UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNIFORMED FIRE OFFICERS ASSOCIATION FAMILY PROTECTION PLAN LOCAL 854 and UNIFORMED FIRE OFFICERS ASSOCIATION FOR RETIRED FIRE OFFICERS FAMILY PROTECTION PLAN, on behalf of themselves and all others similarly situated, Plaintiffs, 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**

Plaintiffs Uniformed Fire Officers Association Family Protection Plan Local 854 and the Uniformed Fire Officers Association for Retired Fire Officers Family Protection Plan (collectively "Plaintiffs" or "UFOA") bring this action on behalf of themselves 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. Plaintiffs seek overcharge damages arising 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. In September and October of 2016, four 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"), Teva Pharmaceuticals USA, Inc. and related entities ("Teva"), and Apotex, Inc. ("Apotex").[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. 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.

[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.

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 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 M. Du Miranda, Federal 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 has been entirely foreclosed from entering that market due to Amarin's use of a series 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.

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[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 (last accessed May 6, 2021).

[4] Product Details for ANDA 209499, https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=209499#312 (last accessed May 6, 2021).

9. Amarin lost its appeal of Judge Miranda'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.

11. Amarin was able to prevent DRL's generic Vascepa launch and limit Hikma's launch by purposely contracting with at least four different API manufacturers[5] – one or two is standard in the pharmaceutical industry – using agreements that prevent these suppliers from selling IPE API to any other manufacturer,[6] and has otherwise foreclosed access to at least one other major supplier.

12. Amarin has no legitimate procompetive reason for entering into exclusive supply agreements with these four manufacturers. The total annual capacity of these suppliers has been more than triple Amarin's requirements at relevant times in the past, and is at least double Amarin's current requirements.

13. Notably, Amarin has repeatedly touted its anticompetitive scheme to investors, often coyly referring to "taking advantage of manufacturing barriers to entry,"[7] but sometimes bluntly stating that the addition of a new supplier "fortifies Amarin's efforts to shield its Vascepa patent beyond its scheduled 2030 expiration."[8]

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[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).

[7] Amarin Corp. plc, Annual Report (Form 10-K), at 3 (Feb. 29, 2012).

[8] Press Release, Amarin Corp. plc, "Amarin Announces Approval of Supplemental New Drug Application for Chemport as Additional Vascepa® Active Pharmaceutical Ingredient Supplier" (Apr. 18, 2013), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-approval-supplemental-new-drug-application (last accessed May 6, 2021).

14. As a result of Amarin's scheme, DRL's launch of generic Vascepa has been delayed since August 2020, Hikma's launch of generic Vascepa has been constrained by limited supply, and Plaintiffs and members of the class have been forced to pay anticompetitive prices for Vascepa and its generic equivalent.

JURISDICTION AND VENUE

15. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds $5,000,000, exclusive of interest and costs; there are more than one hundred members of each class; and at least one member of each of the putative classes is a citizen of a state different from that of one of the Defendants.

16. This Court also has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367(a).

17. Venue is appropriate within this District under 28 U.S.C. § 1391. Defendants transact business within this District and/or have agents in and/or that can be found in this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District. At all relevant times, Amarin's U.S. operations were headquartered in this District.

18. The Court has personal jurisdiction over each of the Defendants. Defendants have transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme throughout the United States, including in this District. The scheme has been directed at and has had the intended effect of causing injury to individuals and companies residing in or doing business throughout the United States, including in this District. Personal jurisdiction lies under Fed. R. Civ. P. 4(k)(2) over the foreign domiciliary defendants.

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