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	)	**Investigation No. 337-TA-___**

AMARIN'S BRIEF ON JURISDICTION

Complainants, Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (collectively "Amarin"), submit this brief in support of their Complaint and to demonstrate that the U.S. International Trade Commission ("ITC" or "Commission") has jurisdiction over the allegations in the Complaint.

I. AMARIN'S COMPLAINT

Amarin's Section 337 Complaint asks the Commission to commence an investigation into the unlawful importation or sale in the United States of synthetically produced omega-3 products that are predominantly comprised of eicosapentaenoic acid ("EPA") in either ethyl ester ("EE") or re-esterified triglyceride ("rTG") form and that are falsely labeled as and/or promoted for use in, or as "dietary supplements" ("Synthetically Produced Omega-3 Products"). As explained in the Complaint, these products are unapproved "new drugs" under the Federal Food, Drug and Cosmetic Act ("FDCA") that are cloaked as "dietary supplements."

This false labeling, promotion, or positioning enables the Proposed Respondents to avoid the drug approval process and the associated time and investment necessary to conduct clinical trials to show that their products are safe and effective for each intended use and to obtain FDA approval for each intended use. *See* 21 U.S.C. § 355. Disregarding the FDA drug approval

process also enables the Proposed Respondents to avoid applicable user fee costs associated with manufacturing drugs, *id.* § 379h, as well as the applicable costs associated with complying with FDA's drug registration, listing, labeling, and manufacturing requirements. *Id.* §§ 360, 502(f), 501(a)(2)(B). It also allows the distributor respondents (*i.e.,* the entities selling the finished products) to avoid the need to sell their products pursuant to a prescription by a licensed healthcare professional. *Id.* § 353(b).

To be clear, FDA need not deem products to be "drugs" for them to be "drugs." Products are "drugs" if they meet any prong in the definition of "drug" in the FDCA. *See* 21 U.S.C. § 321(g)(1). In fact, law-abiding drug sponsors take steps toward drug approval before any FDA involvement at all. Typically, basic scientists collect data from animal studies. If the data look promising, the drug company develops a prototype drug, and it seeks permission from FDA to begin clinical testing in humans by way of an investigational new drug application ("IND"). *See id.* § 355(i). Once the clinical trials are conducted, the sponsor may submit a new drug application ("NDA"), and if FDA believes that the drug is safe and effective, that the proposed labeling[1] is appropriate, and that manufacturing methods assure the drug's identity, strength, quality, and purity, then the agency will approve the drug. *See id.* § 355(d). At that point, the drug may be legally marketed. In other words, it is incumbent upon the sponsor of a "drug" to recognize that a product is a "drug," pursuant to the definition in the FDCA, and to comply with FDA's regulatory requirements for "drugs" accordingly. *See generally*, Susan Thaul, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, Congressional Research Service, June 25, 2012. **Attachment A.**

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[1] Section 201(m) of the FDCA defines the term "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

The importation and sale of the Synthetically Produced Omega-3 Products constitute an unfair trade practice and/or an unfair method of competition. Falsely labeling or promoting unapproved "new drugs" as, or for use in, "dietary supplements" is unfair to pharmaceutical companies who have invested the necessary resources to bring competing products to market, and it serves as a disincentive for drug companies to invest resources in drug development in the future. Combined with Amarin's allegations of domestic industry and injury, the importation and sale of these products constitute unfair acts or unfair methods of competition under Section 337 based upon violations of both Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and the standards set forth in the FDCA, 21 U.S.C. 321 *et seq*.

II. ARGUMENT

A. The Commission's Jurisdiction Under Section 337 Of The Tariff Act

Section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, grants the Commission jurisdiction to investigate and remedy unfair methods of competition and unfair acts in the importation of articles into the United States. Specifically, that section states:

> [T]he following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:
>
> (A) Unfair methods of competition and unfair acts in the importation of articles … into the United States … the threat or effect of which is –
>
> (i) to destroy or substantially injure an industry in the United States;
>
> (ii) to prevent the establishment of such an industry; or
>
> (iii) to restrain or monopolize trade and commerce in the United States.

19 U.S.C. § 1337(a)(1)(A). This remedy for unfair acts and unfair methods of competition is "in addition to any other provision of law." 19 U.S.C. § 1337(a)(1). The legislative history to the

predecessor of Section 337 – Section 316 of the Tariff Act of 1922 – made clear that "[t]he provision relating to unfair methods of competition in the importation of goods [*i.e.,* Section 337] is broad enough to prevent every type and form of unfair practice . . . ." S. Rep. No. 67-595 at 3 (1922).

B. The Commission Has Jurisdiction Over Amarin's Section 337 Claims Based On Violations Of The Lanham Act

1. The Lanham Act false advertising provisions provide a remedy for competitor injury

Section 43(a) of the Lanham Act "creates a cause of action for unfair import competition through misleading advertising or labeling." *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2234 (2014). The Act imposes civil liability on any person who:

> [U]ses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which . . . misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities.

15 U.S.C. § 1125(a)(1). The Lanham Act cause of action belongs to competitors who "allege an injury to a commercial interest in reputation or sales." *Lexmark Int'l, Inc. v. Static Control Components*, 134 S. Ct. 1377, 1390 (2014).

