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,

Civil Action No.

Plaintiffs,

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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.

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"). 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.

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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=2 09499#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 manufacturers⁵ 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," 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."

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.
- This Court also has supplemental jurisdiction over state law claims pursuant to 28U.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.

THE PARTIES

A. Plaintiffs

- 19. Plaintiff Uniformed Fire Officers Association Family Protection Plan Local 854 ("UFOAFPP") is a health and welfare benefits plan headquartered and with a principal place of business in New New York, New York. UFOAFPP administers the assets of defined contribution plans formed to provide certain benefits including prescription drug benefits. UFOAFPP provides health and welfare benefits to members and participants who reside in numerous locations in the United States. UFOAFPP purchased and/or provided reimbursement for some or all of the purchase price for Vascepa other than for re-sale, in at least Connecticut, New York, and New Jersey at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that UFOAFPP will in the future purchase Vascepa manufactured by Amarin, and it has purchased and/or intends to purchase generic versions of Vascepa, other than for re-sale, once they become available. UFOAFPP paid and reimbursed more for these products than they would have absent Defendants' anticompetitive conduct to fix, raise, maintain, and stabilize the prices and allocate markets for Vascepa.
- 20. Plaintiff Uniformed Fire Officers Association For Retired Fire Officers Family Protection Plan ("RFOFPP") is a health and welfare benefits plan headquartered and with a principal place of business in New New York, New York. RFOFPP administers the assets of defined contribution plans formed to provide certain benefits including prescription drug benefits. RFOFPP provides health and welfare benefits to members and participants who reside in numerous locations in the United States. RFOFPP purchased and/or provided reimbursement for some or all of the purchase price for Vascepa other than for re-sale, in at least Connecticut, Delaware, Florida, New York, New Jersey, Pennsylvania, South Carolina, and Virginia at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability

that RFOFPP will in the future purchase Vascepa manufactured by Amarin, and it has purchased and/or intends to purchase generic versions of Vascepa, other than for re-sale, once they become available. RFOFPP paid and reimbursed more for these products than they would have absent Defendants' anticompetitive conduct to fix, raise, maintain, and stabilize the prices and allocate markets for Vascepa.

B. Defendants

- 21. Defendant Amarin Pharma, Inc. is a company organized and existing under the laws of Delaware with its principle place of business at 1430 Route 206, Bedminster, NJ 07921.
- 22. Defendant Amarin Pharmaceuticals Ireland Limited is a company incorporated under the laws of Ireland with registered offices at 88 Harcourt Street, Dublin 2, Dublin, Ireland.
- 23. Defendant Amarin Corporation plc is a company incorporated under the laws of England and Wales with principal executive offices at 77 Sir John Rogerson's Quay, Block C, Gran Canal Docklands, Dublin 2, Ireland. Defendants Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Amarin Corporation plc are collectively referred to herein as "Amarin."
- 24. Defendant BASF Americas Corporation is a company organized and existing under the laws of Delaware with its principle place of business at 1105 North Market Street, Suite 1306, P.O. Box 8985, Wilmington, DE 19899.
- 25. Defendant BASF Corporation is a company organized and existing under the laws of Delaware with its principle place of business at 100 Park Avenue, Florham Park, NJ 07932.
- 26. Defendant BASF Pharma (Callanish) Limited is a company incorporated under the laws of England with registered offices at 2 Stockport Exchange, Railway Road, Stockport, SK1 3GG, United Kingdom.

- 27. Defendant BASF USA Holding LLC is a company organized and existing under the laws of Delaware with its principle place of business at 100 Park Avenue, Florham Park, NJ 07932. Defendants BASF Americas Corporation, BASF Corporation, BASF Pharma (Callanish) Limited, and BASF USA Holding LLC are collectively referred to herein as "BASF."
- 28. Defendant Chemport Inc. is a company incorporated under the laws of the Republic of Korea with its principal place of business at 15-1, Dongsu-dong, Naju-si, Jeollanam-do 520-330 Korea.
- 29. Defendant Nisshin Pharma, Inc. is a company incorporated under the laws of Japan with its principal place of business at 25, Kanda-Nishiki-cho 1-chome, Chiyoda-ku, Tokyo 101-8441, Japan.
- 30. Defendant Novasep, LLC is a company organized and existing under the laws of New Jersey with its principal place of business at 23 Creek Circle, Boothwyn, PA 19061.
- 31. Defendant Novasep, Inc. is a company organized and existing under the laws of New Jersey with its principal place of business at 23 Creek Circle, Boothwyn, PA 19061.
- 32. Defendant Groupe Novasep SAS is a company incorporated under the laws of France with its principal place of business at 39, Rue Saint Jean De Dieu Lyon, 69007 France.
- 33. Defendant Finorga SAS is a company organized and existing under the laws of France with its principal place of business at Route De Givors Chasse Sur Rhone, 38670 France. Defendants Novasep, LLC, Novasep, Inc., Group Novasep SAS, and Finorga SAS are collectively referred to herein as "Novasep."

REGULATORY BACKGROUND

A. Approval of a first entrant

34. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., manufacturers that create a new drug must obtain approval from the FDA to sell the product

by filing a New Drug Application ("NDA"). An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 10

35. When the FDA approves a brand pharmaceutical manufacturer's NDA, the manufacturer may list in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") certain patents that the manufacturer asserts could reasonably be enforced against a manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. After the FDA approves the NDA, the brand manufacturer may list such patents in the Orange Book.¹¹

36. When they do not face generic competition, brand manufacturers can usually sell the branded drug far above the marginal cost of production, generating profit margins well in excess of 70% while making hundreds of millions of dollars in sales.

B. Approval of a generic drug

37. Once lawful periods of patent exclusivity expire on branded drug products, generic drug manufacturers can seek FDA approval to market and sell generic versions of the branded drug. Under the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984)—commonly known as "Hatch-Waxman"—competitors wishing to sell a generic equivalent of a branded drug may file an abbreviated new drug application ("ANDA"), which relies in substantial part on the scientific findings of safety and efficacy contained in the branded drug manufacturer's NDA. The brand drug is called the reference listed drug ("RLD").

⁹ 21 U.S.C. §§ 301-392.

¹⁰ 21 U.S.C. §§ 355(a), (b).

¹¹ 21 U.S.C. §§ 355(b)(1), (c)(2).

38. To gain FDA approval, generic drugs must be bioequivalent to their branded counterparts. Bioequivalence means that the active ingredient of the proposed generic would be present in the blood of a patient to the same extent and for the same amount of time as the active ingredient of the brand. Bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another. The FDA assigns an "AB" rating to generics that meet the necessary criteria in relation to their branded counterparts.

