Nos. 18-1247, 18-114

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMARIN PHARMA, INC. AND
AMARIN PHARMACEUTICALS IRELAND LTD.,
Appellants,

v.

INTERNATIONAL TRADE COMMISSION,
Appellee,

ROYAL DSM NV, DSM MARINE LIPIDS PERU S.A.C.,
DSM NUTRITIONAL PRODUCTS LLC, DSM NUTRITIONAL
PRODUCTS CANADA, INC., PHARMAVITE LLC,
NORDIC NATURALS, INC. AND NORDIC PHARMA, INC.
Intervenors.

On Appeal from the U.S. International Trade Commission, ITC Docket No. 3247
(*Caption continued below*)

CORRECTED BRIEF OF *AMICUS CURIAE* COUNCIL FOR RESPONSIBLE NUTRITION AND GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S IN SUPPORT OF APPELLEE FOR DISMISSAL

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In re: AMARIN PHARMA, INC.
AMARIN PHARMACEUTICALS IRELAND LTD.,
Petitioners

On Petition for Writ of Mandamus to the United States International Trade Commission, ITC Docket No. 3247

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Amarin Pharma, Inc., et al **v.** International Trade Commission

Case No. 18-1247 - 114

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ☐ (appellant) ☐ (respondent) ☐ (appellee) ■ (amicus) ☐ (name of party)

Council for Responsible Nutrition

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Council for Responsible Nutrition	None	None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me 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:

None.

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).

None.

3/22/2018
Date

/s/ Deanna Tanner Okun
Signature of counsel

Please Note: All questions must be answered

Deanna Tanner Okun
Printed name of counsel

cc: _____

Reset Fields

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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☐ (petitioner) ☐ (appellant) ☐ (respondent) ☐ (appellee) ■ (amicus) ☐ (name of party)

Global Organization For EPA and DHA Omega-3S

certifies the following (use "None" if applicable; use extra sheets if necessary):

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Global Organization For EPA and DHA Omega-3S	None	None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me 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:
Joseph E. Cwik.

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).

None.

3/22/2018
Date

/s/ Deanna Tanner Okun
Signature of counsel

Please Note: All questions must be answered

Deanna Tanner Okun
Printed name of counsel

cc: Joseph E. Cwik

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IDENTITY AND INTEREST OF AMICUS CURIAE[1]

Council for Responsible Nutrition ("CRN") is a leading trade association in the field of dietary supplements, representing over 150 companies comprising dietary supplement and functional food manufacturers, as well as suppliers of ingredients and ancillary services to dietary supplement manufacturers. CRN's members include popular name brands and less-known generic store brands often marketed by supermarkets and drug stores; its members produce dietary supplements across a wide range of industries, including vitamins, minerals, and specialty supplements like the concentrated omega-3 products at issue here. CRN provides its members with industry guidance on, *inter alia*, matters relating to science and research, regulations, legislation, and international affairs related to the dietary supplement industry. CRN also takes a leadership role, often advocating for public policies to ensure consumer access to a wide array of high quality, safe, and effective dietary supplement products.

The Global Organization for EPA and DHA Omega-3s ("GOED") is a 501(c)(6) not for profit dietary supplement trade association with over 200 members involved in all segments of the omega-3 supply chain. The organization's mission

[1] No counsel for a party authored this brief, in whole or in part, and no party or party's counsel contributed money intended to fund the preparation or submission of this brief. No person, other than *amicus curiae*, its members, or its counsel, contributed money intended to fund this brief's preparation or submission.

is to educate the public regarding the health benefits of omega-3 fatty acids such as eicosapentaenoic acid ("EPA"), to ensure high quality standards and to support sustainable practices for the industry.

Together, CRN's and GOED's members produce a large percentage of the dietary supplements marketed in the United States and globally. Many of CRN's and GOED's members were named by Appellants Amarin Pharma, Inc., and Amarin Pharmaceuticals Ireland Ltd. (collectively, "Amarin") in the Complaint underlying this Appeal, such as the Intervenors.

Because the underlying Complaint seeks a general exclusion order—which would affect unnamed providers of concentrated omega-3 products—many of CRN's and GOED's members that were not named as Proposed Respondents in the Complaint could nonetheless be implicated and adversely affected by Amarin's claims. Accordingly, CRN and GOED seek to utilize their unique positions as trade associations to advocate for the interests of the dietary supplement industry members and consumers, and to address matters relevant to the disposition of this case, such as the Food and Drug Administration's ("FDA") regulation of dietary supplements, the FDA's application of the Federal Drug and Cosmetic Act ("FDCA") to dietary supplements, and the likely complications of both the FDA and the U.S. International Trade Commission ("Commission") interpreting regulations governing the dietary supplement industry.

CRN's and GOED's authority to file this brief comes from Federal Rule of Appellate Procedure 29 and Federal Circuit Rule 29, which permit amicus curiae to file a brief with the consent of all parties. All parties have consented to CRN's and GOED's filing of this amicus brief.

