Patent Appeals concluded that the Commission was not required to institute an investigation because the "petitioner's allegations are no more than conclusory," *Syntex Agribusiness, Inc. v. U.S. Int'l Trade Comm'n*, 659 F.2d 1038, 1044–45, 1047 (C.C.P.A. 1981) (Nies, J., concurring), and did not include "an adequate factual basis" for its claims. *Id.* at 1045–46 (majority).

None of these narrow exceptions applies in this case. Amarin's complaint, as well as the numerous exhibits and other materials attached to the complaint, contains sufficient allegations and factual support to invoke the Commission's jurisdiction. Significantly, unlike

in one of the few other cases where the Commission has declined to institute an investigation, the Commission did not identify any allegations lacking sufficient information or give Amarin an opportunity to re-file its complaint. *Cf. Compl. of Prospera Corp.* (ITC Docket No. 2997) (dismissing a complaint without prejudice and permitting the complainant to re-file with sufficient allegations). Instead, the only ground the Commission identified for not complying with its statutory obligations was its conclusion that "the Lanham Act allegations in this case are precluded by the Food, Drug and Cosmetic Act," which FDA has authority to administer. Appx1. That conclusion is contrary to controlling precedent and a clear abuse of any discretion the Commission may have.

II. The FDCA Does Not Preclude Amarin's Section 337 Claims.

The Supreme Court in *POM Wonderful* rejected the view that the FDCA precludes Lanham Act claims challenging a product's false and deceptive labeling, even though the product is regulated by FDA under the FDCA. As the Supreme Court held, "Congress did not intend the FDCA to preclude Lanham Act suits" challenging the labeling of products subject to FDA regulation. *POM Wonderful*, 134 S. Ct. at

2241. The Commission's decision here cannot be reconciled with *POM Wonderful*.

A. The FDCA Does Not Preclude Suits Challenging The Labeling Of Products Subject To FDA Regulation.

In *POM Wonderful*, the plaintiff alleged that the labeling of the defendant's "pomegranate blueberry" beverage product misled consumers into believing that the product consisted predominantly of pomegranate and blueberry juice, when in fact it contained only small amounts of those juices. In the Ninth Circuit, the defendant argued that the FDCA precluded the Lanham Act claim because FDA has authority to regulate food and beverage labels and, as a result, only FDA has authority to determine whether the product's labeling was appropriate. 134 S. Ct. at 2233. The Ninth Circuit accepted that argument, noting that FDA exercised "comprehensive regulation" of juice labeling and expressing concern that permitting the Lanham Act claim to proceed "would risk undercutting" FDA's "expert judgments and authority." *Id.* at 2236.

The Supreme Court reversed, holding that "Congress did not intend the FDCA to preclude Lanham Act suits like POM's." *Id.* at 2241. The Court noted that "the Lanham Act subjects to suit any

person who 'misrepresents the nature, characteristics, qualities, or geographic origin' of goods and services" and that "this comprehensive imposition of liability extends, by its own terms, to misrepresentations on labels, including food and beverage labels." *Id.* at 2237. The Court further noted 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." *Id.* The Court also considered the structure of the two statutes and recognized that they protect different interests: the Lanham Act protects commercial interests, while the FDCA protects public health and safety interests. *Id.* at 2238. As the Court concluded, "the FDCA and the Lanham Act complement each other in the federal regulation of misleading labels," *id.* at 2241, and "[a]llowing Lanham Act suits takes advantage of synergies among multiple methods of regulation" — consistent with Congress's "design to enact two different statutes, each with its own mechanisms to enhance the protection of competitors and consumers," *id.* at 2239.

Accordingly, the Supreme Court held that "[c]ompetitors, in their own interest, may bring Lanham Act claims like POM's that challenge food and beverage labels that are regulated by the FDCA." *Id.* at 2233.