The elements of a false advertising claim under the Lanham Act require a showing that respondents (i) made false or misleading statements of fact about a product; (ii) "such statement deceived or had the capacity to deceive a substantial segment of potential consumers;" (iii) "the deception is material, in that it is likely to influence a purchasing decision;" (iv) "the product is in interstate commerce;" and (v) the complainant "has been or is likely to be injured as a result of the statement." *Clock Spring, L.P. v. Wrapmaster, Inc.*, 560 F.3d 1317, 1331, n. 10 (Fed. Cir. 2009). When a complainant can show that a statement is "literally false," however, consumer

deception is presumed, such that proving the element of materiality is not necessary. *See id.* at 1329. The Commission has repeatedly held that claims under the Lanham Act are cognizable as unfair methods of competition or unfair acts under Section 337. *See, e.g., Certain Carbon And Alloy Steel Products*, Inv. No. 337-TA-1002; *Certain Light-Emitting Diode Products And Components Thereof,* Inv. No. 337-TA-947.

2. The Supreme Court's *POM Wonderful* decision clarifies that competitors, such as Amarin, may bring federal court Lanham Act claims challenging misleading food labels that are regulated by the FDCA

Private parties have no private right of action under the FDCA. 21 U.S.C. § 337. In *POM Wonderful LLC v. Coca-Cola Co.*, however, the Supreme Court held that the FDCA does not preclude a private party from bringing a Lanham Act claim in U.S. District Court challenging a misleading food label that is regulated under the FDCA. *See POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2241 (2014). The plaintiff in *POM Wonderful* brought a Lanham Act false advertising claim alleging that the labeling of defendant's "pomegranate blueberry" beverage product misled consumers because the product contained only 0.3 percent pomegranate juice and 0.2 percent blueberry juice. *Id.* at 2233. The defendant successfully argued to the Ninth Circuit that the claim was precluded because the FDA had the sole authority to regulate food and beverage labels. *Id.*

The Supreme Court reversed, finding that "Congress did not intend the FDCA to preclude Lanham Act suits." *Id.* at 2241. In doing so, the Court observed 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.* at 2237. The Court also considered the structure of the two acts and noted that they protect different interests: the Lanham Act protects commercial interests, while the FDCA protects public health and safety interests. *Id.* at 2238. The Court further explained that the acts were complementary because the FDA is able to handle the "detailed

prescriptions" of the FDCA, while the Lanham Act permits competitors to more adeptly address market dynamics. *Id.* at 2238-39. As the Court observed that allowing Lanham Act suits for food mislabeling that also violates the FDCA:

> [T]akes advantage of synergies among multiple methods of regulation. This is quite consistent with the congressional design to enact two different statutes, each with its own mechanisms to enhance the protection of competitors and consumers. 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. Unlike other types of labels regulated by FDA, such as drug labels . . . , it would appear the FDA does not preapprove food and beverage labels under its regulations and instead relies on enforcement actions, warning letters, and other measures . . . . Because the FDA acknowledges that it does not necessarily pursue enforcement actions 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. It is unlikely that Congress intended the FDCA's protection of health and safety to result in less policing of misleading food and beverage labels than competitive markets for other products.

POM Wonderful, 134 S. Ct. at 2239.

POM Wonderful is directly on point. The Synthetically Produced Omega-3 Products are labeled as "dietary supplements," or are intended for use in "dietary supplements," such that FDA and potential customers are tricked into believing that these products in fact meet the definition of "dietary supplement" in the FDCA, 21 U.S.C. § 321(ff), even though that is not the case. Like the beverage at issue in *POM Wonderful*, the purported "dietary supplements" at issue here are sold without FDA premarket review.

"Dietary supplements," like beverages, are in fact a type of "food" under the FDCA. *See id.* § 321(f), (ff). As with beverages, to police purported "dietary supplements," FDA has to rely

on enforcement actions, warning letters, and other measures.[2] Because of limited resources, however, the agency cannot detect every violation nor, as the Supreme Court observed in *POM Wonderful*, can it pursue every violation it detects. Indeed, according to a recent PBS "Frontline" documentary, produced in collaboration with *The New York Times*, FDA has only about 25 people in the division that oversees dietary supplements, and more than 85,000 dietary supplement products are sold each year. As reported in that program, "[FDA] target[s] companies they consider to be the most risky, but agree the problem remains much bigger than that." *See* Frontline: Supplements and Safety, PBS and The New York Times. **Attachment B.** Thus, as in *POM Wonderful*, the regulatory synergies between the Lanham Act and the FDCA are important here – if a federal district court were to preclude the Lanham Act claims over dietary supplements, commercial interests and, indirectly, the "public at large" would be unprotected. Importantly, the Ninth Circuit agrees that the holding in *POM Wonderful* can easily be extended to "dietary supplements." *See Thermolife Int'l., LLC v. Gaspari Nutrition Inc.*, 648 Fed. Appx. 609, 612 (9th Cir. 2016) (finding, in light of the decision in *POM Wonderful*, that

