What is the status of the ITC lawsuit Amarin filed in August 2017 to prevent the import and sale into the United States of synthetic omega-3 products that are comprised predominantly of EPA and sold for use in, or as, dietary supplements?

In August 2017, Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited, each wholly-owned subsidiaries of Amarin Corporation plc, filed a lawsuit with the United States International Trade Commission (the ITC) that sought an investigation by the ITC under Section 337 of the Tariff Act of 1930 (19 U.S.C. §1337). Section 337 of the Tariff Act of 1930 makes unlawful unfair methods of competition and unfair acts involving the importation and sale of articles in the United States that injure or threaten injury to a domestic industry. Amarin contended that synthetically produced omega-3 products comprised predominantly of EPA and sold as dietary supplements in the United States are unapproved new drugs under applicable law. As such Amarin contended that the import and sale of such articles in the United States is illegal and amounts to injurious unfair competition with Amarin's FDA-approved drug, Vascepa® (icosapent ethyl) capsules, which contains 1 gram of EPA in ethyl ester form in a 1-gram capsule. Amarin contended, consistent with U.S. law and multiple cited FDA statements and actions, that the public is entitled to the benefit of FDA drug regulations to ensure that synthetic products are appropriately manufactured and safe and effective for their intended uses.

Amarin's Vascepa® capsules are a single-molecule, FDA-approved, prescription product consisting of the ethyl ester form of the omega-3 acid commonly known as EPA. Vascepa® is not fish oil, but is derived from fish through a stringent and complex drug manufacturing process. That drug manufacturing process is highly regulated by the FDA, involves chemical alteration, and is designed to effectively eliminate impurities and isolate and protect the fragile single molecule active ingredient from degradation. FDA regulation of drug products like Vascepa® is designed to ensure that patients diagnosed with a disease receive the same drug that demonstrated a favorable efficacy and safety profile in FDA-reviewed human clinical trials.

The lawsuit sought the issuance of a general exclusion order prohibiting importation into the United States of the purported dietary supplement products and oil. The lawsuit also sought related cease and desist orders applicable to inventory of such articles of the named respondents already in the United States.

The lawsuit did not seek action against dietary supplements containing common fish oil (i.e., fish oil in its naturally-occurring chemical composition). A large majority of the omega-3 products that are imported or sold in the United States are legally marketed "dietary supplements" comprised of common fish oil and not intended to treat serious medical conditions. Nor did the lawsuit seek action against synthetically produced omega-3 products that are not predominantly comprised of the omega-3 acid EPA.

In October 2017, the ITC (aka, the Commission) determined to not institute an investigation into the matter, stating the following:

> 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.

In November 2017, Amarin appealed the ITC non-institution determination to the US Federal Circuit. On May 1, 2019 the Federal Circuit affirmed the ITC determination to not institute an investigation.

Amarin is disappointed with the Federal Circuit decision and is analyzing its options forward.

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