SUMMARY OF THE ARGUMENT

Amarin is once again before the wrong arbiter of the question central to its Lanham Act claim: whether the Proposed Respondents' concentrated omega-3 products meet the statutory definition of "dietary supplements" in the FDCA, 21 U.S.C. § 321(ff). Instead of bringing its concerns about an FDCA violation to the FDA, the agency exclusively tasked to enforce the FDCA, Amarin filed the Complaint underlying this appeal before the Commission. Rather than accept the Commission's appropriate dismissal of its Complaint, Amarin now improperly attempts to force the requested investigation through appeal or mandamus.

Amarin's appeal and petition for a writ of mandamus must be dismissed. Amarin has not shown it is entitled to the extraordinary and unprecedented relief it seeks from this Court—an order requiring the Commission to investigate claims predicated on interpreting a statutory definition exclusively enforced by the FDA. Amarin has not shown the FDA is unable or unwilling to take action against the Proposed Respondents, if it agreed with Amarin's view. Nor can Amarin show such inability or unwillingness in the face of decades of FDA awareness of concentrated

omega-3 dietary supplements and FDA efforts to issue industry guidance. Rather, than pursue relief from the FDA, which Amarin has not shown would be inadequate, Amarin pursues concurrent interpretation and enforcement of the FDCA by the Commission. That outcome would undoubtedly create confusion not only for the Proposed Respondents, but the dietary supplement industry at large.

More critically, Amarin's pleas for institution ignore the fundamental flaw in the Lanham Act claim for false advertising it filed with the Commission, and its failure to comply with the Commission's pleading requirements. The Commission's requirements for a properly pled complaint are clear and long-standing, as are the elements for false advertising. Amarin's Complaint failed to allege the objective facts necessary for the Commission to investigate its claim, based on literal falsity, and was consequently dismissed without prejudice. Inherent in the Commission's dismissal is recognition that Amarin could not, and still cannot, properly plead false advertising because the requisite factual premise—that the Proposed Respondents' products are not "dietary supplements" under the FDCA—does not exist and will not exist until the FDA makes such a determination. Because Amarin's pleading deficiency was and remains incurable, the Commission's dismissal of its Complaint was proper and should be upheld through dismissal of this appeal and petition.

ARGUMENT

I. There Is No Basis to Grant Amarin's Petition for Writ of Mandamus

Even if this Court determines it has mandamus jurisdiction, there is no basis to grant Amarin's petition for a writ of mandamus compelling the Commission to institute an investigation based on Amarin's Complaint. *See* Intervenors Br. at 34–37. "A writ of mandamus is a 'drastic and extraordinary remedy'" reserved for "'exceptional circumstances'" involving "'a clear abuse of discretion'" by the Commission. *Shaw Indus. Group, Inc. v. Automated Creel Sys., Inv.*, 817 F.3d 1293 (Fed. Cir. 2016) (citing *Cheney v. U.S. Dist. Court for D.C.*, 542 U.S. 367, 380 (2004)). Issuance of a writ requires Amarin to show that it has a "'clear and indisputable' right to the writ," and "no other adequate means to attain [its] desired relief," as well as this Court's satisfaction that compelling the Commission to institute an investigation "is appropriate under the circumstances" of Amarin's Complaint. *Id.*; *see also* Amarin Opening Br. at 27.

Amarin has not established a "clear and indisputable right" to a Commission investigation and, therefore, to a writ of mandamus compelling institution of an investigation. Furthermore, the Commission does not have a "clear duty to act [i.e., institute]" regardless of whether the preconditions to institution of an investigation are met. *See In re Cypress Semiconductor Corp.*, 321 Fed. Appx. 964, 967 (Fed. Cir. 2009) ("To decide the question presented by this mandamus petition, we need

only decide whether Cypress has shown that the Commission clearly and indisputably erred . . . . We determine that Cypress has not met its burden and thus deny the petition."). The Commission's decision to institute an investigation is discretionary and depends on satisfaction of its rules governing complaints. As discussed in Section IV., *infra*, Amarin's Complaint fails to satisfy those requirements.

Amarin has also failed to show that it has "no other adequate means to attain" the relief it seeks—injunctive relief based on a finding that Respondents' products do not meet the FDCA definition of "dietary supplement." *See* Appx112. Amarin can, and should, pursue the FDCA enforcement it seeks before the FDA, and has not argued that it has exhausted its ability to do so. *See* 21 U.S.C. §§ 337(a), 393(a); *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 928 (9th Cir. 2010) (describing means by which a private litigant can present a complaint or alleged violation of the FDCA to the FDA). Amarin has not shown that the FDA is unwilling or unable to take enforcement action against the Proposed Respondents Amarin believes to be violating the FDCA. Instead, Amarin attempts to bypass the regulatory framework established by Congress and exclusively delegated to the FDA by forcing the Commission to interpret and enforce the FDCA where the FDA has not elected to take action. *See infra* Sec. III; *see also PhotoMedex*, 601 F.3d at 928 ("PhotoMedex is not permitted to circumvent the FDA's exclusive enforcement authority by seeking

to prove that Defendants violated the FDCA, when the FDA did not reach that conclusion.").