It also criticized the same position that FDA urged the Commission to resurrect in this case: "A holding that the FDCA precludes Lanham Act claims challenging food and beverage labels would not only ignore the distinct functional aspects of the FDCA and the Lanham Act but also would lead to a result that Congress likely did not intend." *Id.* at 2239; *see also Wyeth v. Levine*, 555 U.S. 555, 575 (2009) (stating that "Congress did not intend FDA oversight" to be the "exclusive means" of regulating products subject to the FDCA). Because FDA "does not preapprove food and beverage labels . . . [and] does not necessarily pursue enforcement measures regarding all objectionable labels . . . [,] if Lanham Act claims were to be precluded then commercial interests — and indirectly the public at large — could be left with less effective protection in the food and beverage labeling realm than in many other, less regulated industries." *POM Wonderful*, 134 S. Ct. at 2239. As the Court explained, there is no reason to think that "Congress intended the FDCA's protection of health and safety to result in less policing of misleading food and beverage labels than competitive markets for other products." *Id.*

The Commission's non-institution decision in this case cannot be reconciled with *POM Wonderful*. "Dietary supplements," like beverages, are a type of "food" regulated by FDA. 21 U.S.C. § 321(f), (ff). And, just like beverages, FDA does not preapprove the distribution or the labeling of purported dietary supplements. Instead, manufacturers interpret and apply the statutory definitions of "drug" and "dietary supplement" to determine for themselves whether a product is a drug, which requires FDA approval, or a dietary supplement, which does not. When manufacturers incorrectly decide that a drug is a dietary supplement, FDA can only police the purported dietary supplement's lack of compliance with the FDCA by relying on enforcement actions, warning letters, and other measures taken after a product is brought to market. Because of limited resources, however, the agency cannot pursue every violation. *POM Wonderful,* 134 S. Ct. at 2239. To the contrary, FDA has only about 25 employees to oversee the more than 85,000 products that each year are sold as dietary supplements. *See* Appx130–155 (Frontline: Supplements and Safety, PBS and The New York Times).

Claims that a manufacturer has falsely labeled or deceptively described a product as a dietary supplement when, in reality, it is an unapproved drug — like claims that a manufacturer has falsely labeled a beverage as a type of juice — are not precluded under the FDCA. *See POM Wonderful*, 134 S. Ct. at 2237 ("food and beverage labels regulated by the FDCA are not . . . off limits to Lanham Act claims"); *see also Thermolife Int'l, LLC v. Gaspari Nutrition Inc.*, 648 Fed. Appx. 609, 612 (9th Cir. 2016) (holding that plaintiff's allegations that defendant had falsely advertised a "dietary supplement" as "safe," "natural," and "legal" were not precluded by the FDCA). FDA has authority to enforce the FDCA to protect public health (and it does so when it detects a violation and has adequate resources to pursue it), but FDA has no authority to enforce the Lanham Act to preserve fair competition by protecting against deceptive advertising. And as explained above, the Supreme Court has already held that Congress did not intend its grant of one type of authority to FDA to protect health and safety interests to limit Congress's separate grant of a different type of authority to competitors to bring private actions under the Lanham Act to protect fair competition.

B. The FDCA Does Not Preclude Section 337 Claims That Refer To Terms Defined In The FDCA.

POM Wonderful addressed Lanham Act claims brought by private parties in district court, but the legal principles it recognized and announced apply with full force here.

There is no indication that Congress intended the FDCA to preclude private-party claims under Section 337 of the Tariff Act seeking to enforce the Lanham Act before the Commission any more than it intended to preclude private-party claims seeking to enforce the Lanham Act before district courts. To the contrary, Congress made clear that Section 337's remedies for unfair competition through misleading advertising or labeling are "*in addition to* any other provision of law." 19 U.S.C. § 1337(a)(1) (emphasis added); *see also* S. Rep. No. 93-1298, 93 Cong. 2d Sess. 196 (Nov. 26, 1974) (noting that "[t]he relief provided for violations of section 337 is 'in addition to' that granted in 'any other provisions of law'"). Section 337 also serves different purposes and protects different interests than the FDCA. *See Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1488 (Fed. Cir. 1986) (noting that "the thrust of the statute" is to protect domestic industry against "unfair trade practices in international commerce").