[2] FDA often sends warning letters to companies that falsely label unapproved "new drugs" – as "dietary supplements" to evade FDA's drug requirements. For example, in late May and early June 2017, FDA sent three separate warning letters to different companies that cited the companies for selling products containing synthetic steroids as "dietary supplements" when (1) the products did not meet the definition of "dietary supplement" and (2) the products were actually unapproved "new drugs." *See* FDA Warning Letter to Flex Fitness Products and Big Dan's Fitness, dated May 25, 2017, **Attachment C**; FDA Warning Letter to Hardcore Formulations, dated June 5, 2017, **Attachment D**; FDA Warning Letter to AndroPharm LLC, dated June 5, 2017 **Attachment E**. And, FDA takes similar actions against unapproved "new drugs" falsely labeled as "medical foods." Indeed, FDA took action in May 2017 against Enzymotec Ltd. (and one of its suppliers) for falsely labeling three omega-3 fatty acid products – Vayarol®, Vayarin®, and Vayacog® – as "medical foods," when they were actually unapproved "new drugs." *See* BRIEF-Enzymotec Ltd- FDA issued import alert that included vayarol, vayarin and vayacog products, Reuters.com, May 10, 2017, **Attachment F**; Import Alert 66-41, Detention Without Physical Examination of Unapproved New Drugs Promoted in the U.S., dated June 19, 2017, **Attachment G**; Enzymotec Ltd., SEC Form 6-K, dated May 2017, **Attachment H**; FDA Warning Letter to Rainbow Gold Products, Inc. dated May 4, 2017, **Attachment I** (citing Vayarin® as an unapproved "new drug").

plaintiff's allegations that the defendant falsely advertised a "dietary supplement" as "safe," "natural," and "legal" were not precluded by the FDCA).

The fact that the Synthetically Produced Omega-3 Products are actually unapproved "new drugs" under the FDCA does not change this analysis. As explained above, FDA need not deem products to be "drugs," for them to be "drugs." Rather, products are drugs based on whether they meet the applicable FDCA statutory definitions. Accordingly, as with the beverage in the *POM Wonderful* case, FDA has not reviewed or approved the labeling of the Synthetically Produced Omega-3 Products.

Since the *POM Wonderful* decision, courts have declined to preclude Lanham Act challenges based on allegedly false and misleading labeling (and other promotional materials) for unapproved "new drugs" – *i.e.,* labeling and promotional materials that have never been reviewed or approved by FDA. *See, e.g., JHP Pharm., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 998 (C. D. Ca. 2014) (involving an unapproved "new drug" that defendant allegedly represented as a safe and effective FDA-approved drug); *Par Sterile Prod. LLC v. Fresenius Kabi USA LLC*, 2015 WL 1263041, *4 (N. D. Ill. March 17, 2015) (same). In those cases, the plaintiffs alleged that defendants were falsely labeling unapproved "new drugs" as FDA-approved drugs, whereas here, the Proposed Respondents are falsely labeling or promoting unapproved "new drugs" as, or for use in, "dietary supplements." *See JHP Pharmaceuticals*, 52 F. Supp.3d at 998; *Par Sterile Products*, 2015 WL 1263041 at *4. There is no material reason to distinguish the present case from these precedents.

The Commission also has instituted at least one case where the Section 337 and Lanham Act claims involved allegations that an FDA-regulated product was mislabeled. In *Certain Potassium Chloride Powder Products*, Inv. No. 337-TA-1013 ("*Potassium Chloride*"), many of

the complainant's Lanham Act allegations focused on the respondent's violation of the FDA's various drug labeling requirements. *See Potassium Chloride* Complaint at ¶¶ 2, 4, 24-56. Specifically, the complainant alleged that the respondents were selling a potassium chloride product – an unapproved "new drug" – with labeling that suggested the product was actually an FDA-approved drug. The Commission instituted the investigation on a 6-0 vote and eventually terminated the investigation based on a settlement agreement.

Amarin's central allegation in this case is that the Proposed Respondents are falsely labeling or promoting Synthetically Produced Omega-3 Products for use in, or as, "dietary supplements," when these products , like the potassium chloride product in *Potassium Chloride*, are actually unapproved "new drugs." In *Potassium Chloride*, as in this case, the respondents were using false labeling to hide the fact that the products are actually unapproved "new drugs." And the false labeling in *Potassium Chloride* and this case have the same purpose – they enable the products to evade FDA premarket review requirements for drugs as well as other drug requirements. In *Potassium Chloride*, the respondents evaded FDA premarket review and other drug regulations by attempting to mislead FDA and consumers into believing that the potassium chloride products had already been reviewed by FDA. In this case, the Proposed Respondents are evading FDA premarket review and other drug regulations by attempting to mislead FDA and potential customers into believing that the Synthetically Produced Omega-3 Products are "dietary supplements," or are intended for use in "dietary supplements." As demonstrated above, "dietary supplements," unlike "drugs," are not subject to premarket review. As such, FDA would not review the labeling of those products before the products are marketed, nor would FDA have the occasion to consider whether the products are actually unapproved "new drugs." Even after the products are marketed, FDA still may not be aware of the statements made in the

labeling or other promotional materials for the products or have the occasion to consider whether the products are actually unapproved "new drugs." Accordingly, as in *Potassium Chloride,* the Proposed Respondents' false statements may go undetected by FDA absent an investigation by the Commission.

Finally, if Proposed Respondents were to strip the "dietary supplement" label and/or other promotional materials from their products, the labeling and other promotional materials would still be literally false by virtue of the failure of the labeling and other promotional materials to state that the products are illegally marketed unapproved "new drugs," whose safety and effectiveness are unknown. If the Proposed Respondents were to disclose that the Synthetically Produced Omega 3 Products were illegally marketed unapproved "new drugs" whose safety and effectiveness are unknown, it is beyond dispute that such disclosure would materially affect purchasing decisions. *See Pfizer Inc. v. Miles Inc.*, 868 F.Supp. 437 (D. Conn. 1994) (holding that an omission that is likely to deter physicians from using an FDA-approved drug is material and makes the advertisement's statement "a literal falsity").