- 39. Because generic drugs are therapeutically equivalent to brand-name drugs, generic manufacturers compete by offering their drugs at low prices. Entry of a single generic can result in steep price reductions for purchasers. Entry of several generics tends to result in even steeper price reductions, driving price down close to marginal manufacturing costs.
- 40. To benefit from these low prices, every state has adopted substitution laws requiring or permitting pharmacies to substitute AB-rated generic equivalents when filling branded drug prescriptions, unless the prescribing physician specifically directs otherwise. Due in part to these substitution laws, the launch of AB-rated generics causes a rapid price decline and shift from branded to generic drug sales. A generic that is unconstrained by supply issues often captures 80% or more of the market within the first six months of entry, regardless of the number of generic entrants. The effects of generic entry are still more dramatic after a year. In a review of industry

¹² 21 U.S.C. § 355(j)(8)(B).

data, the FTC found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and prices had dropped 85% with multiple generics on the market.¹³

C. Regulatory exclusivities

41. A "new chemical entity" is a drug that contains an active moiety—the part of the drug responsible for the physiological or pharmacological action of the drug—that the FDA has not previously approved in another NDA.¹⁴ Approval of an NDA with a new chemical entity provides a five-year exclusivity ("NCE exclusivity") during which the FDA cannot approve an ANDA for a drug containing the same active moiety as the new chemical entity.¹⁵

D. Supply and Use of API in Drug Products

- 42. Final drug products consumed by patients and the active pharmaceutical ingredients contained in those final drug products are frequently manufactured by different companies. In such cases the manufacturer of the final drug product, whether brand or generic, combines the API purchased from other sources with inactive ingredients to manufacture the final dosage form. Although a generic manufacturer's process for manufacturing the final dosage form may be different from the manufacturer of the RLD, it is typical for the different manufacturers to use identical API.
- 43. As part of the process for obtaining regulatory approval to sell an active pharmaceutical ingredient in the United States, the API manufacturer ordinarily must file a Drug

¹³ See Federal Trade Commission, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions 8 (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-payoffs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

¹⁴ 21 C.F.R. § 314.108(a).

¹⁵ 21 C.F.R. § 314.108(b)(2).

Master File ("DMF") with the FDA. The DMF provides "confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of" the API. The manufacturer of a final dosage form, in turn, references the DMF of each of its API suppliers in its New Drug Application (whether Abbreviated or full). The FDA then reviews the technical information contained in, and inspects the relevant facilities described in, each DMF referenced in the ANDA or NDA. A single DMF may be referenced by multiple manufacturers.

- 44. It takes significant time to develop a process for manufacturing an API and then prepare and file the necessary DMF.
- 45. If a manufacturer wants or needs to change its API supplier for a drug, it must file a supplement with the FDA referencing the new API supplier's DMF and submit data for drug batches using the new supplier's API. The manufacturer may only market its drug using the new supplier's API if the FDA approves of the change. It is time consuming to prepare and file the necessary supplement and then obtain FDA approval of the change in API supplier.
- 46. If a current DMF holder is willing, a generic drug manufacturer may use API from an API supplier that already has a DMF on file and reference that DMF in their ANDAs. If, however, no current DMF holder is willing to supply the generic manufacturer with API, it must identify a new API supplier (who does not yet have a DMF on file) and work with that supplier to develop the API and submit a DMF.
- 47. Generally, because of the significant costs involved in qualifying an API supplier as well as the need to continue to ensure quality control by the API supplier, it is industry practice

¹⁶ Guidelines For Master Drug Files, § I, https://www.fda.gov/drugs/guidances-drugs/drug-master-files-guidelines (last accessed May 13, 2021).

¹⁷ 21 CFR 314.420(b).

for both brand and generic drug manufacturers to use only one or two API suppliers to support a drug application.¹⁸

FACTS

A. Vascepa

- 48. Vascepa is the brand name for the icosapent ethyl drug product marketed by Amarin, manufactured using the active pharmaceutical ingredient IPE, which is derived from eicosapentaenoic acid ("EPA"), a type of omega-3 fatty acid derived from fish oil.
- 49. On July 26, 2012, Amarin received FDA approval to market Vascepa: "as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia." Subsequently, the FDA determined that Vascepa was entitled to NCE exclusivity, *see supra* at paragraph 41, which ran from the NDA approval date to July 26, 2017.
- 50. On December 13, 2019, the FDA approved a new indication for Vascepa: "as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and . . . established cardiovascular disease or . . . diabetes mellitus and 2 or more additional risk factors for cardiovascular disease." The new indication is entitled to data exclusivity, which is scheduled to expire on December 13, 2022.
- 51. Amarin currently markets Vascepa in the 1g and 500mg strengths. Amarin has raised the price of 1g Vascepa dramatically since its launch: the list price for the 1mg strength of Vascepa was

¹⁸ See, e.g., Mallu UR, Nair AK, Bapatu HR, Pavan Kumar M, Narla S, et al., "API Supplier Change or Addition of Alternate API Supplier in Generic Drug Products: Cost, Quality and Regulatory Factors" (Pharmaceutical Analytica Acta 2015) at 2 ("[T]wo suppliers shall be selected one as main and another one as alternative supplier for generic DP development.").

estimated to be \$308.25 per month in 2019, 19 \$355 per month in 2020, 20 and is currently estimated to be around \$368.86.21

52. Vascepa is Amarin's only product, with revenues of \$607 million in 2020.²²

B. Amarin set out to lock up the world's supply of Vascepa API for the explicit purpose of preventing generic competition

- 53. As discussed above, the API for Vascepa is IPE, which is derived from fish oil.
- 54. For more than a decade, Amarin has set out to lock up the world's supply of IPE for the explicit purpose of "protecting the potential commercial exclusivity" of Vascepa.²³
- 55. From the beginning Amarin stated its intention to take advantage of manufacturing barriers to entry to prevent competition: "We will seek to protect the potential commercial exclusivity of [Vascepa] through a combination of obtaining and maintaining intellectual property rights and regulatory exclusivity, *taking advantage of manufacturing barriers to entry* and maintaining trade secrets."²⁴

¹⁹ "J&J's Xarelto, Amarin's Vascepa are cost-effective, not budget friendly," EndpointsNews (Oct. 18, 2019), https://endpts.com/jjs-xarelto-amarins-vascepa-are-cost-effective-but-not-budget-friendly-icer/ (last accessed May 6, 2021).

²⁰ "A cardiologist asks: How much is too much to pay for a promising drug?," The Philadelphia Inquirer (Jan. 20, 2020), https://www.inquirer.com/health/expert-opinions/vascepa-price-cardiology-triglycerides-fish-oil-20200122.html (last accessed May 6, 2021).

²¹ "Vascepa Prices, Coupons, and Patient Assistant Programs," https://www.drugs.com/price-guide/vascepa (last accessed May 6, 2021).

²² Amarin Corp. plc, Annual Report (Form 10-K), at F-5 (Feb. 25, 2021).

²³ Amarin Corp. plc Annual Report (Form 10-K), at 3 (Feb. 20, 2012).

²⁴ *Id.* (emphasis added); *see also* Amarin Corp. plc Annual Report (Form 10-K), at 21 (Feb. 27, 2014) ("FDA marketing exclusivity is separate from, and in addition to, patent protection, trade secrets and manufacturing barriers to entry which also help protect Vascepa against generic competition.").

