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?

On December 9, 2019, the U.S. Supreme Court made public its determination to not hear Amarin's August 2019 appeal, which asked the Court to decide whether Amarin can to pursue a lawsuit through the U.S. International Trade Commission ("ITC") to protect the *Vascepa*® (icosapent ethyl) franchise against a certain class of synthetically produced omega-3 products that Amarin views as deceptively advertised through their sale in the United States as dietary supplements. It is not uncommon for the US Supreme Court to elect not to hear a case.

As part of an appeal related to the 2017 Amarin-ITC lawsuit, the U.S. Federal Circuit concluded that "Amarin's claims are precluded *at least* until the FDA has provided guidance as to whether the products at issue are dietary supplements." Amarin intends to continue to pursue other paths to protect the *Vascepa*® franchise against this class of synthetically produced omega-3 products.

Vascepa® is a single-molecule, prescription product consisting of the ethyl ester form of the omega-3 acid, which is commonly known as EPA. *Vascepa*® is not fish oil; it is derived from fish through a stringent and complex drug-manufacturing process. That process, which is highly regulated by FDA, involves chemical alteration and is designed to eliminate impurities while isolating and protecting the fragile single-molecule active ingredient from degradation. FDA regulation of drugs like *Vascepa*® ensures that patients diagnosed with a disease receive the same drug that demonstrated a favorable efficacy and safety profile in FDA-reviewed human-clinical trials.

To aid in understanding the issues underlying this matter, see Amarin's July 26, 2019, responsive submissions, available here, to a citizen petition filed on July 8, 2019. Amarin's submission details how applicable law demonstrates that such products are not lawful dietary supplements based, in part, on over 18 years of FDA determinations. As discussed in greater detail in Amarin's submissions, products that are synthetically modified from their natural form have historically been classified as drugs and not dietary supplements by FDA. There are risks to Congress's carefully designed regulatory regimes should FDA change its longstanding approach. That is because such a change would upset the well-known and well-defined pathways for dietary supplements and drugs to be marketed in the United States. In short, Amarin believes that all drugs should have to go through the same rigorous FDA-approval process as *Vascepa*®—and not through the less-regulated dietary-supplement pathway—to ensure a level playing field for all products.

Separately, Amarin remains fully committed to defending the *Vascepa*® franchise against any company that seeks to mislead the public and cardiovascular patients in need by fraudulently leveraging the landmark REDUCE-IT® study results or the REDUCE-IT® and *Vascepa*® names as part of marketing their products. For more information on Amarin's success against such illegal drug claims, see our investor FAQ titled, **What is Amarin doing to protect the *Vascepa*® franchise against dietary supplement manufacturers that mislead the public by referencing REDUCE-IT™ or *Vascepa*®? (updated May 7, 2019)**, available here.

Updated: December 10, 2019