3. Amarin does not request that the Commission review any FDA drug labeling

Under the FDCA, FDA may not approve a drug if the labeling is "false or misleading in any particular." 21 U.S.C. § 355(d)(7). In this case, however, the Synthetically Produced Omega-3 Products have not been reviewed or approved as drugs by FDA, such that FDA had actually reviewed and approved the labeling for the products. FDA approval or even FDA labeling review is not at issue here. Accordingly, Amarin is not asking the Commission to second-guess FDA's determination that FDA-approved drug labeling is false or misleading. Rather, Amarin is asking the Commission to determine simply whether the labeling of a product

that was never reviewed by FDA is false and misleading, just as the plaintiff in *POM Wonderful* asked a district court to review labeling that had never been reviewed by FDA.

Even if Amarin were asking the Commission to review FDA's drug labeling – which it is not – such request would fall within the Commission's jurisdiction. The Second Circuit faced a similar question – whether FDA clearance of a medical device through the 510(k) process precluded a Lanham Act suit challenging the device labeling and other promotional materials as false or misleading – and found that FDA clearance did not immunize the device labeling and promotional materials from Lanham Act claims. *Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics*, 843 F. 3d 48, 63-64 (2d. Cir. 2016). In so holding, the Second Circuit observed that the Supreme Court in *POM Wonderful* had rejected an argument proposed by the government as *amicus curaie* – namely, that when the FDCA or FDA's regulations specifically require or authorize the challenged aspect of a label, the Lanham Act suit should be precluded. *See id.* at 63. According to the Supreme Court, the FDCA and its regulations do not place a "ceiling" on the regulation of food and beverage labeling. *POM Wonderful*, 134 S. Ct. at 2240.

C. The Commission Has Jurisdiction Over Amarin's Section 337 Claims Based On Violations Of The Standards Set Forth In The FDCA

1. Amarin has alleged all the elements of a properly pleaded complaint under Section 337(a)(1)(A)

Section 337(a)(1)(A) provides a stand-alone cause of action for private parties to remedy injury from import competition provided that the complainant can meet all the elements of the statute: importation, domestic industry, injury, standing, and unfair act or unfair method of competition. 19 U.S.C. § 1337(a)(1)(A). *See also, Akzo N.V. v. U.S. Int'l Trade Comm'n,* 808 F.2d 1471, 1486 (Fed. Cir. 1986) ("to prove a violation of § 337, the complainant must show both an unfair act and a resulting detrimental effect or tendency"), citing *New England Butt Co. v. U.S. Int'l Trade Comm'n*, 756 F.2d 874, 876 (Fed. Cir. 1985). Amarin has alleged that the

Proposed Respondents have imported articles into the United States that are being imported or sold using one or more unfair acts or unfair methods of competition. *See* Complaint, § VII. Amarin also has alleged that it has a domestic industry that has been injured by the Proposed Respondents' unfair importation and of articles. *See* Complaint, § X. Further, to the extent Article III standing applies in Commission investigations,[3] Amarin has alleged all the elements of Article III standing required by *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560-61 (1992): (i) it has been injured in fact, *see* Complaint, § XI; (ii) the Proposed Respondents' unfair acts have caused Amarin's injury, *see id.*; and (iii) an exclusion order would likely redress Amarin's injury.[4]

Finally, Amarin has alleged the existence of an unfair act or unfair method of competition. "The concept of unfair competition and unfair practices in trade is a broad concept that covers a wide range of conduct and is not susceptible to precise limitation or definition." *Certain Universal Transmitters for Garage Door Openers*, Inv. No. 337-TA-497 (Initial Determination Concerning Temporary Relief on Violation of Section 337), 2003 WL 22811119 (Nov. 4, 2003). According to the Federal Circuit,

> As a trade statute, the purpose of Section 337 is to regulate international commerce. . . . Section 337 necessarily focuses on commercial activity related to cross-border movement of goods. . . . While Congress has addressed domestic commercial practices under various statutory regimes, such as antitrust (15 U.S.C. §§ 1-38), patent (35 U.S.C. §§ 1-390), and copyright (19 U.S.C. §§ 1-1332), it has established a distinct legal regime in Section 337 aimed at curbing unfair trade practices that involve the entry of

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[3] "Article III standing is not necessarily a requirement to appear before an administrative agency." *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258, 1261 (Fed. Cir. 2014).

[4] Amarin recognizes that the Commission is currently considering the scope of its jurisdiction in a potentially related matter in *Certain Alloy Steel Products*, Inv. No. 337-TA-1002. In the event the Commission issues a decision in that case that affects its jurisdiction in this investigation, Amarin will provide further briefing at an appropriate time.

> goods into the U.S. market via importation. In sum, Section 337 is an enforcement statute enacted by Congress to stop at the border the entry of goods, *i.e.*, articles, that are involved in unfair trade practices.