- Application ("sNDA") to add Chemport Inc. ("Chemport") as an API supplier. In that announcement Amarin confirmed that the "manufacturing barriers to entry" that it intended to take advantage of are the various exclusive contracts that it used to foreclose the supply of Vascepa API: "The addition of Chemport contributes to the planned expansion of the Vascepa manufacturing supply chain and is additional progress toward Amarin's goal to protect the commercial potential of Vascepa to beyond 2030 through a combination of patent protection, regulatory exclusivity, trade secrets and by taking advantage of manufacturing barriers to entry."²⁶
- 57. Joseph Zakrewski, Amarin's CEO, further confirmed that the key barrier to entry was the supply of API, stating that: "The move [to add Chemport as an API supplier] also fortifies

 Amarin's efforts to shield its Vascepa patent beyond its scheduled 2030 expiration." 27
- 58. Amarin further explained its anticompetitive strategy in its 2014 Annual Report: "Certain of our agreements with our suppliers include minimum purchase obligations and limited exclusivity provisions based on such minimum purchase obligations. If we do not meet the respective minimum purchase obligations in our supply agreements, our suppliers, in certain cases, will be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors . . .

²⁵ 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).

²⁶ *Id.* (emphasis added).

²⁷ "Amarin wins U.S. nod to add S. Korea supplier," Hartford Business Journal (Apr. 19, 2013) (emphasis added), https://www.hartfordbusiness.com/article/amarin-wins-us-nod-to-add-s-korea-supplier (last accessed May 6, 2021).

While we anticipate that intellectual property barriers and FDA regulatory exclusivity will be the primary means to protect the commercial potential of Vascepa, the availability of Vascepa active pharmaceutical ingredient from our suppliers to our potential competitors would make our competitors' entry into the market easier and more attractive."²⁸

- April 2012, the FDA published draft guidance for companies that may seek to develop generic versions of Vascepa. If an application for a generic version of Vascepa were filed and if new chemical entity, or NCE exclusivity is not granted to Vascepa, the FDA may accept the filing for review and we would likely engage in costly litigation with the applicant to protect our patent rights. If the generic filer is ultimately successful in patent litigation against us, meets the requirements for a generic version of Vascepa to the satisfaction of the FDA (after any applicable regulatory exclusivity period and, typically, the litigation-related 30-month stay period expires), and is able to supply the product in significant commercial quantities, the generic company could, with the market introduction of a generic version of Vascepa, limit our U.S. sales, which would have an adverse impact on our business and results of operations."²⁹
- 60. Amarin further warned the market that failure of its anticompetitive scheme was a material investment risk: "Risks Related to our Reliance on Third Parties We may not be able to maintain our exclusivity with our third-party Vascepa suppliers if we do not meet minimum purchase obligations due to lower than anticipated sales of Vascepa."³⁰

²⁸ Amarin Corp. plc, Annual Report (Form 10-K), at 40 (March 3, 2015).

²⁹ Amarin Corp. plc, Quarterly Report (Form 10-Q), at 31 (Aug. 8, 2013) (emphasis added).

³⁰ Amarin Corp. plc, Quarterly Report (Form 10-Q), at 46 (Nov. 7, 2013); *see also* Amarin Corp. plc, Quarterly Report (Form 10-Q), at 59 (Aug. 7, 2014) ("Certain of our agreements with our suppliers include minimum purchase obligations and limited exclusivity provisions based on such minimum purchase obligations. If we do not meet the respective minimum purchase obligations

C. Amarin has, in fact, locked up the world's supply of Vascepa API

- 61. To effectuate its anticompetitive scheme, Amarin has entered into exclusive or *de facto* exclusive agreements with at least four of the largest suppliers for icosapent ethyl API, and has otherwise secured exclusive supply from yet another supplier.
- 62. In February 2009 Amarin entered into a supply agreement with Japan-based Nisshin Pharma Inc. ("Nisshin") pursuant to which Nisshin agreed to supply Amarin with IPE (referred to as E-EPA in the agreement).³¹ Amarin paid Nisshin \$500,000 when the agreement was signed, and agreed to pay Nisshin another \$500,000 when Amarin obtained approval to market Vascepa either in the U.S. or the European Union.³² The agreement contained a minimum purchase commitment.³³
- 63. Amarin believed that Nisshin was capable of producing sufficient quantities of API to support Amarin's launch of Vascepa.³⁴ Nonetheless, it continued to amass API supply and suppliers.

in our supply agreements, our suppliers, in certain cases, will be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors of Vascepa. Similarly if we terminate certain of our supply agreements, such suppliers may be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors of Vascepa. While we anticipate that intellectual property barriers and FDA regulatory exclusivity will be the primary means to protect the commercial potential of Vascepa, the availability of Vascepa active pharmaceutical ingredient from our suppliers to our potential competitors would make our competitors' entry into the market easier and more attractive.").

Supply Agreement Between (1) Nisshin Pharma Inc. ("Nisshin") and (2) Amarin Pharmaceuticals (Ireland) Ltd. ("Amarin"), dated February 23, 2009, https://www.sec.gov/Archives/edgar/data/897448/000095016209000453/ex4_86.htm (last accessed May 6, 2021).

³² *Id.* at 15.

 $^{^{33}}$ *Id*.

³⁴ Amarin Corp. plc, Annual Report (Form 10-K), at 10-11 (February 29, 2012); *see also* Press Release, Amarin Corp. plc, "Amarin Announces Additional Vascepa® (icosapent ethyl) Supplier" (Dec. 11, 2012) ("Amarin's current plan is to launch Vascepa based on product produced by its

64. In June 2011, the BBC reported that Amarin had entered into a supply agreement with Scotland-based Equateq Ltd. ("Equateq") pursuant to which Equateq agreed to supply Amarin with the API needed to manufacture Vascepa. Amarin again committed to significant, long-term purchases: "Under the terms of the contract, Amarin Corporation is committed to buying £6.1m worth of API concentrate from Equateq in year one, rising to £12.3m in year four." In fact, although the CEO of Equateq refused to provide further specifics of the supply agreement, he claimed it was worth £100m over its life. Amarin revealed to investors in August 2011 that the minimum purchase commitment was intended to prevent Equateq from selling Vascepa API to any potential competitor of Amarin. Amarin also paid Equateq a \$1m "commitment fee" in May 2011. Equateq was acquired by BASF in May 2012.

existing API supplier, Nisshin Pharma"), https://www.globenewswire.com/en/news-release/2012/12/11/510754/18362/en/Amarin-Announces-Additional-Vascepa-R-icosapent-ethyl-Supplier.html (last accessed May 6, 2021)

³⁵ "Drug firm Equateq secures big US order," BBC News (July 4, 2011), https://www.bbc.com/news/uk-scotland-scotland-business-14013747 (last accessed May 6, 2021). ³⁶ *Id*.

³⁷ "Equateq nets £100m deal to supply fish oil for heart treatment," The Scotsman (June 29, 2011), https://www.scotsman.com/business/equateq-nets-ps100m-deal-supply-fish-oil-heart-treatment-1670500 (last accessed May 6, 2021).