Amarin also has potential private causes of action available to it, should the FDA choose not to act. In that circumstance, Amarin may pursue district court action, either to compel FDA enforcement improperly withheld, or to take private action against the Proposed Respondents if the FDA determines that their products are not "dietary supplements." *See, e.g.*, *Cook v. Food & Drug Admin.*, 733 F.3d 1 (D.C. Cir. 2013) (affirming district court injunction of FDA's refusal to enforce its statutory mandate); *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 510, 513 (7th Cir. 2009) ("Schering jumped the gun by suing before the FDA addressed the misbranding issue."). Further, because the Commission's dismissal of Amarin's Complaint is without prejudice, Amarin may re-file its Complaint if the missing fact—a finding that the products at issue are not "dietary supplements"—is established by the FDA. *See infra* Sec. IV.B. Because Amarin has other potential avenues of relief, which it has not shown to be exhausted or inadequate, this Court should not grant Amarin's petition.

II. The Requested Investigation Would Frustrate the Established Framework Governing Interpretation of the FDCA

The FDA is explicitly authorized to apply its unique expertise to interpret the FDCA, and to enforce any violations thereof. Amarin's Complaint requests that the Commission inject itself into the statutory and regulatory framework, a request

properly rejected by the Commission. Here, Amarin now asks that this Court mandate that the Commission conduct an investigation in which it makes its own interpretation under the FDCA to determine whether Proposed Respondents' products are properly labeled as "dietary supplements." Amarin's requested relief would frustrate Congress's clear intent that the FDA interpret and enforce the FDCA, and would frustrate the FDA's own efforts to do so. Mandating that the Commission make the requested determination would also cause confusion and disruption in the dietary supplement market, as well as in the markets for the wide range of products regulated by the FDA.

A. The FDA Regulates Products and Conducts Enforcement Pursuant to the FDCA

The FDCA provides the FDA the authority to regulate, *inter alia*, whether products are "drugs" or "dietary supplements." 21 U.S.C. §§ 355, 350b. Indeed, the FDCA established the FDA to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products . . . ." 21 U.S.C. § 393(a)–(b).

The Supreme Court has stated that the "heart" of the procedures designed by Congress for determining whether products are, for example, "drugs" under the FDA "is the grant of primary jurisdiction to FDA, the expert agency [Congress] created." *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973). Lower courts have also recognized the FDA's exclusive jurisdiction to determine whether

a product qualifies as a "dietary supplement" or a "drug" under the FDCA. *See Hi-Tech Pharms., Inc. v. Hodges Consulting, Inc.*, 230 F. Supp. 3d 1323, 1330–31 (N.D. Ga. 2016) (noting "Congress has delegated exclusively to the FDA" the ability to make a determination of whether a drug is a new drug or a prescription drug under the FDCA).

The FDA, in making such determinations, applies its acquired expertise and experience. *See Hi-Tech Pharms., Inc.*, 230 F. Supp. 3d at 1330 ("'The determination of whether a drug is "new," and whether it can be lawfully marketed under the FDCA, involves complex issues of history, public safety, and administrative priorities . . . .'") (quoting *JHP Pharm., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 999 (C.D. Cal. 2014)). In its letter to the Commission urging the Commission not to institute the requested investigation, the FDA noted the undeniable complexity of the statutory scheme surrounding the requested determination of whether a product is a dietary supplement. *See* Appx628. As the FDA succinctly stated, determinations such as the one requested by Amarin require, *inter alia*, "a careful and thorough scientific review of the ingredients of the product at issue as well as a review of the history of those ingredients." *Id.* The FDA, specifically created to develop and apply expertise and experience in making such complex determinations, should be permitted to do so as the exclusive administrative arbiter of statutory and regulatory interpretation of the FDCA.

B. The FDA Is Actively Analyzing what Constitutes a "Dietary Supplement" under the FDCA

Concentrated omega-3 fish oil products, like the Proposed Respondents' products, are derived from oil extracted from fish, i.e., common fish oil, and, contrary to Amarin's misleading Complaint caption, are not created in a laboratory or by other "synthetic" means. Concentrated omega-3 fish oil products are frequently taken by healthy individuals to maintain and promote health—i.e., *not* as "drugs" intended to treat disease. As Amarin acknowledges, the FDA has been aware of concentrated omega-3 products being marketed as "dietary supplements" since the "late 1980s." Appx45. Nonetheless, the FDA has not excluded those products from its definition of "dietary supplement," nor determined that these products violate the standards of the FDCA.

That does not, as Amarin suggests, mean that the FDA is sitting idle or is insufficiently staffed to perform its duties under the FDCA. Appx19–20. To the contrary, the record demonstrates that the FDA is in the process of applying its specialized expertise to comprehensively address the complex issues surrounding the interpretation of "dietary supplements" under the FDCA. Appx627–629. As part of its analysis, the FDA is developing a guidance document regarding when a dietary supplement ingredient is a new dietary ingredient ("NDI") under the FDCA, the evidence needed to document the safety of an NDI, and other related issues. *See* Appx628; *see also* 21 U.S.C. § 371(h)(1)(A) (directing the FDA to create and

develop such guidance documents). The FDA published a draft guidance document in 2011 and, after thousands of public comments, issued revised draft guidance in 2016. *See* Appx628–629, *see also Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Availability*, 76 Fed. Reg. 39,111 (Jul. 5, 2011); *Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Availability*, 81 Fed. Reg. 53,486 (Aug. 12, 2016). The FDA also held a public meeting to discuss issues related to its draft guidance in October 2017. *See* Appx629.

