CONTAINS HIKMA CONFIDENTIAL INFORMATION

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, AND HEALTH NET, LLC, Defendants.	C.A. No. 20-1630-RGA-JLH

PLAINTIFFS' INITIAL INFRINGEMENT CONTENTIONS AND CLAIM CHARTS

Pursuant to Paragraph 7(c) of the Court's Scheduling Order (D.I. 50), Plaintiffs Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited ("Amarin"), and Mochida Pharmaceutical Co., Ltd. ("Mochida") (collectively "Plaintiffs") provide their Initial Infringement Contentions and Claim Charts to Defendants Hikma Pharmaceuticals USA Inc. and Hikma Pharmaceuticals PLC ("Hikma") and Health Net, LLC ("Health Net") (collectively "Defendants"), including Exhibits A through F.

In support of their Initial Infringement Contentions and Claim Charts, Plaintiffs have cited representative documents from Hikma's generic icosapent ethyl product's ANDA No. 209457[1], as well as the related labelling and marketing materials, and documents related to Health Net's relevant formularies and prior authorization for VASCEPA® (icosapent ethyl). Plaintiffs expressly reserve the right to modify, amend, and/or supplement their Initial Infringement

[1] "Hikma's generic product" as used herein refers to Hikma's icosapent ethyl capsule product described in ANDA No. 209457.

Contentions and Claim Charts based on their continued investigation, study and analysis, Defendants' document productions, discovery taken in the case, the claim construction positions taken by the parties, any orders from the Court, or any information learned subsequent to the date of these Initial Infringement Contentions and Claim Charts, consistent with the Federal Rules of Civil Procedure, Local Rules of this District, and this Court's procedures and Orders.

In particular, Plaintiffs expressly reserve the right to modify, amend, and/or supplement their Initial Infringement Contentions and Claim Charts upon learning further information about Hikma's generic product and/or the Defendants' inducing acts during discovery. As of the date of this submission, Defendants have not produced information regarding their knowledge of the FDA's approval of the CV Indication for VASCEPA® or documents regarding non-infringing uses of Hikma's generic product. Further, Hikma has not produced requested documentation regarding the planning, decision, and/or strategy to market Hikma's generic product, the total volume of Hikma's generic product prescribed or dispensed versus VASCEPA®, the percentage or volume of Hikma's generic product being prescribed to treat the CV Indication, or correspondence with insurers and pharmacies regarding this litigation. Additionally, thus far, Health Net has produced zero documents in this litigation. Plaintiffs reserve the right to supplement these disclosures after Defendants provide the requested discovery. Plaintiffs thus expressly reserve the right to identify and advance alternative theories of literal infringement and/or infringement under the doctrine of equivalents as well as additional indirect infringement theories.

I. ACCUSED PRODUCT

Plaintiffs accuse Hikma and Health Net of indirectly infringing the below Asserted Claims by inducing the infringing use of Hikma's generic product for reasons including but not limited to

those set forth in Plaintiffs' Amended Complaint and Plaintiffs' Oppositions to Defendants' Motions to Dismiss, and as further discussed in the Report and Recommendation to deny the Motions to Dismiss. (D.I. 17 (¶¶ 80, 92-135 as to the Hikma Defendants and ¶¶ 81-92, 136-162 as to Health Net); D.I. 22 (as to the Hikma Defendants), D.I. 42 (as to Health Net); D.I. 64). Plaintiffs' inducement theories are further discussed in Plaintiffs' forthcoming responses to both Hikma's and Health Net's objections to the Report and Recommendations to deny the Motions to Dismiss.

II. ASSERTED CLAIMS

Plaintiffs contend that Defendants infringe the following claims (the "Asserted Claims"):

Patent Number	Asserted Claims
8,642,077	1, 8, 14, 15, 16, 17, 18, and 19
9,700,537	1, 4, 5, 7, 8, 9, 12, 13, 15 and 16
10,568,861	1-7

Hikma infringes each Asserted Claim under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, importing, promoting, distributing, and/or acting in concert with other entities to sell Hikma's generic product and inducing healthcare providers and/or patients (either by acting alone, or directing and/or controlling the infringing actions of others) to use Hikma's generic product within the United States for patented uses covered by these claims and according to the instructions set forth in Hikma's Label[2], including the affirmative removal of the CV Limitation of Use, and any other instructions, recommendations or communications made by Hikma and/or its agents to healthcare providers, such as through promotional and marketing materials, to use

[2] "Hikma's Label" refers to what Plaintiffs understand to be the FDA-approved label for Hikma's generic product, 1 gram, produced with at the following bates number range: HIK(ICO)-DE-00009675-9685.