³⁸ Amarin Corp. plc Quarterly Report (Form 10-Q), at 9 (Aug. 9, 2011) ("Following FDA approvals of [Vascepa], both agreements [with Equateq and Chemport Inc. (see para. 53 below)] include annual purchase levels *to enable Amarin to maintain exclusivity with each respective supplier*, and to prevent potential termination of the agreements.").

³⁹ *Id*.

⁴⁰ "BASF completes omega-3 portfolio with Equateq buy," NUTRAingredients.com (May 8, 2012), https://www.nutraingredients.com/Article/2012/05/09/BASF-completes-omega-3-portfolio-with-Equateq-buy# (last accessed May 6, 2021).

- 65. Also in 2011, Amarin secured an exclusive supply contract with Korea-based Chemport Inc. ("Chemport").⁴¹ This agreement also contains minimum purchase requirements to prevent Chemport from selling API to potential generic manufacturers,⁴² and Amarin is required to pay Chemport in cash for any shortfall in the minimum purchase obligations.⁴³ As part of the agreement, Amarin agreed to pay Chemport \$1.1m for the purchase of raw materials and to provide an additional \$3.3m to Chemport as as equity investment.⁴⁴ During the nine months ended September 30, 2013, the Company made payments of \$4.8 million to Chemport.⁴⁵
- 66. Equateq and Chemport were approved by the FDA to manufacture Vascepa API in April 2013.⁴⁶
- 67. In December 2012, Amarin announced that it had entered into an additional exclusive agreement with a fourth supplier, an "exclusive consortium" of companies including Canada-based Slanmhor Pharmaceutical, Inc., Ocean Nutrition Canada, and Novasep (collectively referred to in this Complaint as "Novasep").⁴⁷ As part of the agreement, Amarin agreed to pay up to \$2.3 million in development fees and a "commitment" of up to \$15 million, credited against future API material purchase.⁴⁸ The Company made payments of \$3.9 million to Novasep in the

⁴¹ Amarin Corp. plc Quarterly Report (Form 10-Q), at 9 (Aug. 9, 2011).

⁴² *Id.* ("Following FDA approvals of [Vascepa], both agreements [with Equateq and Chemport] include annual purchase levels *to enable Amarin to maintain exclusivity with each respective supplier*, and to prevent potential termination of the agreements.").

⁴³ Amarin Corp. plc Annual Report (Form 10-K), at F-25 (Feb. 27, 2014).

⁴⁴ *Id*.

⁴⁵ Amarin Corp. plc Quarterly Report (Form 10-Q), at 15 (Nov. 7, 2013).

⁴⁶ Amarin Corp. plc Quarterly Report (Form 10-Q), at 13 (May 9, 2013).

⁴⁷ Press Release, Amarin Corp. plc, "Amarin Announces Additional Vascepa® (icosapent ethyl) Supplier" (Dec. 11, 2012).

⁴⁸ Amarin Corp. plc Quarterly Report (Form 10-Q), at 13 (May 9, 2013).

quarter in which the agreement was signed,⁴⁹ and an additional \$1.4 million in the following quarter.⁵⁰ The Novasep agreement includes minimum purchase obligations, and Amarin is required to make cash payments to Novasep in the event of a shortfall.⁵¹ During the nine months ended September 30, 2013, the Company made payments of \$6.1 million to Novasep.⁵² In July 2014 Amarin cancelled the agreement with the consortium and in July 2015 it entered a new agreement with Novasep in its own right.⁵³

- 68. The Company purchased approximately \$25.7 million worth of Vascepa API in 2013 from Nisshin and Chemport, and also paid \$13.9 million to Novasep related to "commitments," stability and technical batches, and advances on future API purchases.⁵⁴
- 69. In October 2013, Amarin received bad news from the FDA which "was seen by most observers as the death blow for Amarin's efforts to gain wider approval."⁵⁵ Although this was expected to result in less-than-hoped-for demand for Vascepa, Novasep and BASF planned to continue supplying Vascepa API at the agreed-upon pace.⁵⁶

⁴⁹ *Id*.

⁵⁰ Amarin Corp. plc Quarterly Report (Form 10-Q), at 15 (Aug. 8, 2013).

⁵¹ *Id*.

⁵² Amarin Corp. plc Quarterly Report (Form 10-Q), at 15 (Nov. 7, 2013).

⁵³ Amarin Corp. plc Annual Report (Form 10-K), at 14 (Feb. 25, 2016).

⁵⁴ Amarin Corp. plc Quarterly Report (Form 10-Q), at 33 (Nov. 7, 2013).

⁵⁵ "Novasep to keep supplying Amarin with Vascepa API," Outsourcing-Pharma.com (Oct. 30, 2012), https://www.outsourcing-pharma.com/Article/2013/10/30/Novasep-to-keep-supplying-Amarin-with-Vascepa-API (last accessed May 6, 2021).

⁵⁶ *Id*.

- 70. Finally, Amarin has secured significant additional supply from an another Japan-based supplier, Nippon Suisan, and that company's supply is not available to any U.S. generic.⁵⁷
- 71. The foregoing agreements between Amarin and the Vascepa API suppliers were intended to and have limited competition in the market for generic Vascepa. At bottom, the API suppliers took millions of dollars in payments from Amarin in exchange for an agreement *not* to sell the essential API, regardless of whether Amarin needed the API for its own production needs or whether there were other market opportunities for the sale of the API. By foreclosing API supply from generic competitors, Amarin has been able to capture supracompetitive profits from the inflated sales of Vascepa, and has shared those supracompetitive profits with the API suppliers to buy their complicity in the anticompetitive scheme.

D. Amarin secured more than twice the API supply than it needs for legitimate business purposes

72. In February 2019, Amarin's CEO John Thero stated that Amarin's anticipated 2019 sales of Vascepa amounted to \$350 million, but the company was purchasing API to support sales of more than \$700 million.⁵⁸ Thero was clear that Amarin was *not* raising its guidance or expecting to sell more than \$700 million in Vascepa that year, but was merely purchasing excess supply.⁵⁹

⁵⁷ "Amarin: What The Street Hasn't Factored In And Why Amarin Is Worth \$80," Seeking Alpha (Oct. 9, 2018) ("Nippon Suisan (1332 JT), or better known as "Nissui" in the Japanese stock market, has 420 tons worth of annual high-grade EPA supply, solely aimed for the further roll-out of Amarin's Vascepa."), https://seekingalpha.com/article/4210747-amarin-what-street-hasn't-factored-in-and-why-amarin-is-worth-80 (last accessed May 6, 2021).

⁵⁸ Amarin Corp. plc Earnings Call (Feb. 27, 2019), https://www.fool.com/earnings/call-transcripts/2019/02/27/amarin-corporation-plc-amrn-q4-2018-earnings-confe.aspx (last accessed May 6, 2021).