Accordingly, allowing Section 337 claims based on the Lanham Act "takes advantage of synergies among multiple methods of regulation" — consistent with Congress's "design to enact . . . different statutes, each with its own mechanisms to enhance the protection of competitors and consumers," *POM Wonderful*, 134 S. Ct. at 2239.

Congress's grant of authority to the Commission under Section 337 also should be read to complement and to work in synergy with Congress's grant of authority to FDA under the FDCA. Amarin's claims under Section 337 of the Tariff Act, like the Lanham Act claims considered in *POM Wonderful*, seek to protect competitors against unfair competition and unfair trade practices. Both the Lanham Act and the Tariff Act complement the FDCA, and "it would show disregard for the congressional design to hold that Congress nonetheless intended one federal statute [the FDCA] to preclude the operation of the other[s]." *POM Wonderful*, 134 S. Ct. at 2238 (citing *J.E.M. Ag Supply, Inc. v. Pioneer Hi–Bred Int'l, Inc.*, 534 U.S. 124, 144 (2001) ("we can plainly regard each statute as effective because of its different requirements and protections")).

That the disposition of Amarin's claims turns on market participants' understanding of what products qualify as "dietary supplements" or "drugs," which is informed by the FDCA's statutory definitions and administrative guidance, does not change this analysis. Although *POM Wonderful* stopped short of rejecting the possibility that FDA could limit the scope of the Lanham Act as it relates to FDA-regulated products by promulgating a regulation carrying the force of law that so provided, *see* 134 S. Ct. at 2240–41, FDA has not promulgated any such regulation addressing dietary supplements. Similarly, although the Court cast doubt on whether a Lanham Act claim would be precluded even if it conflicted with the plain terms of an FDA regulation, the Court entertained that possibility. *See id*. at 2241. But that is irrelevant, because there is no such conflict here. As in *POM Wonderful*, this "is not a case where a lawsuit is undermining an agency's judgment," *id.*, or where there will be "any difficulty in fully enforcing each statute according to its terms," *id.* at 2240.

Amarin's claims do not conflict with the FDCA or FDA regulations. To the contrary, Amarin is asking the Commission to find that certain products do not qualify as "dietary supplements" because,

among other reasons, the substances in them are not "dietary ingredients," as confirmed by the statute's text. *See* 21 U.S.C. § 321(ff)(1) (listing substances that are dietary ingredients). If there were any doubt, it is dispelled by long-standing administrative precedent, which publicly announces FDA's interpretation of what the law requires. For more than 15 years, FDA has stated on numerous occasions that certain types of synthetically produced substances are not "dietary ingredients" and, therefore, cannot be sold as (or for use in) dietary supplements. Appx51–54 ¶¶ 67–68; *see also* 21 U.S.C. § 321(ff)(1); FDA Ltr. to AIBMR Life Sciences, Inc. (Mar. 19, 2014) (determining that synthetic fatty acid esters derived from fish oil "do not fit within the statutory definition of 'dietary ingredient' because they are not constituents of a dietary substance for use by man under section 201(ff)(1)(F)"). These earlier administrative determinations thus confirm that there is no conflict between Amarin's request that the Commission enforce the laws protecting against unfair trade practices and FDA's responsibility to protect public health and safety under the FDCA.

This Court has already rejected the argument that a claim under a different statute is barred merely because it entails referring to, applying, or interpreting terms defined in the FDCA. In *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (Fed. Cir. 2013), the manufacturer of an FDA-approved eyelash growth drug alleged that a competitor unfairly competed by selling its eyelash growth product as a "cosmetic," without obtaining FDA approval of the product as a "drug." In short, Allergan alleged that Athena had engaged in an unfair trade practice by improperly marketing an unapproved "drug" as a "cosmetic."