Suprema, Inc. v. Int'l Trade Comm'n, 796 F.3d 1338, 1344-45 (Fed. Cir. 2015). "When Congress used the words 'unfair methods of competition and unfair acts in the importation of articles,' that language is 'broad and inclusive and should not be limited to, or by, technical definitions of those types of acts.'" *Id.* at 1350. *Accord, In re Von Clemm*, 43 C.C.P.A. 56, 229 F.2d 441, 443 (1955) (Section 337 "provides broadly for action by the Tariff Commission in cases involving 'unfair methods of competition and unfair acts in the importation of articles' but does not define those terms nor set up a definite standard.").

The Commission has looked to Section 5 of the Federal Trade Commission Act ("FTC Act") for guidance on the implementation of Section 337. *Certain Welded Stainless Pipe and Tube*, Inv. No. 337-TA-29, USITC Pub. 863, Comm'n Determ., 1978 WL 50692 at* 18, n. 69 (Feb. 1978) ("Section [337] extends to import trade practically the same prohibition against unfair methods of competition which the [FTC Act] provides against unfair methods of competition in interstate commerce."). *See also Tractor Parts*, Inv. No. 337-22, TC Publ 443 at 14 (Dec. 1971) (Statement of Commissioner Leonard) ("Precedents arising under section 5 of the [FTC Act] are particularly helpful in interpreting Section 337 because of the similarity in the language of the two statutes."). Under Section 5 of the FTC Act, the FTC examines "whether the practice, without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, the common law, or otherwise – whether, in other words, it is within at least the penumbra of some common-law, statutory, or other established concept of unfairness." *Federal Trade Comm'n v. Sperry & Hutchinson Co.,* 405 U.S. 233, 244 n. 5 (1972). *Accord, Certain Universal Transmitters for Garage Door Openers*, Inv. No. 337-TA-497, OUII

Br. On Jurisdiction at 6 (Sept. 16, 2003) ("In a Section 337 investigation, the Commission looks to other statutes, like the Patent Act or Lanham Act, or the common law or other indicia of public policy, to determine the standards by which to judge if acts and practices involving import trade are unfair; but the Commission does not enforce those laws *per se*, it only enforces the provisions of Section 337").

The FDCA provides the standards by which to judge whether the Proposed Respondents' acts and practices involving import trade are unfair. Amarin does not seek to enforce the FDCA or vindicate any public health and safety interests protected by the FDCA. It recognizes that the FDCA is "designed primarily to protect the health and safety of the public at large." *POM Wonderful LLC v. Coca-Cola*, 134 S.Ct. 2228, 2234 (2014). Rather, Amarin seeks to enforce Section 337 against its competitors, which is the appropriate statutory vehicle to redress competitive injury. *See, e.g., TianRui Group Co., Ltd. v. U.S. Int'l Trade Comm'n*, 661 F.3d 1322, 1327 (Fed. Cir. 2011) ("The question under Section 337 is … whether goods imported from abroad should be excluded because of a violation of the congressional policy of protecting domestic industries from unfair competition…."). *Accord*, H.R. Rep. No. 67-1223 at 146 ("[t]he Senate Amendment [to Section 316 of the Tariff Act of 1922, the precursor of Section 337] inserts a new section making unlawful unfair methods of competition and unfair acts in the importation of merchandise into the United States, which threatens the stability or existence of American industry"). Indeed, the scope of the Synthetically Produced Omega-3 Products that Amarin seeks to exclude under the Tariff Act is narrowly tailored to protect Amarin's competitive interest. Amarin has limited its Complaint to the class of products consisting solely of synthetically produced omega-3 products in EE or rTG form that contain more EPA than

DHA, or any other single component, because EPA is the active pharmaceutical ingredient in Amarin's domestic industry product, Vascepa®.

Further, Section 337 complements the FDCA in the same manner as the Lanham Act. As discussed above, in *POM Wonderful*, the Supreme Court found that neither the text of the FDCA, nor the text of the Lanham Act, precludes Lanham Act claims challenging food labels regulated by the FDCA. *POM Wonderful*, 134 S.Ct. at 2237. Similarly, nothing in the text of the FDCA, nor the text of Section 337, forecloses the use of Section 337 to remedy harm from unfair methods of competition or unfair acts in the importation of articles that violate the standards announced in the FDCA:

> The [FDCA and the Lanham Act and, by extension, Section 337] complement each other with respect to remedies in a more fundamental respect. Enforcement of the FDCA and the detailed prescriptions of its implementing regulations is largely committed to the FDA. The FDA, however, does not have the same perspective or expertise in assessing marketing dynamics that day-to-day competitors possess. Competitors who manufacture or distribute products have detailed knowledge regarding how consumers rely upon certain sales and marketing strategies. Their awareness of unfair competition practices may be far more immediate and accurate than that of agency rulemakers and regulators. Lanham Act [and, by extension, Section 337] suits, draw upon this market expertise by empowering private parties to sue competitors to protect their interests on a case-by-case basis. By "serv[ing] a distinct [remedial] function that may motivate injured persons to come forward," Lanham Act [and, by extension, Section 337] suits, to the extent they touch on the same subject matter as the FDCA, "provide incentives" for manufacturers to behave well. . . . Allowing Lanham Act [and, by extension, Section 337] suits takes advantage of synergies among multiple methods of regulation. This is quite consistent with the congressional design to enact two different statutes, each with its own mechanisms to enhance the protection of competitors and consumers. . . .

