UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

LOCAL 464A UNITED FOOD AND COMMERCIAL WORKERS UNION WELFARE SERVICE BENEFIT FUND, on behalf of itself and all others similarly situated, Plaintiff, v. AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, AMARIN CORPORATION PLC, BASF AMERICAS CORPORATION, BASF CORPORATION, BASF PHARMA (CALLANISH) LTD, BASF USA HOLDING LLC, CHEMPORT, INC., NISSHIN PHARMA, INC., NOVASEP LLC, NOVASEP, INC., GROUPE NOVASEP SAS, AND FINORGA SAS, Defendants.	**Civil Action No.** **COMPLAINT and DEMAND FOR JURY TRIAL**

Plaintiff Local 464A United Food and Commercial Workers Union Welfare Service Benefit Fund ("Plaintiff") brings this action on behalf of itself and all others similarly situated against Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, Amarin Corporation PLC (collectively "Amarin"); BASF Americas Corporation, BASF Corporation, BASF Pharma (Callanish) Limited,

BASF USA Holding LLC (collectively "BASF"); Chemport, Inc. ("Chemport"); Nisshin Pharma, Inc. ("Nisshin"); Novasep, LLC, Novasep, Inc., Groupe Novasep SAS, Finorga SAS (collectively "Novasep," together with Amarin, BASF, Chemport, and Nisshin, "Defendants"). These allegations are based on investigations of counsel, publicly available materials and knowledge, information, and belief.

INTRODUCTION

1. This case arises from Defendants' illegal scheme to delay competition in the United States and its territories for Vascepa, a prescription medication approved by the U.S. Food and Drug Administration ("FDA") to treat hyperglyceridemia in adults. In particular, Plaintiff seeks overcharge damages arising from Amarin's sham litigation against generic manufacturers, which delayed the regulatory approval and launch of generic versions of Vascepa and from Defendants' unlawful scheme to prevent generic competition for Vascepa by hoarding the world's supply of the active pharmaceutical ingredient needed to make the drug.

2. The active ingredient in Vascepa is icosapent ethyl ("IPE"), made from eicosapentaeonic acid ("EPA"), an omega-3 fatty acid found in fish oil. Vascepa has been shown both to lower triglycerides and to reduce the risk of cardiovascular events in patients who have high triglycerides (150 mg/dL or

higher). In 2020, annual sales of Vascepa in the United States were over $600 million.

3. Beginning July 26, 2016, three generic drug companies filed applications with the FDA to launch generic versions of Vascepa: Roxane Laboratories, Inc. and related entities, later acquired by Hikma Pharmaceuticals Plc ("Hikma"), Dr. Reddy's Laboratories Inc. ("DRL"), and Teva Pharmaceuticals USA, Inc. and related entities ("Teva").[1] Hikma, DRL, and Teva each contended that all of the asserted patent claims were either invalid or not infringed by their respective generic version of Vascepa. Amarin sued each of these generics in turn in the U.S. District Court for the District of Nevada – *Amarin Pharma, Inc. v. Roxane Laboratories, Inc*., No. 2:16-cv-02525-MMD-NJK (consolidated action) (the "Vascepa Patent Litigation"), which delayed their final approval and launch. Another application for generic Vascepa, which was amended in May 2020, was filed by Apotex, Inc. ("Apotex"). Apotex contended that some of the asserted patent claims were either invalid or not infringed by Apotex's generic version of Vascepa, but did not challenge all of the asserted patent claims.

4. Amarin settled with Teva in May 2018 and Apotex in June 2020. Pursuant to those agreements, Teva and Apotex have agreed to forego selling their

[1] Applications were previously filed with the FDA, but they were rejected after Amarin successfully extended its New Chemical Entity exclusivity period, rendering those earlier-filed applications premature

respective generic versions of Vascepa in the United States until August 9, 2029, or earlier under certain circumstances.

5. Hikma and DRL, however, continued their patent fight and won at trial – on March 30, 2020, Judge Miranda M. Du, District Court Judge for the District of Nevada, held that Amarin's patents were invalid due to obviousness.

6. After its patent victory, DRL promptly began preparations to launch generic Vascepa, "only to discover that Amarin had foreclosed all the suppliers of the icosapent ethyl API who have sufficient capacity to support a commercial launch in a timely manner."[2]

7. Hikma received FDA approval to launch its generic version of 1mg Vascepa on May 22, 2020.[3]

8. DRL received FDA approval to launch its generic version of 1mg Vascepa on August 7, 2020.[4] As of that date, DRL had removed all legal and regulatory barriers to its entry into the market for 1mg Vascepa, but it was nonetheless foreclosed from entering that market due to Amarin's use of a series

[2] Complaint, Doc. No. 1, *Dr. Reddy's Laboratories Inc. v. Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Amarin Corporation PLC*, No. 3:21-cv-10309-BRM-ZNQ (D.N.J. Apr. 27, 2021) ("DRL Complaint"), ¶ 3.

[3] "Hikma receives FDA approval for its generic Vascepa," PR Newswire (May 22, 2020), https://www.prnewswire.com/news-releases/hikma-receives-fda-approval-for-its-generic-vascepa-301064061.html

[4] Product Details for ANDA 209499, https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=209499#312

of exclusive contracts and other anticompetitive conduct to lock up the world's supply of IPE, the active pharmaceutical ingredient in Vascepa. Amarin had secured a supply of several times Amarin's own needs based on its anticipated sales.

9. Amarin lost its appeal of Judge Du's March 30, 2020, invalidity order on September 3, 2020.

10. Hikma launched limited amounts of its 1mg generic Vascepa on November 5, 2020, hampered by Amarin's anticompetitive capture of the world's supply of IPE. And, DRL was unable to launch its generic Vascepa product until June 22, 2021.

11. Amarin was able to delay and limit Hikma and DRL's launches of generic Vascepa (and potentially prevent the approval and/or launches of other generic manufacturers) by initiating its sham patent litigation. Further, by purposely contracting with at least four different API suppliers[5] – one or two is standard in the pharmaceutical industry – Amarin prevented these suppliers from selling IPE API to any other generic manufacturer.[6]

12. Amarin, by any means necessary, sought to prevent, delay and/or

[5] Nisshin Pharma Inc., Equatez Ltd., Chemport Inc., and Novasep.

[6] *See*, *e.g.*, Amarin Corp. plc, Quarterly Report (Form 10-Q), at 16 (Nov. 8, 2011) ("Following FDA approval of [Vascepa] both agreements [with Equateq and Chemport] include annual purchase levels enabling Amarin to ***maintain supply exclusivity*** with each respective supplier") (emphasis added).

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