This Court held that Allergan's claim under California's unfair competition law was not preempted by the FDCA and affirmed the grant of summary judgment in Allergan's favor. Applying and interpreting the FDCA's definition of "drug" (which had been incorporated into California law) to include "any article other than food that is used or intended to affect the structure . . . of the body of human beings," *id.* at 1356, the Court concluded that Athena intended its product to be used as a "drug" and, therefore, Athena violated the prohibitions on unfair competition by selling its unapproved drug as if it were a cosmetic. The Supreme Court called for the views of the

Solicitor General in response to Athena's petition for certiorari, and the government defended this Court's decision, explaining that Allergan's suit did not conflict with the FDCA or FDA's exclusive authority to enforce that statute. *See* Br. of United States, *Athena Cosmetics,* 2015 WL 2457643, at *10–14 (noting that the "state-law suit to enjoin the sale of an unapproved drug does not compromise FDA's objectives"). The Supreme Court denied certiorari. *See Athena Cosmetics, Inc. v. Allergan, Inc.*, 135 S. Ct. 2886 (Mem.) (June 29, 2015). Neither FDA's letter nor the Commission's decision mentioned this Court's binding precedent in *Allergan v. Athena* or the United States' defense of that decision before the Supreme Court.

III. Congress Anticipated That Other Agencies Will Participate In Section 337 Investigations And Required Them To Cooperate With The Commission.

FDA's letter urged the Commission to "decline to initiate an investigation under principles of comity to FDA," suggesting that investigating Amarin's claims might require resolving complex questions necessitating FDA's scientific expertise. Appx165. That is wrong on its own terms, as Amarin's claims raise straightforward legal and factual issues that the Commission and this Court are entirely

competent to decide. FDA's "comity" request is contrary to the statute in any event. The Tariff Act includes detailed provisions specifying the role that other agencies play in connection with Section 337 complaints filed with the Commission. That role is to participate in and cooperate with a Commission investigation — not to block the Commission from instituting an investigation in the first place.

As explained above, nothing in the FDCA ousts the courts or the Commission from deciding whether a product meets either definition when that issue arises in a claim pleaded under the Lanham Act or some other source of law. Nor is any specialized scientific expertise required to determine whether a product qualifies as a "dietary supplement" or "drug" as those terms are defined by statute. Just as this Court had no difficulty in *Athena* applying the statutory definition of "drug" to the product improperly marketed as a mere "cosmetic," no expertise beyond the ken of the Commission or this Court is required to apply the definitions of "drug" and "dietary supplement." *Athena*, 738 F.3d at 1355–56, 1359–60.

That distinguishes this case from those where *courts* have referred matters to FDA to resolve questions of scientific judgment falling within

FDA's special expertise. *See JHP Pharms., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 1001 (C.D. Cal. 2014). For example, courts have sometimes referred cases to FDA when asked to assess the safety or effectiveness of a drug — questions that require scientific expertise concerning the design of clinical trials and the analysis of clinical data. *See id.* at 1003–05.

Nothing in Amarin's complaint requires the Commission to undertake that type of scientific inquiry. The pivotal issue — whether certain products are falsely labeled and deceptively described as (or for use in) "dietary supplements" — is a question that can be readily resolved by the Commission. Indeed, the Commission is as capable of making that determination as this Court was in applying the definition of "drug" to the facts in *Athena*. To determine whether the challenged products are falsely labeled or deceptively described, the Commission need only consider whether the substances they contain qualify as "dietary ingredients" as that term is expressly defined in the statute, *see* 21 U.S.C. § 321(ff)(1), and, if they do, whether they are otherwise precluded from being sold as "dietary supplements" because they were first studied or approved as a "drug," as that term is defined in the

statute, *see id.* § 321(ff)(3)(B). Appx49–62. ¶¶ 61–83. Resolving those issues requires nothing more than looking at the statute itself and the many decisions that have interpreted the relevant statutory terms and set market expectations. As discussed, FDA has already determined that synthetic fatty acid esters derived from fish oil — substances exceedingly similar to the accused products in all material respects — "do not fit within the statutory definition of 'dietary ingredient' because they are not constituents of a dietary substance for use by man under section 201(ff)(1)(F)." Appx156–161 (Compl., Ex. 33).