POM Wonderful LLC, 134 S.Ct. at 2238-39. As mentioned above, since the Supreme Court's *POM Wonderful* decision, the Commission has instituted at least one investigation that alleged

violations of the Tariff Act based on the standards set forth in the FDCA in conjunction with false advertising claims under the Lanham Act. *Potassium Chloride,* Inv. No 337-TA-1013. And, there is no material reason to distinguish the allegations in *Potassium Chloride* from the allegations here.

Finally, Section 337 investigations are not constrained by the absence of a private right of action under the FDCA. The courts have recognized that actions under Section 337(a)(1)(A) are distinct trade enforcement proceedings, separate from private court actions under other provisions of federal law. *Spansion Inc. v. Int'l Trade Comm'n,* 629 F.3d 1331, 1359 (Fed. Cir.. 2010) (holding that the Commission should follow the "remedial scheme established by Congress for proceedings before the Commission," and not "the statutory remedies available in proceedings before the district courts.").

The Federal Circuit's landmark decision on trade secret misappropriation in *Tian Rui Group Co., Ltd. v. U.S. Int'l Trade Comm'n*, 661 F.3d 1322 (Fed. Cir. 2011), supports Commission jurisdiction over Amarin's FDCA-related claims. In earlier Section 337 investigations involving trade secret misappropriation, the unfair trade practice was alleged to be a violation of state trade secret theft law. In *Tian Rui,* however, the Federal Circuit held that "a single federal standard, rather than the law of a particular state, should determine what constitutes a misappropriation of trade secrets sufficient to establish an 'unfair method of competition' under Section 337." *Id.* at 1327. Since then, the Commission has investigated a number of violations of trade secret theft under Section 337(a)(1)(A) using the judicially created federal common law standard. Notably, the Federal Circuit's "federal common law" standard did not give rise to a private right of action in federal court for trade secret misappropriation, and no parallel federal cause of action for trade secret theft existed until the 2016 enactment of the

Defend Trade Secret Act ("DTSA"). Nevertheless, the Commission exercised jurisdiction over a number of post-*Tian Rui*, pre-DTSA trade secret theft investigations even though no provision of substantive federal law provided a parallel federal cause of action at the time.

Commission precedent also makes clear that Section 337 is a separate statutory remedy that is not constrained by the pleading requirements of other federal statutes. *See, e.g., Certain Elec. Audio and Related Equip.*, Inv. No. 337-TA-7, Comm'n Op. 1976 (Apr. 2, 1976) ("[S]ection 337 is a unique statute, applicable to the importation of merchandise, and therefore may reach conduct which might not apply to other ... laws."). It would be error to impose the pleading requirements of a statute like the FDCA on a statutory scheme like Section 337.

2. Amarin's claims are not barred by the primary jurisdiction doctrine

Proposed Respondents are likely to argue that the Commission should decline to institute this investigation under the "primary jurisdiction" doctrine and, instead, refer this matter to the FDA for its decisions on the merits. Under the primary jurisdiction doctrine, "a court, though having jurisdiction to hear the complaint, may in some situations be required to 'refer' the matter to an administrative agency for resolution of a particular technical issue." *JHP Pharm*, 52 F. Supp. 3d at 1001, citing *Reiter v. Cooper*, 507 U.S. 258, 268 (1993) ("[C]laims properly cognizable in court [may] contain some issue within the special competence of an administrative agency."). The primary jurisdiction doctrine, however, does not authorize an agency seized with jurisdiction over a matter not to exercise that jurisdiction in deference to another agency. *See Certain Alkaline Batteries,* Inv. No. 337-TA-165, Order No. 18 at 2 (Mar. 26, 1984) ("There exists no legal precedent for expanding th[e] common law doctrine [of primary jurisdiction] beyond its present parameters so as to incorporate those instances where one agency refrains from exercising its own jurisdiction until a second agency first addresses the questions presented. ... Therefore, [respondents'] assertion that the Customs Service has primary jurisdiction over

alleged failures to mark country of origin as well as alleged trademark and trade dress violations and that both the Customs Service and the Federal Trade Commission have primary jurisdiction over alleged violations of the Fair Packaging and Labeling Act lacks legal foundation."). *Accord Certain Light-Emitting Diode Products and Components Thereof*, Inv. No. 337-TA-945, Initial Determination at 422-430 (Sept. 2, 2016) (exercising jurisdiction over complainants' false advertising claims and rejecting respondents' primary jurisdiction defense).

The primary jurisdiction doctrine cannot foreclose institution of a Section 337 investigation based on Amarin's properly pleaded Complaint. The Commission is an administrative agency, not a part of the judicial branch. It has an independent statutory mandate to institute an investigation into unfair trade practices and unfair methods of competition based on a properly pleaded complaint. 19 U.S.C. § 1337(b)(1) ("The Commission *shall investigate* any alleged violation of this section on complaint under oath . . . .") (emphasis added). To the extent Amarin's Complaint properly alleges all the elements of a violation of Section 337, the Commission must institute an investigation. [5]

Section 337 further makes clear that the Commission must proceed with a properly pleaded Section 337 investigation even if FDA provides input. According to the statute, "[d]uring the course of each investigation, the Commission shall consult with, and seek advice and information from, [FDA]." 19 U.S.C. § 1337(b)(2). *See also* 19 C.F.R. § 210.11(a)(4)

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[5] The Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration, MOU 225-71-8003 (1971), does not support the exercise of primary jurisdiction of the FDA. First, the ITC was not a party to that MOU. Second, unlike the FTC and FDA, which have discretion to enforce violations of the FTC Act and the FDCA, respectively, the ITC is required to investigate properly pleaded complaints within its jurisdiction. 19 U.S.C. § 1337(b)(1). Accordingly, no agency-driven division of enforcement authority can foreclose institution of a Section 337 investigation based on a properly pleaded complaint. Finally, the MOU pre-dates *POM Wonderful*, which makes clear that private causes of action are available to redress competitor injury based on false food labeling.