Amarin's Complaint points to no enforcement actions taken by the FDA against the Proposed Respondents' products, despite the FDA's awareness and extensive, ongoing analysis. Amarin brushes these facts aside, arguing that the FDA's failure to issue warning letters or take other enforcement actions against concentrated omega-3 products is due to "limited resources" or failure to "act[] to the full extent of [its] authority." Appx19–20. The actions detailed above demonstrate the falsity of this premise; the FDA is actively conducting the analysis it is commanded and exclusively authorized by the FDCA to undertake. Indeed, the amount of time and effort put in by the FDA demonstrates the impracticality of an agency that specializes in international trade making the same determination on a compressed statutory timeframe. 19 U.S.C. § 1337(b)(1) (mandating that the Commission complete investigations at "the earliest practicable time").

C. Interpretation of the FDCA Definition of "Dietary Supplement" by the ITC Would Cause Market Confusion and Create a Risk of Inconsistent Agency Determinations

Industry participants in the dietary supplement market operate in a regulatory environment in which pre-market approval is not required to advertise or sell "dietary supplements" under 21 U.S.C. § 321(ff). Nevertheless, industry participants who market products as dietary supplements are subject to the FDA's extensive authority over the manufacturing, marketing and labeling of their products, and to its authority to interpret the term "dietary supplements" in a manner that could require changes in their product labeling. *See, e.g.*, 21 C.F.R. §§ 101, 111, and 190. This relative uncertainty is mitigated by the understanding, supported by the FDCA and by relevant case law, that the FDA is the sole administrative arbiter of whether labeling of such products comports with the FDCA. *See infra* Sec. IV.B.2.b (addressing the FDA's exclusive authority to interpret and enforce the FDCA). Here, Amarin's request would compound the existing uncertainty by forcing the ITC to concurrently interpret the FDCA, which would cause significant market disruption.

This is particularly true under the current circumstances, where market participants have significant reason to believe that the current practice of labeling concentrated omega-3 products as "dietary supplements" is proper. In addition to the absence of any enforcement action relating to concentrated omega-3 products,

the FDA's Draft 2016 "Guidance for Industry" document indicates that the FDA considers esterification and the use of ethanol to be accepted chemical reactions that are commonly used in the production of dietary ingredients for use in dietary supplements. *See* Appx747, Appx749, Appx822. Amarin concedes that Respondents' products are created by "react[ion] with ethanol through a process known as esterification." Appx13. This strongly suggests that the FDA's inaction is due to a preliminary conclusion that concentrated omega-3 products are properly labeled as dietary supplements. *See also* 81 Fed. Reg. at 53,488. (noting that the 2016 Draft Guidance document contains a discussion of when synthetic copies of dietary ingredients qualify as dietary ingredients under the FDCA).

Whether or not the FDA has made any preliminary conclusions, the FDA should be permitted to take the time necessary to apply its unique expertise to interpret the FDCA in an orderly manner. While the FDA evaluates the issue, parties like Amarin should not be permitted to forum-shop in the hope that the Commission yields quicker—and perhaps inconsistent—results. Allowing such forum-shopping would leave market participants with no way of knowing which agency will make the decision, or which decision to follow if the agencies make inconsistent determinations on this issue.

This burden and uncertainty can be avoided by this Court following its sister circuits and affirming the Commission's decision that Amarin's Complaint was not

cognizable under Section 337. As discussed below, that conclusion is consistent with established Commission interpretations of its governing statute and regulations implemented thereunder.

III. The Commission Correctly Dismissed Amarin's Complaint for Failing to Satisfy Its Pleading Standards

The Commission's discretion not to institute an investigation is properly exercised where a complaint fails to allege facts constituting an unfair method of competition or unfair act. Amarin's Complaint alleges a violation of Section 337 tethered to, and necessarily requiring an interpretation of, the FDCA to render its claims actionable. As filed with the Commission, Amarin's Complaint fails to plead a legally cognizable claim under Section 337 and, consequently, the Commission's determination not to institute should be affirmed.

A. The Commission's Rules Require Factual and Legal Sufficiency in a Complaint

Even accepting Amarin's (incorrect) argument that Section 337 mandates institution of investigations based on complaints, the question of whether a Section 337 investigation should be instituted based on a complaint nonetheless depends on whether that particular complaint complies with the Commission's pleading requirements. Through the Tariff Act of 1930, Congress explicitly authorized the Commission to adopt procedures, rules, and regulations for fulfilling its statutory mandate, including its mandate to "investigate any alleged violation of this section

on complaint." *See* 19 U.S.C. §§ 1335, 1337(b)(1). The Commission has adopted Rules of Practice and Procedure, which it must follow with consistency. *See, e.g.*, 19 C.F.R. §§ 201, 210; *see also Align Tech., Inc. v. Int'l Trade Comm'n*, 771 F.3d 1317, 1325 (Fed. Cir. 2014) ("[T]he Commission cannot circumvent its own rules."). As demonstrated below, these rules require non-institution of the requested investigation.

