IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, MOCHIDA PHARMACEUTICAL CO., LTD., Plaintiffs, v. HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS PLC, Defendants.	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT AND DEMAND FOR JURY TRIAL

Plaintiffs Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited ("Amarin") and Mochida Pharmaceutical Co., Ltd. ("Mochida") (collectively, "Plaintiffs"), by their attorneys, hereby allege as follows:

THE NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 9,700,537 ("the '537 patent"), 8,642,077 (the "'077 patent"), and 10,568,861 (the "'861 patent") (collectively, the Asserted Patents") under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., including § 271(b). In violation of these laws, Defendants are marketing their generic version of Amarin's ground-breaking VASCEPA® product to reduce the risk of cardiovascular events such as heart attack and stroke ("cardiovascular risk reduction"). VASCEPA® is the first and only innovative omega-3 acid-based product approved for cardiovascular risk reduction by the United States Food and Drug Administration.

THE PARTIES

2. Amarin Pharma, Inc. is a company organized under the laws of Delaware with its principal place of business at 440 Route 22, Suite 330, Bridgewater, NJ 08870.

3. Amarin Pharmaceuticals Ireland Limited is a company incorporated under the laws of Ireland with registered offices at 88 Harcourt Street, Dublin 2, Dublin, Ireland.

4. Mochida Pharmaceutical Co., Ltd. is a company incorporated under the laws of Japan with its principal place of business at 1-1, Ichigayahonmuracho, Shinjuku-ku, Tokyo 162-0845, Japan.

5. On information and belief, Defendant Hikma Pharmaceuticals USA Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 246 Industrial Way West, Eatontown, NJ 07724.

6. On information and belief, Defendant Hikma Pharmaceuticals PLC is a corporation organized and existing under the laws of the United Kingdom with its principal place of business at 1 New Burlington Place, London W1S 2HR.

7. Upon information and belief, Hikma Pharmaceuticals USA Inc. is a wholly-owned subsidiary of Hikma Pharmaceuticals PLC.

8. Upon information and belief, Hikma Pharmaceuticals USA Inc. acts at the direction, and for the benefit, of Hikma Pharmaceuticals PLC, and is controlled and/or dominated by Hikma Pharmaceuticals PLC. Hikma Pharmaceuticals USA Inc. and Hikma Pharmaceuticals PLC are hereinafter referred to together as "Defendants" or "Hikma."

9. Upon information and belief, Defendants collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Defendants are agents of each other and/or operate in concert

as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

10. Upon information and belief, Hikma Pharmaceuticals USA Inc. is the current owner of ANDA No. 209457 for 1g and 0.5 g icosapent ethyl capsules purportedly bioequivalent to VASCEPA®.

11. Upon information and belief, on May 21, 2020, FDA granted final approval for Defendants' 1g icosapent ethyl capsules under ANDA No. 209457.

12. Attached hereto as Exhibit A is a press release issued by Hikma Pharmaceuticals PLC on or about May 22, 2020 announcing that "Hikma Pharmaceuticals USA Inc. has received approval from the US Food and Drug Administration (FDA) for its Icosapent Ethyl Capsules, 1 gm, the generic equivalent to Vascepa®."

13. Attached hereto as Exhibit N is a press release issued by Hikma Pharmaceuticals PLC on or about November 5, 2020 announcing the launch of Hikma's icosapent ethyl capsules. On information and belief, on November 5, 2020, Hikma launched and began offering for sale and/or selling its generic icosapent ethyl capsules in the United States, including this jurisdiction.

14. Upon information and belief, Defendants act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell Hikma's icosapent ethyl capsules in the United States, including this jurisdiction.

JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a).

16. This Court has personal jurisdiction over Hikma Pharmaceuticals USA Inc. because it is incorporated in Delaware and thus is present in and resides in this District, and because Hikma

Pharmaceuticals USA Inc. is doing business in this District and has thus purposefully availed itself to the privileges of conducting business in Delaware.

17. Venue is proper in this District over Hikma Pharmaceuticals USA, Inc. under 28 U.S.C. § 1400(b).

18. This Court has personal jurisdiction over Hikma Pharmaceuticals PLC because, on information and belief, it manufactures, imports, offers for sale, and sells pharmaceutical drugs that are sold in the United States, including in Delaware, and derives substantial income therefrom.

19. In the alternative, this Court may exercise personal jurisdiction over Hikma Pharmaceuticals PLC pursuant to Fed. R. Civ. P. 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Hikma Pharmaceuticals PLC is a foreign company not subject to personal jurisdiction in the courts in any state, and (c) Hikma Pharmaceuticals PLC has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Hikma Pharmaceuticals PLC satisfies due process.

20. Venue is proper in this District with respect to Hikma Pharmaceuticals PLC pursuant to 28 U.S.C. § 1391(c)(3) because it is not resident in the United States.

FACTUAL BACKGROUND

A. VASCEPA®, REDUCE-IT, JELIS and EPA's Reduction of Cardiovascular Risk

21. The three types of omega−3 fatty acids involved in human physiology are α-linolenic acid (ALA), found in plant oils, and eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), both commonly found in marine (fish) oils.

22. Amarin and Mochida are recognized worldwide as the leading innovation-driven companies committed to the research and development of EPA-based drug products to treat the needs of millions of patients who are at risk of cardiovascular disease

23. Mochida developed and markets a prescription pure EPA drug product, Epadel, in Japan.

24. Amarin developed and markets VASCEPA®, a prescription drug that contains pure EPA, in the United States.

25. Amarin conducted a series of clinical trials to support FDA approval of VASCEPA®.

26. In the MARINE trial that led to VASCEPA®'s first approval, VASCEPA® was found to lower triglycerides in patients with severe hypertriglyceridemia (≥500 mg/dL) without raising bad cholesterol, or LDL-C, levels. Upon FDA approval in 2012, VASCEPA® became the first (and still only) approved medication for treating severe hypertriglyceridemia that does not raise LDL-C.

27. After that approval to treat severe hypertriglyceridemia, Amarin continued its clinical work towards its primary goal, approval of VASCEPA® for use in cardiovascular risk reduction. Based on an agreed protocol with the FDA, Amarin had conducted a clinical trial known as ANCHOR, in which Amarin examined VASCEPA® as an add-on to statin therapy in patients with persistent high (≥200 mg/dL and <500 mg/dL) triglycerides. As agreed with FDA, Amarin evaluated VASCEPA®'s effect on cardiovascular risk reduction based on triglyceride level lowering as a surrogate, or substitute, for cardiovascular risk reduction while awaiting the results of Amarin's REDUCE-IT trial.

28. While ANCHOR met its clinical endpoints, including the exploratory endpoint of median placebo-adjusted percent change in high-sensitivity C reactive protein (hs-CRP), *see* Ex.

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