("The Commission shall serve copies of the notice of investigation upon [FDA]"). In other words, FDA's views can be provided under existing ITC procedures within the structure of a Section 337 investigation, not to the exclusion of the Section 337 investigation. The fact that the Commission must seek FDA's input, or that the FDA may wish provide the Commission with an interpretation of the FDCA, does not deprive the Commission of jurisdiction.

Finally, even if the primary jurisdiction doctrine were to apply – which it does not -- there is no need to apply it in this case. "The doctrine applies where there is '(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory scheme that (4) requires expertise or uniformity in administration.'" *JHP Pharma*, 52 F. Supp. 3d at 1001, citing *United States v. Gen. Dynamics Corp.*, 828 F.2d 1356, 1362 (9th Cir. 1987). The doctrine is not designed to "secure expert advice" from an agency "every time a court is presented with an issue conceivably within the agency's ambit." *Clark v. Time Warner Cable,* 523 F.3d 1110, 1114 (9th Cir. 2008).

No legal or policy issues presented by Amarin's Complaint require resolution by the FDA. As discussed extensively in Section VI.A.1 of the Complaint, Amarin's arguments that the Synthetically Produced Omega-3 Products do not meet the definition of "dietary supplement" reflect FDA's well-established policies and pronouncements in that area, and the products at issue clearly meet the definition of "drug" in the FDCA.

3. The Commission's decision in *Hydroxyprogesterone Caproate* has no bearing on the Commission's jurisdiction over Amarin's Complaint

Before the Supreme Court's *POM Wonderful* decision, the Commission declined to institute a Section 337 investigation based on allegations that the respondents had violated

certain provisions of the FDCA. *See Hydroxyprogesterone Caproate And Products Containing The Same*, ITC Docket No. 2991 ("*HPC*"). According to the Commission:

> KV'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 also notes that the Food and Drug Administration ("FDA") is charged with the administration of the Food, Drug, and Cosmetic Act. *See KV Pharmaceutical Co. v. FDA*, 1:12-cv-001105-ABJ, __ F. Supp. 2d __ (D.D.C. Sept. 6, 2012).

HPC, ITC Docket No. 2919, Letter to Counsel for K-V dated December 21, 2012. Two Commissioners filed a Concurring Memorandum in which they agreed with the Commission's decision, but noted "that they do not reach the issue of whether properly pleaded claims based on the Food, Drug, and Cosmetic Act may be cognizable under Section 337(a)(1)(A)." *HPC*, ITC Docket No. 2919, Concurring Memorandum dated December 21, 2012.

The Commission's *HPC* decision has no bearing on the Commission's jurisdiction over Amarin's Complaint. First, *HPC* was decided before the Supreme Court's *POM Wonderful* decision. As discussed above, *POM Wonderful* authorized the use of a private right of action under the Lanham Act to redress competitive injury arising from food mislabeling, even though the FDA also had jurisdiction over food mislabeling under the FDCA. As further discussed above, Section 337, like the Lanham Act, provides a vehicle for vindicating competitor claims based on mislabeling of imported food and other violations of the FDCA. And nothing in the text of the FDCA, nor Section 337, precludes Section 337 challenges involving the labeling and promotion of FDA-regulated products.

Second, HPC was decided against a legal background that has changed radically since the Commission's decision. The *HPC* complainant filed its Section 337 complaint after it unsuccessfully brought an action in U.S. district court to compel the FDA to enforce the Orphan

Drug provisions of the FDCA against certain drug compounders. *K-V Pharm. Co. v. U.S. Food and Drug Admin.*, 889 F. Supp. 119 2d (D.D.C. 2012), *vacated and remanded*, 2014 WL 68499 (D.C. Cir. Jan. 7, 2014) ("*K-V Pharma*"). The district court in that case refused to review the FDA's decision not to enforce the FDCA against compounding pharmacies that were selling unapproved versions of one of K-V Pharma's FDA-approved drugs. In so refusing, the district court cited the Supreme Court's decision in *Heckler v. Chaney*, 470 U.S. 821 (1985).

In *Heckler*, inmates who had been sentenced to death by lethal injection sued the FDA for failing to take action against the drugs used for lethal injection. They argued that FDA was compelled to take action because the drugs were "misbrand[ed]" and unapproved "new drugs" for the purpose of lethal injection in violation of the FDCA. *Heckler*, 470 U.S. at 823-24. The Supreme Court observed that "an agency's decision not to take enforcement action should be presumed immune from judicial review under § 701(a)(2) [of the APA]." *Id.* at 832. But the Court conceded that "the presumption may be rebutted where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers." *Id.* at 832–33. Nevertheless, the Court found that (1) none of the enforcement provisions in the FDCA (*i.e.*, 21 U.S.C. §§ 332 (injunctions), 333 (criminal sanctions), 334 (seizure), and 335 (criminal sanctions)) – which enforce the prohibitions in Section 301 of the FDCA, 21 U.S.C. § 331 – provided any such guidelines limiting FDA's enforcement discretion (*i.e.*, making FDA enforcement mandatory), and (2) the misbranding and the unapproved "new drug" provisions in Sections 502(f) and 505(a) of the FDCA, 21 U.S.C. §§ 352(f), 355(a), were "irrelevant to the agency's discretion to refuse to initiate proceedings." *Heckler*, 470 U.S. at 835-36. Therefore, the Supreme Court held that the presumption against reviewability had not been rebutted.