⁵⁹ *Id.* ("Hey, we could be wrong on our guidance. Our guidance doesn't assume any earlier approval from the FDA. And they had their mind to our product as four-year dating. Dating, one of the things we spent a lot of time in the development of this product was the stability of it and

73. At the same time that Amarin was purchasing more than twice its supply needs for 2019 from its existing suppliers, Amarin was in the process of locking up 420 tons worth of additional annual supply.⁶⁰ For comparison, the entire U.S. market for Vascepa is estimated to require 450 tons per year.

E. Amarin's excess supply makes no economic sense absent anticompetitive advantages, and is contrary to industry practice

- 74. In Amarin's own words: "The agreements with each of our API suppliers contemplate phased manufacturing capacity expansions designed to create sufficient manufacturing capacity to meet anticipated demand for API material for [Vascepa] following FDA approval. Accordingly, Nisshin and our other potential suppliers are currently working to expand and qualify their production capabilities to meet regulatory requirements to manufacture the API for [Vascepa]. These API suppliers are self-funding these expansion and qualification plans with contributions from Amarin."61
- 75. Amarin provided further detail about the expenses necessary to develop and maintain so many API suppliers: "Among the conditions for FDA approval of a pharmaceutical product is the requirement that the manufacturer's quality control and manufacturing procedures conform to current Good Manufacturing Practice, or cGMP, which must be followed at all times. The FDA typically inspects manufacturing facilities before regulatory approval of a product

preventing oxidation, etc. So, it's got a long shelf life. So, they figure that that's the right investment to be made.").

⁶⁰ "Amarin: What The Street Hasn't Factored In And Why Amarin Is Worth \$80," Seeking Alpha (Oct. 9, 2018), https://seekingalpha.com/article/4210747-amarin-what-street-hasnt-factored-in-and-why-amarin-is-worth-80 ("Nippon Suisan (1332 JT), or better known as "Nissui" in the Japanese stock market, has 420 tons worth of annual high-grade EPA supply, solely aimed for the further roll-out of Amarin's Vascepa.").

⁶¹ Amarin Corp. plc Annual Report (Form 10-K), at 11 (Feb. 20, 2012) (emphasis added).

candidate, such as [Vascepa], and on an ongoing basis. In complying with cGMP regulations, pharmaceutical manufacturers must expend resources and time to ensure compliance with product specifications as well as production, record keeping, quality control, reporting, and other requirements. Our NDA filed with the FDA for [Vascepa] references one supplier of our API, Nisshin, with which we have had the longest relationship and which we believe is qualified to support our initial commercial launch of [Vascepa]. We have defined with the FDA our plan and specifications for qualifying the additional API suppliers. We intend to submit sNDAs⁶² for the use of these additional API suppliers after the suppliers successfully complete the specified process and facility qualifications and after the NDA for the MARINE indication is approved."⁶³

- 76. As these public statements confirm, it is expensive and time consuming for each new API supplier to develop, obtain regulatory approval for, and maintain quality control of its API manufacturing process, and Amarin bears a significant share of that burden.
- 77. On the other hand, it is possible⁶⁴ and less expensive to scale up the supply from an existing manufacturer than it is to qualify additional suppliers. Consequently, standard industry practice is to have only one or two API suppliers.
 - 78. In addition to saving initial setup costs, the benefits of scale result in volume

⁶² Defined in paragraph 68 above.

⁶³ *Id.*; see also Amarin Corp. plc Quarterly Report, at 16 (Nov. 8, 2011) ("We anticipate incurring certain costs associated with the qualification of product produced by [Nishhin, Equateq, and Chemport].").

⁶⁴ Amarin Corp. plc Annual Report (Form 10-K), at 75 (Feb. 27, 2019) ("our current supply chain is scalable"); *see also*, Amarin Corp. plc Earnings Conference Call Transcript (Feb. 27, 2019) ("We have a supplier network that consists of over 20 independent companies. The API piece of that – we have multiple suppliers on. They're competing with one another. *And they're interested in expanding capacity*."), https://www.fool.com/earnings/call-transcripts/2019/02/27/amarin-corporation-plc-amrn-q4-2018-earnings-confe.aspx (last accessed May 6, 2021).

discounts,⁶⁵ which Amarin foregoes by engaging additional suppliers with minimum purchase requirements.

79. Given these inefficiencies, the only economic advantages from having four API suppliers, and obtaining excess API inventory, results from the inability of generic competitors to obtain API supply.

F. Amarin's scheme succeeded in thwarting generic competition

- 80. DRL obtained final FDA approval on August 7, 2020,⁶⁶ but has still been unable to secure a supply of API sufficient to support a launch of its generic Vascepa.⁶⁷
- 81. Hikma, on the other hand, was able to launch on November 5, 2020,⁶⁸ but was forced to release limited quantities due to supply constraints.⁶⁹

⁶⁵ Amarin Corp. plc Annual Report (Form 10-K), at 75 (Feb. 27, 2019) ("Certain of our API supply agreements contain provisions under which the cost of supply to us decreases as we purchase increased product volume.").

Product Details for ANDA 209400, https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=2 09499#312 (last accessed May 6, 2021).

⁶⁷ DRL Complaint at ¶ 81 ("Nonetheless, despite DRL's best efforts to launch in a timely manner, it is still unable to do so. The only reason why DRL still cannot launch is because Amarin contracted with suppliers of icosapent ethyl API not to sell to generic manufacturers including DRL, either through literal exclusive contract or through buying up all available supplies, such that DRL cannot acquire the necessary API to support a timely commercial launch.") *see also id.* at ¶ 8 ("But for Amarin's locking up of the icosapent ethyl API supply, DRL would have been ready, willing, and able to launch in August 2020, upon receiving regulatory approval.").

⁶⁸ Press Release, Hikma Pharmaceuticals plc, "Hikma launches Icosapent Ethyl Capsules" (Nov. 5, 2020), https://www.hikma.com/newsroom/article-i4928-hikma-launches-icosapent-ethyl-capsules/ (last accessed May 6, 2021).

⁶⁹ "Amarin launches Vascepa in all-important Europe as it slowly bleeds share to U.S. generic," Fierce Pharma (Apr. 6, 2021), https://www.fiercepharma.com/marketing/amarin-launches-vascepa-all-important-europe-as-blockbuster-to-be-heart-drug-slowly (last accessed May 6, 2021).

82. For its part, Amarin believes its scheme is working, and wants the market to know: "We have heard from various suppliers that they have been approached regarding supplying API for generic use. These suppliers informed us that they turned down such approaches for various reasons including that they don't have excess capacity."⁷⁰ And in a press release discussing the Court of Appeals decision Amarin knowingly conveyed that generic manufacturers "are likely to have limited supply capacity."⁷¹

CAUSATION

- 83. But for the anticompetitive conduct alleged above, generic icosapent ethyl would have entered the market as early as August 2020, the date of DRL's final ANDA approval, because, absent Amarin's anticompetitive conduct, there would have been sufficient supply of Vascepa API for DRL to do so.
- 84. Likewise, absent the Defendants' anticompetitive conduct, Hikma would have launched its generic Vascepa at full supply because, absent Amarin's anticompetitive conduct, there would have been sufficient supply of Vascepa API for Hikma to do so.
- 85. Instead, Defendants willfully and unlawfully maintained Amarin's monopoly power in the relevant market by engaging in a conspiracy to exclude competition and maintain supracompetitive prices for Vascepa. Defendants implemented their conspiracy *via* their exclusive contracts and other conduct alleged herein.