Hikma's generic product according to the methods of these claims or as a substitute for VASCEPA® to reduce CV risk and lower TGs in specific patient populations.

Health Net indirectly infringes each Asserted Claim under 35 U.S.C. § 271(b) by inducing healthcare providers, including physicians and/or pharmacies (either by acting alone, or directing and/or controlling the infringing actions of others), to use Hikma's generic product within the United States for patented uses covered by these claims through its instructions, recommendations or communications made by Health Net and/or its agents, including those related to the relevant formularies and prior authorizations, to healthcare providers to use Hikma's generic product according to the methods of these claims or as a substitute for VASCEPA® to reduce CV risk and lower TGs in specific patient populations.

III. INFRINGEMENT

As described below and in the accompanying claim charts, Exhibits A-C, Hikma's generic product, when offered for sale, sold, prescribed, or used for the patented used, including for the CV Indication or to lower TGs in specific patient populations, meets each element of the Asserted Claims.

IV. HIKMA HAS INDUCED INFRINGEMENT OF THE ASSERTED CLAIMS

As described below and in the accompanying claim charts, Exhibits A-C, Hikma's Label demonstrates that Hikma's generic version of VASCEPA® product is marketed and sold with instructions to healthcare providers to administer it to patients according to the methods of the relevant Asserted Claims.

In 2016, Hikma submitted its ANDA to the FDA with proposed labeling that included the same Severe Hypertriglyceridemia Indication ("SH Indication") and CV Limitation of Use that appeared on the VASCEPA® label at that time. *See* HIK(ICO)-DE-00000035; *see also*

HIK(ICO)-DE-00002474. From 2016 to 2018, Hikma revised its label three times, with each revision maintaining the SH Indication and CV Limitation of Use. *See*, *e.g.*, HIK(ICO)-DE-00000111; HIK(ICO)-DE-00000135; HIK(ICO)-DE-00003028; HIK(ICO)-DE-00003052; HIK(ICO)-DE-00004435; HIK(ICO)-DE-00004573. One of these revisions, occurring in October 2018, was in response to a Complete Response Letter from the FDA requesting the labelling be revised "in accordance with the most recently approved labeling for the reference listed drug (RLD), VASCEPA, NDA 202057." HIK(ICO)-DE-00004429; *see also* HIK(ICO)-DE-00004427; HIK(ICO)-DE-00004435; HIK(ICO)-DE-00004573.

In 2019, VASCEPA® was approved for the Cardiovascular Risk Indication ("CV Indication") allowing Amarin to remove the CV Limitation of Use from the VASCEPA® label. *See* HIK(ICO)-DE-00006942; *see also* HIK(ICO)-DE-00005969 at -5986.This set VASCEPA® apart from the other FDA-approved drugs in its therapeutic category. For example, the FDA required the labelling for LOVAZA®, an omega-3 acid ethyl ester, approved by the FDA for the reduction of triglyceride levels in patients with triglyceride (TG) levels ≥ 500 mg/dL, to include the CV Limitation of Use. D.I. 17-20 (Pls.' Am. Compl. Ex. S (LOVAZA® Label)) (example of how CV Limitation of Use was required by the FDA for other products in the therapeutic category).

Along with the changes in labelling, various patents covering the use of VASCEPA® for the CV Indication were listed in the Orange Book, including those asserted here. HIK(ICO)-DE-00008864. Hikma thus had to choose between including the CV Indication on its own label and challenging the Asserted Patents or avoid the Asserted Patents by "carving out" the CV Indication through Section viii statements. Hikma chose to carve-out the CV Indication from its label and submitted its Section viii statements to the FDA. HIK(ICO)-DE-00005895; *see* HIK(ICO)-DE-00006090; HIK(ICO)-DE-00010526. By including these self-proclaimed "section viii

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