After the Commission decided not to institute the *HPC* investigation, however, the D.C. Circuit Court vacated *K-V Pharma* and remanded the case to the district court for reconsideration of its decision in part, because of the decision in *Cook v. Food & Drug Admin*, 733 F.3d 1 (D.C. Cir. 2013). *K-V Pharmaceutical Co. v. U.S. Food and Drug Admin,* 2014 WL 68499 (Jan. 7, 2014). As in *Heckler*, *Cook* involved inmates on death row who sued FDA alleging that the agency's policy of permitting state correctional departments to import a drug used for lethal injection (again, a "misbranded" and unapproved "new drug") violated the FDCA, among other laws. *Cook,* 733 F.3d at 3. Unlike the inmates in *Heckler*, however, the inmates in *Cook* won. *See id.* at 12. The D.C. Circuit permanently enjoined FDA from permitting the entry into the United States of, or releasing any future shipments of, foreign manufactured sodium thiopental that appears to be misbranded or an unapproved "new drug." *See id.*

The decision in *Cook* turned upon the mandatory language in Section 801(a) of the FDCA, 21 U.S.C. § 381(a). Section 801(a) provides:

> The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services [HHS], upon his request, samples of ... drugs ... being imported or offered for import into the United States.... The Secretary of [HHS] shall furnish to the Secretary of the Treasury a list of establishments registered [with the FDA] ... and shall request that if any drugs ... manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs ... be delivered to the Secretary of [HHS].... If it appears from the examination of such samples or otherwise that ... such article is adulterated, misbranded, or [an unapproved new drug] ..., then such article shall be refused admission.

Cook, 733 F.3d at 3. In other words, Section 801(a) requires FDA to (1) sample any drugs that have been manufactured in an unregistered establishment and (2) examine samples to determine whether any appear to be misbranded, adulterated, or unapproved "new drugs." *See id.* And, if FDA finds an apparent FDCA violation (*e.g.,* that a product is an unapproved, misbranded, and

adulterated "new drug"), it must refuse the drug admission to the United States. *See id.* According to the D.C. Circuit, the language in Section 801(a) gave sufficient guidance to FDA, limiting the agency's enforcement discretion, to rebut the presumption articulated in *Heckler*. *See Cook*, 733 F.3d at 10.

The D.C. Circuit's *Cook* decision supports the institution of this investigation notwithstanding *HPC*. As explained above, FDA's jurisdiction, pursuant to the FDCA, over "dietary supplement" labeling and unapproved "new drugs" does not preclude a Section 337 investigation here; nor must a Section 337 investigation be based upon the violation of standards set forth in a statute with a private right of action. But, even if that were not the case, in *Cook*, the D.C. Circuit made clear that private parties have a right to challenge an FDA decision not to enforce Section 801(a) of the FDCA, particularly when the drugs are being imported. In other words, Section 801(a) of the FDCA provides a derivative private right of action. If FDA were to refuse to enforce Section 801(a) of the FDCA against the Proposed Respondents importing synthetically produced omega-3 products, Amarin could sue FDA to force the agency to refuse admission of the imported products because (1) upon information and belief, the products are manufactured in an unregistered establishment and (2) as established in Section VI.A. of the Complaint – the products are misbranded, adulterated, and unapproved "new drugs."

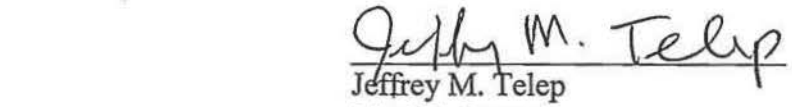
Third, unlike *K-V Pharma*, the FDA has not refused to enforce the FDCA against the importers of the Synthetically Produced Omega-3 Products in this investigation. Rather, as shown in paragraph 67 of the Complaint, the FDA's enforcement actions and pronouncements over the last fifteen years FDA support Amarin's arguments that the Synthetically Produced Omega-3 Products do not meet the definition of "dietary supplement." In fact, Amarin's arguments are based on long-settled FDA interpretations of the definition of "dietary

supplement" in Section 201(ff) of the FDCA, 21 U.S.C. § 321(ff). Further, for the reasons explained in Section VI.A.1.b of the Complaint, the Synthetically Produced Omega-3 Products each meet the definition of "drug" in the FDCA. Again, FDA need not deem products to be "drugs," for them to be "drugs." Because Amarin's arguments do not turn on open questions of law or policy, there is no reason for the Commission to wait for FDA to weigh in on the issues raised here; FDA has already weighed in.

III. CONCLUSION

For the foregoing reasons, Amarin respectfully submits that the Commission has jurisdiction over all the claims in Amarin's Complaint.

Respectfully submitted,



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