⁷⁰ Amarin Corp. plc Earnings Call Transcript (Apr. 13, 2020), https://www.fool.com/earnings/call-transcripts/2020/04/13/amarin-corporation-plc-amrn-q1-2020-earnings-call.aspx (last accessed May 6, 2021).

⁷¹ Press Release, Amarin Corp. plc, "Amarin Provides Update Following Ruling in Vascepa® ANDA Patent Litigation" (Sep. 3, 2020), https://investor.amarincorp.com/news-releases/news-release-details/amarin-provides-update-following-ruling-vascepar-anda-patent.

- 86. The only impediment to DRL's generic icosapent ethyl entering the market is Defendants' unlawful conduct.
- 87. Likewise, the only impediment to Hikma's fully supplying demand for generic icosapent ethyl is Defendans' unlawful conduct.
- 88. Defendants' conspiracy had the purpose and effect of preventing competition to Vascepa, permitting Amarin to maintain supracompetitive prices for Vascepa, enabling Amarin to sell Vascepa without competition, and allowing Amarin to reap monopoly profits (and share those monopoly profits with the API-supplier defendants), to the detriment of purchasers.

MARKET POWER AND DEFINITION

- 89. The pharmaceutical marketplace is characterized by a "disconnect" between product selection and the payment obligation. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Vascepa, to patients without a prescription. The prohibition on dispensing certain products without a prescription creates this disconnect. The patient's doctor chooses which product the patient will buy while the patient (and in most cases his or her insurer) has the obligation to pay for the product.
- 90. Brand manufacturers, including Amarin, exploit this price disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors of the cost of the branded products. Studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are largely insensitive to price differences because they do not pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.
 - 91. The relative unimportance of price in the pharmaceutical marketplace reduces what

economists call the price elasticity of demand - the extent to which unit sales go down when price goes up. This lower price elasticity, in turn, gives brand manufacturers the ability to raise prices substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is what economists and antitrust courts refer to as market power. The result of these pharmaceutical market imperfections and marketing practices is that brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals, including Vascepa.

- 92. Throughout the relevant time period, Amarin had monopoly power in the market for Vascepa because they had the power to exclude competition and/or raise or maintain the price of Vascepa and generic equivalents at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable.
- 93. A small but significant non-transitory increase to the price of brand Vascepa would not have caused a significant loss of sales sufficient to make the price increase unprofitable.
- 94. Brand Vascepa does not exhibit significant, positive cross-elasticity of demand with respect to price with any other product for the treatment of hypertriglyceridemia.
- 95. Brand Vascepa is differentiated from all other products currently on the market for treatment of hypertriglyceridemia.
- 96. Amarin needed to control only brand Vascepa and its AB-rated generic equivalents, and no other products, in order to maintain the price of icosapent ethyl profitably at supracompetitive prices. Only the market entry of competing, AB-rated generic versions of Vascepa unconstrained by supply issues would render Amarin unable to profitably maintain their prices for Vascepa without losing substantial sales.
 - 97. Amarin had, and exercised, the power to exclude generic competition to brand

Vascepa.

- 98. At all material times, high barriers to entry protected branded Vascepa from the forces of price competition.
- 99. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Amarin's ability to control the price of Vascepa and generic Vascepa, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, inter alia, the following facts: (a) generic Vascepa would have entered the market at a substantial discount to brand Vascepa but for Defendants' anticompetitive conduct; (b) Amarin's gross margin on Vascepa at all relevant times was very high; and (c) Amarin never lowered the price of Vascepa to the competitive level in response to the pricing of other brand or generic drugs, and indeed enjoyed rising sales as it dramatically increased the price of Vascepa.
- 100. To the extent proof of monopoly power by defining a relevant product market is required, Plaintiffs allege that the relevant antitrust market is the market for Vascepa and its ABrated generic equivalents.
- 101. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.
- 102. Amarin market share in the relevant market was 100% prior to Hikma's constrained generic launch, implying substantial monopoly power.

MARKET EFFECTS

103. Amarin willfully and unlawfully maintained their market power by engaging in an overarching scheme to exclude competition. Amarin designed a scheme to delay competition on the products' merits to further Amarin's anticompetitive purpose of forestalling generic competition against Vascepa. Amarin carried out the scheme with the anticompetitive intent and

effect of maintaining supra-competitive prices for icosapent ethyl.

- 104. Defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Vascepa from competition. These actions allowed Amarin to maintain a monopoly and exclude competition in the market for Vascepa and its AB-rated generic equivalents, to the detriment of Plaintiffs and all other members of the Classes.
- 105. Defendants' exclusionary conduct delayed generic competition and unlawfully enabled Amarin to sell Vascepa without generic competition. Were it not for Defendants' illegal conduct, one or more generic versions of Vascepa would have entered the market sooner.
- 106. Defendants' exclusionary conduct also limited Hikma's launch of generic Vascepa, enabling Amarin to sell Vascepa with reduced generic competition.
- 107. Competition among drug manufacturers enables all purchasers of the drug to buy drugs, including both the original drug and its subsequent competitors, at substantially lower prices. Consequently, drug manufacturers—and those that share in their profits—have a strong incentive to delay and limit competition, and purchasers experience substantial cost inflation from any such delay or limitation.
- 108. Defendants' anticompetitive conduct caused Plaintiffs and all members of the Classes to pay more than they would have paid for Vascepa and generic equivalents absent their illegal conduct.
- 109. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, Plaintiffs and members of the Classes would have paid less for icosapent ethyl by (a) paying lower prices on their remaining brand purchases of Vascepa, and/or (b) substituting purchases of less-expensive generic Vascepa for their purchases

of more-expensive brand Vascepa.

110. Thus, Defendants' unlawful conduct deprived Plaintiffs and members of the Classes of the benefits from the competition that the antitrust laws are designed to ensure.

ANTITRUST IMPACT

- substantial amounts of Vascepa indirectly from Amarin. As a result of Defendants' illegal conduct, Plaintiffs and the members of the Classes were compelled to pay, and did pay, artificially inflated prices for Vascepa. Those prices were substantially greater than the prices that members of the Classes would have paid absent the illegal conduct alleged herein, because: (1) the price of brandname Vascepa was artificially inflated by Defendants' illegal conduct, and (2) members of the Classes have been deprived of the opportunity to purchase lower-priced generic versions of Vascepa. The supracompetitive prices were paid at the point of sale, which is where Plaintiffs and the Classes suffered antitrust impact.
- 112. As a consequence, Plaintiffs and members of the Classes have sustained substantial damages to their business and property in the form of overcharges. The full amount and form of such damages will be calculated after discovery and upon proof at trial. Commonly used and well-accepted economic models can be used to measure both the extent and the amount of the supracompetitive charge passed through the chain of distribution to Plaintiffs and the members of the Classes.
- 113. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. *See* Hovenkamp, FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE (1994) at 624.