Commission Rules 210.9 and 210.10 require the Commission to "examine the complaint for sufficiency and compliance" to determine whether it "is properly filed and whether an investigation should be instituted," while Commission Rule 210.12 defines the contents required for a "complaint." 19 C.F.R. §§ 210.9(a), 210.10(a)(1), 210.12. Commission Rule 210.12(a)(2) specifically requires a "properly-filed" complaint to "[i]Include a statement of the facts constituting the alleged unfair methods of competition and unfair acts[.]" 19 C.F.R. § 210.12(a)(2).

The Tariff Act and the Commission Rules contemplate institution of an investigation ***only*** if a complaint includes each of the elements required by Commission Rule 210.12. Thus, the Commission has the authority and discretion not to institute an investigation upon receiving a complaint, if that complaint fails to comply with its pleading requirements. *See Syntex Agribusiness, Inc. v. Int'l Trade Comm'n*, 659 F.2d 1038, 1044–45 (C.C.P.A. 1981) (upholding Commission's determination not to institute an investigation based on a complaint that "disclose[d]

no facts which show the alleged [unfair] acts"); *see also Dunlop v. Bachowski*, 421 U.S. 560, 572–73 (1975) (finding agency authority and discretion to determine the adequacy of the prerequisite showing that would trigger mandatory action). The Commission's discretion not to institute an investigation upon complaint is further confirmed by the statutory language in Section 330 of the Tariff Act. *See* 19 U.S.C. § 1330(d)(5) ("Whenever, in any case in which the Commission is authorized to make an investigation . . . , one-half of the number of commissioners voting agree that the investigation should be made, such investigation shall thereupon be carried out . . . ."). While the Commission has infrequently exercised this discretion, it has declined to institute investigations based on complaints lacking any of the elements necessary to plead an unfair method of competition or an unfair act. *See Certain Carbon & Alloy Steel Prods.*, Inv. No. 337-TA-1002, Comm'n Op. at 12–15 (Mar. 19, 2018) (listing claims dismissed for failure to allege elements necessary to establish "an unfair method of competition or an unfair act").

A Section 337 violation must be tethered to some wrongful conduct that is actionable, that is, it must "identify some sort of *legally cognizable* 'unfairness' in that conduct." *Certain Bearings & Packaging Thereof*, Inv. No. 337-TA-469, Comm'n Order at 3 (Sept. 23, 2002); *see also* 19 U.S.C. §§ 1337(a)(1)(A)–(E) (listing permitted bases for a Section 337 violation). "[A]ny determination of unfair acts is dependent upon the private rights between" a complainant and respondent,

but "unfair methods of competition and unfair acts" do not encompass all private claims. *Young Eng'rs Inc. v. Int'l Trade Comm'n*, 721 F.2d 1305, 1315 (Fed. Cir. 1983). Furthermore, when "asked to look to a body of established federal statutory law for defining an unfair act, the Commission is guided by the express congressional limitations on the scope of that federal law as applied in district court." *Certain Carbon & Alloy Steel Prods.*, Inv. No. 337-TA-1002, Comm'n Op. at 12–15 (Mar. 19, 2018) (citing *TianRui Group Co. Ltd. v. Int'l Trade Comm'n*, 661 F.3d 1322, 1333 (Fed. Cir. 2011).

Thus, for a Section 337 complaint to be properly pled, its underlying claim must allege all elements of a legally cognizable unfair method of competition or unfair act, and must not be prohibited by "express congressional limitations" on any federal law implicated by that claim. *Id.*

B. Amarin's Complaint Fails to Allege a Legally Cognizable Claim under Section 337

Amarin failed to comply with the Commission's requirements by failing to plead facts showing each element of a false advertising claim. As demonstrated below, Amarin's brief attempts to avoid these failures by mis-stating the allegations in its Complaint. Moreover, Amarin's false advertising claim is critically distinct from those found actionable in cases relied upon by Amarin, *POM Wonderful* and *Allergan*. This Court should, therefore, affirm the Commission's dismissal of Amarin's Complaint without prejudice.

1. Amarin's Brief Does Not Accurately Describe the Two Claims Pled in its Complaint

Amarin's brief applies a revisionist lens to bring its claims closer to those found sufficient in *POM Wonderful* and *Allergan*. Amarin suggests that its Complaint was based on customer confusion or deception, but a review of Amarin's false advertising claim demonstrates that it was premised on "literal falsity," relying on Amarin's preferred interpretation of the FDCA. Appx32–34; *see also Hall v. Bed Bath & Beyond, Inc.*, 705 F.3d 1357, 1366 (Fed. Cir. 2013) ("Lanham Act § 43(a)(1) may be violated by advertising that is either 'literally false,' or when 'the advertisement, while not literally false, is nevertheless likely to mislead or confuse consumers.'").

