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No. 17-____

IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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

v.

UNITED STATES INTERNATIONAL TRADE COMMISSION, Respondent/Appellee.

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

PETITION FOR REVIEW

Of Counsel:
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Counsel for Petitioners Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

CERTIFICATE OF INTEREST

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

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

Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

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

Not applicable.

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

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

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

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

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

December 1, 2017 Respectfully submitted,

<u>/s/ Ashley C. Parrish</u>
Ashley C. Parrish

Counsel for Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

PETITION FOR REVIEW

Pursuant to Rule 15(a) of the Federal Rules of Appellate Procedure and Rule 15(a) of the Rules of this Court, Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd., respectfully petition this Court for review of the following final decision by the United States International Trade Commission entered on October 27, 2017:

In the Matter of Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form, Order on Complaint, ITC Docket No. 3247.

The order on review is attached to this petition as Exhibit A.

Respectfully submitted,

Of Counsel:

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/s/ Ashley C. Parrish

Ashley C. Parrish

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Counsel for Petitioners Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

December 1, 2017

 $*Admission\ Pending$

CERTIFICATE OF SERVICE

Pursuant to Rule 15(c) and Rule 25 of the Federal Rules of Appellate Procedure, I hereby certify that on December 1, 2017, I served or caused to be served copies of this Petition for Review via Hand Delivery or Overnight Mail to the following:

The Honorable Lisa R. Barton Secretary U.S. INTERNATIONAL TRADE COMMISSION 500 E Street, S.W. Washington, DC 20436 Telephone: (202) 205-2000

Respectfully submitted,

<u>/s/ Ashley C. Parrish</u>
Ashley C. Parrish

Counsel for Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

Exhibit A



UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, D.C. 20436

October 27, 2017

Jeffrey M. Telep, Esq. KING & SPALDING LLP 1700 Pennsylvania Avenue, NW Suite 200 Washington, DC 20006-4706

Re: Complaint Filed by Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. Concerning Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form (Docket No. 3247)

Dear Mr. Telep:

Under Commission Rules 210.9, 210.10 and 210.12(a)(2), (3) and (8), 19 C.F.R. §§ 210.9, 210.10, 210.12(a)(2), (3) and (8), the Commission has determined not to institute an investigation based on the complaint filed on behalf of Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (collectively "Amarin") concerning Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form, and has dismissed the complaint.

Amarin's complaint does not allege an unfair method of competition or an unfair act cognizable under 19 U.S.C. § 1337(a)(1)(A), as required by the statute and the Commission's rules. The Commission notes that the Lanham Act allegations in this case are precluded by the Food, Drug and Cosmetic Act ("FDCA"). The Commission also notes that the Food and Drug Administration is charged with the administration of the FDCA.

Documents relating to this institution determination, including comments from the complainant, proposed respondents, and the public, can be found on the Commission's Electronic Document Information System (EDIS) under Docket Number 3247.

Sincerely,

Lisa R. Barton

Secretary to the Commission

cc: Proposed respondents



UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC 20436

CO84-PP-001

October 27, 2017

CONCURRING MEMORANDUM

TO:

THE SECRETARY¹

FROM:

Commissioner Meredith M. Broadben

SUBJECT:

Complaint of Amarin Pharma, Inc. concerning Certain Synthetically Produced,

Predominantly EPA Omega-3 Products in Ethyl Ester or Re-Esterified Triglyceride Form

(Docket No. 3247)

Commissioner Broadbent concurs with the Commission's finding that Amarin's complaint does not allege an unfair method of competition or an unfair act under section 337(a)(1)(A) of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(a)(1)(A). She notes, however, that she does 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).

¹ This is a public document to be filed in EDIS.