According to Professor Hovenkamp, "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top."

- 114. Further, the institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution result in higher prices paid by members of the Classes.
- 115. Defendants' anticompetitive actions enabled them to indirectly charge Plaintiffs and the Classes prices in excess of what they otherwise would have been able to charge absent their unlawful agreements described herein.
- 116. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.
- 117. The inflated prices the Classes paid are traceable to, and the foreseeable result of, the overcharges by Amarin.

INTERSTATE AND INTRASTATE COMMERCE

- 118. During the relevant time period, Defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. All Defendants engaged in illegal activities, as charged herein, within the flow of, and substantially affecting, interstate commerce.
- 119. During the relevant time period, branded Vascepa, manufactured and sold by Amarin, was shipped into each state and was sold to or paid for by Plaintiffs and members of the Classes.
- 120. During the relevant time period, in connection with the purchase and sale of branded Vascepa, money exchanged hands and business communications and transactions occurred in each state.

121. Defendants' conduct as set forth in this complaint had substantial effects on interstate and intrastate commerce in that, *inter alia*, distributors and retailers within each state were foreclosed from offering cheaper Vascepa and generic icosapent ethyl to Plaintiffs and members of the Classes purchasing inside each state. Defendants' conduct materially deprived the consuming public—including hundreds, if not thousands, of purchasers in each state—of choice to purchase more affordable versions of Vescepa. The absence of competition to Vascepa has, and continues to, directly and substantially affect and disrupt commerce within each state. Defendants' unlawful anticompetitive agreement has thus affected commerce in each state.

CLASS ACTION ALLEGATIONS

122. Plaintiffs bring this action on their own behalf and on behalf of all others similarly situated as a class action under Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure ("Damages Class"):

All persons and entities who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Vascepa, other than for resale, in the States of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming, the District of Columbia, and Puerto Rico, at any time during the period from August 7, 2020 through and until the anticompetitive effects of Defendants' challenged conduct cease (the "Class Period").

123. Plaintiffs bring this action on their own behalf and on behalf of all others similarly situated as a class action under Rules 23(a) and 23(b)(2) of the Federal Rules of Civil Procedure ("Injunctive Relief Class")

All persons and entities who purchased, paid and/or provided reimbursement for some or all of the purchase price for Vascepa,

other than for resale, in the United States at any time during the period from August 7, 2020 through and until the anticompetitive effects of Defendants' challenged conduct cease (the "Class Period").

124. Excluded from the Classes are:

- a. Defendants and their counsel, officers, directors, management, employees, subsidiaries, and affiliates;
- b. all federal governmental entities;
- c. all persons or entities who purchased Vascepa for purposes of resale or directly from Amarin or their affiliates;
- d. fully insured health plans (*i.e.*, health plans that purchased insurance from another third-party payer covering 100% of the plan's reimbursement obligations to its members);
- e. any "flat co-pay" consumers whose purchases of Vascepa were paid in part by a third-party payer and whose co-payment was the same regardless of the retail purchase price;
- f. pharmacy benefit managers;
- g. all counsel of record; and
- g. all judges assigned to this case and any members of their immediate families.
- 125. Members of the Classes are so numerous that joinder is impracticable. Plaintiffs believe that there are hundreds of thousands of members of the Classes, in an amount to be determined in discovery and at trial. Further, the identities of class members will be readily ascertainable through business records kept in regular order.
- 126. Plaintiffs' claims are typical of the claims of members of the Classes. Plaintiffs and all members of the Classes were damaged by the same wrongful conduct by Defendants, and all paid artificially inflated prices for Vascepa and were deprived of the benefits of competition from less expensive generic versions as a result of Defendants' conduct.

- 127. Plaintiffs will fairly and adequately protect and represent the interests of the Classes. Plaintiffs' interests are coincident with, and not antagonistic to, the Classes.
- 128. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving the pharmaceutical industry.
 - 129. Questions of law and fact common to the Classes include:
 - a. whether Amarin unlawfully maintained monopoly power through all or part of its overarching scheme;
 - b. whether Defendants' anticompetitive scheme suppressed generic competition to Vascepa;
 - c. as to those parts of Defendants' challenged conduct for which such justifications may be offered, whether there exist cognizable, non-pretextual procompetitive justifications, which Defendants' challenged conduct was the least restrictive means of achieving, that offset the harm to competition in the markets in which Vascepa is sold;
 - d. whether direct proof of Amarin's monopoly power is available, and if available, whether it is sufficient to prove Amarin's monopoly power without the need to also define a relevant market;
 - e. to the extent a relevant market or markets must be defined, what that definition is, or those definitions are;
 - f. determination of a reasonable estimate of the amount of delay Defendants' unlawful monopolistic, unfair, and unjust conduct caused;
 - g. whether Defendants' scheme, in whole or in part, has substantially affected interstate commerce;
 - h. whether Defendants' scheme, in whole or in part, has substantially affected

intrastate commerce;

- i. whether Defendants foreclosed the supply of icosapent ethyl API.
- j. whether Amarin possessed the ability to control prices and/or exclude competition for Vascepa during the Class Period;
- k. Whether Defendants' unlawful monopolistic conduct was a substantial contributing factor in causing some amount of delay of the entry of ABrated generic Vascepa;
- 1. Whether Defendants' unlawful monopolistic conduct was a substantial contribuiting factor in limiting the amount of generic Vascepa available upon the launch of the first generic icosapent ethyl product;
- m. whether Defendants' scheme, in whole or in part, caused antitrust injury to the business or property of Plaintiffs and members of the Damages Class in the nature of overcharges; and
- n. the quantum of overcharges paid by the Damages Class in the aggregate.
- 130. Dendants acted or refused to act on grounds that apply generally to the Classes, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the Classes as a whole.
- 131. Questions of law and fact common to members of the Damages Class predominate over questions, if any, that may affect only individual Damages Class members, because Defendants have acted on grounds generally applicable to the entire Damages Class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.
- 132. Class action treatment is a superior method for the fair and efficient adjudication of this controversy. Among other things, class treatment will permit a large number of similarly

situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

133. Plaintiffs know of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

CLAIMS FOR RELIEF FIRST CLAIM FOR RELEIF For Monopolization Under State Law (Against Amarin)

- 134. Plaintiffs incorporate by reference all of the allegations above as though fully set forth herein.
 - 135. Plaintiffs bring this claim on behalf of the Damages Class.
 - 136. The relevant market consists of Vascepa and its generic equivalents.
- 137. As described above, throughout the relevant time period Amarin possessed monopoly power nationwide and in each of the state and its territories in the market for Vascepa and its generic equivalents.
- 138. At all relevant times, Amarin possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Amarin possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.
- 139. Through their overarching anticompetitive scheme, as alleged above, Amarin willfully maintained their monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or a historic accident, and thereby

injured Plaintiffs and the Classes. Amarin's anticompetitive conduct was done with the specific intent to maintain its monopoly in the market for Vascepa in the United States.