In particular, Amarin's brief suggests that its complaint was premised on allegations that "'drug' and 'dietary supplement' carry meanings that are well understood in the market" and that "falsely labeling or deceptively advertising . . . deceives consumers and others[.]" Amarin Opening Br. at 5, 7, 8, 52. But Amarin's Complaint does not allege the existence of consumer confusion or deception, or market definition or understanding, with respect to the term "dietary supplement," and instead relies on literal falsity based on Amarin's preferred interpretation of the term under the FDCA. Appx31–56. Consequently, this Court's evaluation of the

sufficiency of Amarin's false advertising claim is limited to the only theory Amarin pled: literal falsity.[2]

2. Amarin's Complaint Fails to Allege the Required Elements of False Advertising under the Lanham Act

Amarin has not pled a legally cognizable claim under Section 337 because its Complaint fails to allege all of the facts constituting a claim of false advertising under the Lanham Act. The first element of false advertising requires "a false or misleading statement of fact . . . by the defendant about a product." Appx32. "[A] challenged advertisement must be literally false or, though literally true, likely to mislead or confuse consumers." *Groden v. Random House, Inc.*, 61 F.3d 1045, 1051 (2d Cir. 1995); *see also Hall*, 705 F.3d at 1366. "To be actionable, the statement must be a 'specific and measurable claim, capable of being proved false or of being reasonably interpreted as a statement of objective fact.'" *American Italian Pasta Co. v. New World Pasta Co.*, 371 F.3d 387, 391 (8th Cir. 2004) (quoting *Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 731 (9th Cir. 1999)).

While Amarin's Complaint alleged literal falsity, it failed to plead facts sufficient to show a literally false statement of fact by the Proposed Respondents about their products. This pleading deficiency renders Amarin's false advertising

[2] On appeal, it is unclear whether Amarin has abandoned its second claim, that violations of FDCA standards violate Section 337, but the pleading deficiencies that prevent institution of its false advertising claim are legally the same for Amarin's second claim. *See* Appx56–59; *see also* Comm'n Br. at 15.

claim incomplete and, because the claim implicates the FDCA, the deficiency cannot be cured in a manner that could give rise to a Section 337 violation.

a) Amarin's False Advertising Claim Fails Because Amarin Has Not Pled the Existence of an Objective Fact, as Required for Literal Falsity

Amarin's false advertising claim is deficient because it does not plead the existence of an objective fact, against which a statement could be found false, or any statement of fact, versus of opinion or belief, by the Proposed Respondents about their products. *See* Appx31–56. Amarin's Complaint alleges that the Proposed Respondents' advertising is "literally false" because their products "cannot meet the definition of 'dietary supplement'" in Section 321(ff) and "are actually unapproved 'new drugs.'" Appx32–34.

Amarin, therefore, appears to concede that the factual premise of its Complaint is missing. Amarin does not allege that the FDA has determined either that the Proposed Respondents' products are not "dietary supplements" under Section 321(ff) or that the products are "unapproved 'new drugs.'" *See, e.g.*, Appx19–20, Appx33–34, Appx36–40, Appx45–47, Appx50–51. Without the existence of such a determination, there can be no objective fact by which the Commission could determine whether the Proposed Respondents' advertisement of their products as "dietary supplements" is a literally false statement. *See Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230–31 (3rd Cir. 1990) ("The

FDA has not found conclusively that demulcents must be labelled as active or inactive . . . Thus, we are unable to conclude that Vicks's labeling of Pediatric 44's demulcents as inactive is literally false."). Amarin's insistence that the Proposed Respondents' advertisement of their products as "dietary supplements" is false does not create a Lanham Act violation. *See Schering-Plough Healthcare Prods., Inc.*, 586 F.3d at 510, 513 ("Schering cannot just intone 'literal falsity' and by doing so prove a violation of the Lanham Act."). Nor does the Proposed Respondents' belief that their products are dietary supplements create an objective fact. "Absent a clear and unambiguous ruling from a court or agency of competent jurisdiction, statements by laypersons that purport to interpret the meaning of a statute or regulation are opinion statements, and not statements of fact." *Coastal Abstract Service, Inc.*, 173 F.3d at 731; *see also Dial A Car, Inc. v. Transportation, Inc.*, 82 F.3d 484, 488 (D.C. Cir. 1996) (rejecting appellant's attempt to "us[e] the Lanham Act to try to enforce its preferred interpretation of Order No. 4 instead of adjudicating the issue before the Commission").