Confirming that no special scientific expertise is involved, courts routinely decide similar questions — including whether a purported dietary supplement is an unapproved drug — in enforcement actions brought by FDA, so it cannot be that only FDA can venture into this area.[1] By the same logic, the fact that private parties cannot bring

[1] In 2015, the Department of Justice, which brings enforcement actions on behalf of FDA, filed suit against several companies selling unapproved "new drugs" mislabeled as "dietary supplements." In each case, the court, not FDA, had the responsibility to decide the issue based on its interpretation and application of the definitions of "dietary supplement" and "drug." *See* Justice Department and Federal Partners Announce Enforcement Actions of Dietary Supplement Cases, Nov. 17,

actions to enforce the FDCA does not mean that the Commission is forbidden from applying or interpreting the FDCA when private parties invoke rights of action under other statutes, such as Section 43(a) of the Lanham Act and Section 337 of the Tariff Act. Competitors do not have an open field to engage in unfair trade practices like falsely labeling unapproved drugs as dietary supplements merely because FDA lacks the resources to enforce the FDCA against every violator.

With its focus on the public health, FDA does not have the necessary "perspective or expertise in assessing market dynamics" that give rise to competitive harms. *POM Wonderful*, 134 S. Ct. at 2238. Instead, the reason Congress allowed private parties to invoke Section 337 and the Lanham Act is to police competitive harms that result when competitors fail to comply with the law and to "provide incentives for manufacturers to behave well." *Id.* at 2238–39 (internal quotation marks omitted). Policing unfair trade practices is not FDA's job — it is the Commission's. And Congress made clear that the Commission's duty to investigate claims of unfair trade practices is "*in addition to* any

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2015, https://www.justice.gov/opa/pr/justice-department-and-federal-partners-announce-enforcement-actions-dietary-supplement-cases.

other provision of law." 19 U.S.C. § 1337(a)(1) (emphasis added). The fact that FDA has separate authority to pursue claims under the FDCA therefore cannot justify the Commission's abdication of the duty Congress placed on it under the Tariff Act.

Because of the unique nature of the Commission's duty and authority under the Tariff Act, court decisions that refer matters to FDA for an exercise of its scientific expertise under the "primary jurisdiction" doctrine are not relevant in the context of Section 337. Courts have discretion (albeit limited) to decline to exercise jurisdiction in the first instance and instead to wait for an administrative agency where "a prior agency adjudication . . . will be a material aid." *Wyandot Nation v. United States*, 858 F.3d 1392, 1400 (Fed. Cir. 2017) (quoting *Ricci v. Chicago Mercantile Exch.*, 409 U.S. 289, 305 (1973)). But the Commission has no such discretion; Congress imposed a mandatory duty on the Commission, providing that it "*shall* investigate any alleged violation of" Section 337 "on complaint under oath." 19 U.S.C. § 1337(b)(1) (emphasis added).

Moreover, this congressional mandate to investigate makes perfect sense in the context of the Tariff Act. Congress recognized that

the Commission would sometimes need or benefit from input from other agencies and provided a specific process by which the Commission can obtain such input during its investigation. 19 U.S.C. § 1334 (stating that the "Commission shall in appropriate matters act in conjunction and cooperation with . . . any other department . . . of the Government"). Indeed, Congress specifically mandated 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." 19 U.S.C. § 1337(b)(2).