The factual premise for finding the Proposed Respondents' advertisements "literally false" has not been—and cannot be—pled absent a determination under the FDCA, and the first element of a Lanham Act violation for false advertising is thus absent from Amarin's Complaint.

b) The Commission Cannot Establish the Objective Fact Necessary to Make Amarin's False Advertising Claim Legally Cognizable

Recognizing the absence of facts necessary for its false advertising claim, Amarin improperly invited the Commission to usurp the FDA's exclusive authority and interpret the FDCA on its behalf. *See, e.g.*, Appx112 (requesting the Commission find the Proposed Respondents' products do not "meet[ ] the definition of 'dietary supplement' in the FDCA," but "meet the definition of 'drugs,' under the FDCA"); Appx669 ("[T]he question for the Commission . . . is whether the statements being made today violate [FDA] statutes . . ."); *see also Sandoz Pharm. Corp.*, 902 F.2d at 231 (concluding that a determination under the FDCA "would require us to usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations"). But only the FDA is authorized to "enforce[], or restrain violations," of the FDCA. *See, e.g.*, 21 U.S.C. §§ 337(a), 393(a) (establishing the FDA to enforce the FDCA); *POM Wonderful LLC v. Coca-Cola Co.*, 134 S.Ct. 2228, 2235 (2014) ("[T]he FDCA and its regulations provide the United States with nearly exclusive enforcement authority . . . Private parties may not bring enforcement suits."); *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1359 (Fed. Cir. 2013) ("The FDA—and the FDA alone—has the power and the discretion to enforce the FDCA."); Appx20 ("FDA has primary responsibility for policing the 'labeling' of 'dietary supplements' . . . ."). In

addition, the Commission is constrained by statute to adjudicate unfair methods of competition or unfair acts; it cannot engage in statutory interpretation without an express mandate to do so. *Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1355 (Fed. Cir. 2008) ("The [Commission] is a creature of statute, and must find authority for its actions in its enabling statute."). And, when "asked to look to a body of established federal statutory law for defining an unfair act, the Commission is guided by the express congressional limitations on the scope of that federal law as applied in district court." *See Certain Carbon & Alloy Steel Prods.*, Inv. No. 337-TA-1002, Comm'n Op. at 11 (Mar. 19, 2018). Consequently, neither Section 337 nor the FDCA permits the Commission to interpret the statutory terms "dietary supplement" and "drug" within the meaning of the FDCA. Therefore, the Commission cannot make the determination that could create the facts necessary to render Respondents' statements actionable under the Lanham Act.

The Commission's decision not to institute an investigation that would require it to encroach on the FDA's jurisdiction and authority is consistent with decisions of other jurisdictions. Courts have universally recognized that where, as here, a Lanham Act claim requires it to interpret the FDCA, before the FDA has done so, to create the facts necessary to find a statement "false," that claim cannot be heard. *See, e.g., PhotoMedex, Inc.*, 601 F.3d at 930 ("To permit PhotoMedex to proceed with a claim that Defendants violated [the FDCA] when the FDA did not so

determine would, in effect, permit PhotoMedex to assume enforcement power which the statute does not allow and require the finder of fact to make a decision that the FDA itself did not make."); *Cottrell, Ltd. v. Biotrol Int'l, Inc.*, 191 F.3d 1248, 1254–1255 (10th Cir. 1999) (applying district court's framework for dismissing a Lanham Act claim that "involved interpretation and application of the FDA definition of 'dietary supplement'" to reject a Lanham Act claim based on violation of Environmental Protection Agency standards); *Sandoz Pharm. Corp.*, 902 F.2d at 231–32 (3rd Cir. 1990) (declining "to find, either 'as a matter of common sense' or 'normal English,' that which the FDA, with all of its scientific expertise, has yet to determine").

The Ninth Circuit explained in *PhotoMedex, Inc.* that, while a Lanham Act claim can be brought based on an FDCA violation, it "may not be pursued when . . . the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation." *PhotoMedex, Inc.*, 601 F.3d at 924. More recently, a district court found a Lanham Act claim similar to Amarin's precluded by the FDCA where "'determin[ing] the falsity or misleading nature of the representation" would require the court "'to interpret and apply FDCA statutory regulatory provisions.'" *Hi-Tech Pharm., Inc.*, 230 F. Supp. 3d at 1330–31 (quoting *Mutual Pharm. Co. v. Ivax Pharm., Inc.*, 459 F. Supp. 2d 925, 934 (C.D. Cal. 2006) (concluding that where the

FDA had not had "an opportunity to determine whether [a product] is a new drug or a prescription drug, [] it is inappropriate for the Court to make those determinations in place of the FDA").

Because the FDA has not ruled that the Respondents' products are not "dietary supplements" or are "unapproved 'new drugs'" under the FDCA, and the Commission cannot issue such a ruling on the FDA's behalf, Amarin has not pled, and cannot plead, a cognizable claim of false advertising under the Lanham Act.

c) Amarin's Alleged Examples of Respondents' False Advertising Are Not Actionable

Even if the FDA, or the Commission, were to determine that the Proposed Respondents' products are not "dietary supplements" under Section 321(ff), that future determination cannot render Respondents' past statements literally false. A determination that Respondents' products are not "dietary supplements" under Section 321(ff) would establish the objective fact necessary for Amarin's false advertising claim, but the Proposed Respondents' advertisements pre-dating such a determination would remain statements of belief or opinion, not fact. *See Coastal Abstract Svc., Inc.*, 173 F.3d at 732 (finding that a statement preceding a legal interpretation of licensure requirements "could not give rise to a Lanham Act claim" because "the correct application of [the law] was not knowable to the parties at the time" the statement was made); *Dial A Car, Inc.*, 82 F.3d at 489 ("[A]ppellant cannot pursue this lawsuit with a simple assertion that *current* D.C. law is seen to be clear

and unambiguous, based on an interpretation by the D.C. Taxicab Commission that was issued subsequent to appellees' statements.").

Because the facts required to find "literal falsity" have not yet been determined, Respondents' statements pre-dating a determination that their products are not "dietary supplements" cannot be actionable because the statements were not "statements of fact" when made. Thus, Amarin's Complaint, as currently pled, merely suggests the possibility of "unfair acts in their incipiency," and is not actionable under the Lanham Act or Section 337. *See Certain Carbon & Alloy Steel Prods.*, Inv. No. 337-TA-1002, Comm'n Op. at 11 (Mar. 19, 2018).

3. Dismissal of Amarin's False Advertising Claim Is Consistent with *POM Wonderful*, *Allergan*, and the Commission's Prior Institution Decisions

Amarin's argument that the Commission's dismissal of its Complaint runs afoul of *POM Wonderful* and *Allergan* is not only incorrect, it is contradicted by the Commission's prior institution decisions. *POM Wonderful* and *Allergan* confirm that the Lanham Act can be used to protect competitive interests in a field regulated by the FDA, but neither case demands that all false advertising claims related to FDA regulation must be adjudicated. Unlike Amarin's false advertising claim, neither *POM Wonderful* nor *Allergan* involved a failure to allege the false or misleading statement of fact required for a false advertising claim. And, unlike Amarin's false advertising claim, neither case called upon the court to interpret

definitions codified in the FDCA. Because dismissal of Amarin's Complaint was based on a pleading failure, neither *POM Wonderful* nor *Allergan* required the Commission to institute an investigation.

In *POM Wonderful*, the Supreme Court held that a Lanham Act claim for false advertising can co-exist with the FDA regulations that did not, themselves, prevent defendant's use of the statements alleged to be false. *POM Wonderful LLC*, 134 S.Ct. at 2238–39. *POM Wonderful* was not based on enforcement of the FDCA or interpretation of statutory terms under the FDCA. Moreover, *POM Wonderful* did not relax the pleading requirements for false advertising to allow POM's claim. POM alleged undisputed facts—that the label in question was deemed appropriate under FDA regulations and that Coca-Cola's product contained only 0.3% pomegranate juice and 0.2% blueberry juice. *Id.* at 2235. Thus, POM's false advertising claim did not require the Court to interpret the FDCA, find a violation of the FDCA, or otherwise establish the facts necessary to determine whether Coca-Cola's advertising could be false. The Court determined only whether Coca-Cola's advertisements misled consumers, despite Coca-Cola's compliance with FDA labeling requirements. *Id.* at 2234–35.

Amarin's reliance on *Allergan* fares no better. *Allergan* held that a California state law governing the sale of drugs was not preempted by the FDCA, but did not involve enforcement of the FDCA or the issue of preclusion addressed in cases like

POM Wonderful and *Hi-Tech Pharmaceuticals*. The Federal Circuit explained that California regulation could parallel the FDCA, but could not "stand in the shoes of the FDA to determine whether Athena's sale of the products at issue amounts to the sale of an unapproved drug under the FDCA" because "[t]his enforcement authority relies exclusively with the FDA." *Allergan, Inc.*, 738 F.3d at 1359. Here too, the Federal Circuit noted the absence of a dispute regarding the factual basis for Allergan's violation of the California law; Athena's products were intended to be used as drugs and were not approved for use as drugs. *Id.* at 1357–58. Allergan's claim did not require the Court to interpret or find a violation of the FDCA to determine whether Athena violated California law. *Id.*

Consistent with *POM Wonderful* and *Allergan*, where complaints have alleged facts sufficient to constitute false advertising without requiring an interpretation of the FDCA, the Commission has instituted an investigation. *See Certain Potassium Chloride Powder Products*, Inv. No. 337-TA-1013, Notice of Institution (July 21, 2016); *Certain Periodontal Laser Devices*, Inv. No. 337-TA-1070, Notice of Institution (Sept. 11, 2017). The Complaints in both investigations alleged that the products at issue were subject to FDA premarket approval and were falsely advertised because they were not approved by the FDA. Thus, to adjudicate these false advertising claims, the Commission was required only to verify whether

the FDA listed the products as approved; neither investigation required the Commission to interpret FDCA provisions.

Amarin's claim, in contrast, fails to allege the factual premise and false statements of fact necessary to find literal falsity because they do not yet exist. Put simply, Amarin has not properly pled a claim of false advertising and will be unable to do so unless and until after the FDA determines that Respondents' products are not "dietary supplements" or are "unapproved 'new drugs'" under the FDCA.

CONCLUSION

The Court should reject Amarin's invitation to mandate a Commission investigation for the foregoing reasons and accordingly dismiss Amarin's appeal and dismiss or deny its petition for a writ of mandamus.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 6,677 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

/s/ Deanna Tanner Okun

CERTIFICATE OF SERVICE

I certify that on March 28, 2018 the foregoing document was served on all parties or their counsel of record through the CM/ECF system.

/s/ Deanna Tanner Okun