Congress even recognized that other agencies might not always be eager to provide the input requested by the Commission and specifically chose not to leave that decision to the agencies themselves, instead mandating that such other "departments . . . *shall cooperate fully* with the [C]ommission for the purposes of aiding and assisting in its work[.]" *Id.* § 1334 (emphasis added). Rather than allow another agency to block the institution of an investigation at the front end or to thwart the successful conduct of the investigation by withholding cooperation, Congress built in a process to address any inter-agency conflict at the

back end. Under the Tariff Act, all Commission decisions finding a violation of section 337 are submitted to the President for review during a 60-day period following the investigation's conclusion. *See id.* § 1337(j)(1). The President may disapprove of any Commission decision for "policy reasons," draining the decision of any force or effect. *Id.* § 1337(j)(2). The President has used this authority on two occasions to ensure that Commission decisions did not intrude on the prerogatives of another agency. *See* Presidential Determination, *Welded Stainless Steel Pipe & Tube Indus.*, 43 Fed. Reg. 17,789 (Apr. 26, 1978) (disapproving a cease-and-desist order issued by the Commission on the ground that the Antidumping Act administered by the Treasury Department provided complainant with adequate relief); *Determination of the President Regarding Certain Alkaline Batteries*, 50 Fed. Reg. 1655 (Jan. 11, 1985) (disapproving Commission determination on the ground that the Treasury Department's interpretation of the gray market goods provision of the Lanham Act controlled).

FDA's call for "comity," and the Commission's heeding of that call, cannot be reconciled with the text or structure of the Tariff Act. If any "comity" is owed in this context, it is owed *by* FDA *to* the Commission

under Congress's directive that other agencies "shall cooperate fully with the [C]ommission for the purposes of aiding and assisting in its work." If any special agency expertise were needed in the investigation of Amarin's claims — and none is, as explained above — the statute makes clear that that is not a basis for the Commission to abdicate its duty to institute an investigation. The Commission's job is to enforce the Tariff Act by investigating complaints that the domestic industry is being harmed by unfair trade practices, and to obtain whatever input from FDA or any other agency may be necessary or appropriate in the course of that investigation. In allowing FDA's desire to protect its prerogative to enforce the FDCA to serve as a basis to refuse to institute an investigation into Amarin's claims, the Commission lost sight of the obligations Congress imposed on it.

* * * *

When Amarin brought Vascepa® to market, it made the significant investments needed to comply with U.S. law and sell its product as an FDA-approved drug. The company is now facing unfair competition from a small group of omega-3 products that are in reality unapproved, imported drugs that are being falsely sold and deceptively described "dietary supplements." The Commission has a mandatory obligation to investigate Amarin's allegations on their merits, and it cannot avoid that obligation merely because the imported products are subject to regulation under the FDCA. Because the Commission's refusal to institute an investigation is a clear abuse of discretion, this Court should direct the Commission to comply with its statutory obligations.

CONCLUSION

If the Court concludes that it lacks jurisdiction over Amarin's petition for review appealing the Commission's final decision, it should grant a writ of mandamus ordering the Commission to institute an investigation into the merits of Amarin's claims, as Congress required under Section 337 of the Tariff Act.

Respectfully submitted,

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December 1, 2017

**Admission Pending*

CERTIFICATE OF COMPLIANCE WITH RULE 21(d)(1)

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 21(d)(1). The brief contains 7,639 words, excluding the parts of the brief exempted by Federal Rules of Appellate Procedure 32(a)(7)(A) and 32(f), as well as Federal Circuit Rule 32(b).

This brief complies with requirements of Federal Rule of Appellate Procedure 32(c)(2). This brief has been prepared in a proportionally spaced typeface using Microsoft Office Word Version 2013 in 14-point Century Schoolbook font.

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Dated: December 1, 2017

CERTIFICATE OF SERVICE

I hereby certify that on December 1, 2017, I served or caused to be served copies of this Petition for a Writ of Mandamus via Hand Delivery or Overnight Mail to the following:

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