- 140. Amarin knowingly and intentionally engaged in this anticompetitive scheme to monopolize the Vascepa market as described above. Amarin accomplished this scheme by, *inter alia*, (1) entering into exclusive supply agreements with at least four different icosapent ethyl API suppliers; (2) otherwise foreclosing the supply of icosapent ethyl API; and (3) raising and maintaining prices so that Plaintiffs and members of the Classes would pay for Vascepa at supracompetitive prices.
- 141. The goal, purpose, and effect of Amarin's scheme was to prevent and delay the sale of generic Vascepa in the United States at prices significantly below Amarin's prices for Vascepa, thereby effectively preventing the average market price of Vascepa and its generic equivalents from declining dramatically.
- 142. The goal, purpose and effect of Amarin's scheme was also to maintain and extend its monopoly power with respect to Vascepa and its generic equivalents. Amarin's illegal scheme allowed it to continue charging supracompetitive prices for Vascepa, without a substantial loss of sales, reaping substantial unlawful monopoly profits.
- 143. Plaintiffs and members of the Damages Class purchased substantial amounts of Vascepa indirectly from Amarin.
- 144. As a result of Amarin's illegal conduct, Plaintiffs and members of the Damages Class were compelled to pay, and did pay, more than they would have paid for their requirements of Vascepa and its generic equivalents absent Amarin's illegal conduct. But for Amarin's illegal conduct, competitors would have begun selling generic Vascepa during the relevant period, and prices for Vascepa and its generic equivalents would have been lower, sooner.

- 145. Had manufacturers of generic Vascepa entered the market and lawfully competed with Amarin earlier, Plaintiffs and other members of the Damages Class would have substituted lower-priced generic Vascepa for the higher-priced brand-name Vascepa for some or all of their requirements of Vascepa and its generic equivalents, and/or would have paid lower net prices on their remaining Vascepa and/or AB-rated bioequivalent purchases.
- 146. By engaging in the foregoing conduct, Amarin violated the following state antitrust laws:
 - a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Vascepa in Arizona by members of the Damages Class.
 - b. Cal. Bus. & Prof. Code §§ 16700, with respect to purchases of Vascepa in California by members of the Damages Class.
 - c. C.G.S.A. §§ 35-27, *et seq.*, with respect to purchases of Vascepa in Connecticut by members of the Damages Class.
 - d. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Vascepa in the District of Columbia by members of the Damages Class.
 - e. Hawaii Rev. Stat. 480-1, *et seq*. with respect to purchases of Vascepa in Hawaii by members of the Damages Class.
 - f. Illinois Antitrust Act, 740 Illinois Compiled Statutes 10/1, *et seq.*, with respect to purchases of Vascepa in Illinois by members of the Damages Class.
 - g. Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Iowa by members of the Damages Class.
 - h. Kansas Stat. Ann. § 50-101 *et seq.*, with respect to purchases of Vascepa and ABrated bioequivalents in Kansas by members of the Damages Class.

- i. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Maine by consumer members of the Damages Class.
- j. Md. Com'l Law Code Ann. § 11-204(a), et seq., with respect to purchases of Vascepa and AB-rated bioequivalents in Maryland by members of the Damages Class.
- k. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Michigan by members of the Damages Class.
- Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases of Vascepa and AB-rated bioequivalents in Minnesota by members of the Damages Class.
- m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Vascepa and ABrated bioequivalents in Mississippi by members of the Damages Class.
- n. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Vascepa and ABrated bioequivalents in Nebraska by members of the Damages Class.
- o. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Nevada by members of the Damages Class.
- p. N.H. Rev. Stat. Ann. §§ 356.11, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in New Hampshire by members of the Damages Class.
- q. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Vascepa and ABrated bioequivalents in New Mexico by members of the Damages Class.
- r. N.Y. Gen. Bus. Law § 340, *et seq.*, with respect to purchases of Vascepa and ABrated bioequivalents in New York by members of the Damages Class.

- s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Vascepa and ABrated bioequivalents in North Carolina by members of the Damages Class.
- t. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in North Dakota by members of the Damages Class.
- u. Or. Rev. Stat. § 646.730, *et seq.*, with respect to purchases of Vascepa and ABrated bioequivalents in Oregon by members of the Damages Class.
- v. R.I. Gen. Laws §§ 6-36-5 *et seq.*, with respect to purchases of Vascepa and ABrated bioequivalents in Rhode Island by members of the Damages Class.
- w. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in South Dakota by members of the Damages Class.
- x. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Tennessee by members of the Damages Class.
- y. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Utah by members of the Damages Class.
- z. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Vascepa and ABrated bioequivalents in Vermont by consumer members of the Damages Class.
- aa. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in West Virginia by members of the Damages Class.
- bb. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Wisconsin by members of the Damages Class.
- 147. Plaintiffs and members of the Damages Class have been injured in their business or property by reason of Amarin's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Vascepa, and (2) paying

higher prices for Vascepa and its generic equivalents than they would have paid in the absence of Amarin's conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Amarin's conduct unlawful.

148. Plaintiffs and the Damages Class seek damages and multiple damages as permitted by law for their injuries by Amarin's violations of the aforementioned statutes.

SECOND CLAIM FOR RELIEF Conspiracy and Combination in Restraint of Trade Under State Law (Against All Defendants)

- 149. Plaintiffs incorporate by reference all of the allegations above as though fully set forth herein.
 - 150. Plaintiffs bring this claim on behalf of the Damages Class.
- 151. Defendants violated the state laws identified below by entering into a series of exclusive contracts that were intended to and did lock up supply of Vascepa API, thereby constraining competition in the market for branded and generic Vascepa.
- 152. The agreements between Amarin and each of the API-supplier defendants substantially, unreasonable, and unduly restrained trade in the relevant market, the purpose and effect of which was to:
 - a. prevent generic competitors from obtaining the API necessary to manufacture
 Vascepa;
 - b. delay the entry of generic versions of Vascepa;
 - c. hamper the ability of generic competitors to meet demand for their generic Vascepa product; and
 - d. raise and maintain the prices that Plaintiffs and the Injunction Class members would pay for Vascepa to and at supra-competitive levels.

- 153. There is no legitimate, non-pretextual, procompetitive business justification for the exclusive contracts between Amarin and the API-supplier defendants.
- 154. The agreements between Amarin and each of the API-supplier defendants harmed competition in the relevant market.
 - 155. Defendants' conduct violated the following state antitrust laws:
 - a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Vascepa in Arizona by members of the Damages Class.
 - b. Cal. Bus. & Prof. Code §§ 16700, with respect to purchases of Vascepa in California by members of the Damages Class.
 - c. C.G.S.A. §§ 35-27, *et seq.*, with respect to purchases of Vascepa in Connecticut by members of the Damages Class.
 - d. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Vascepa in the District of Columbia by members of the Damages Class.
 - e. Hawaii Rev. Stat. 480-1, *et seq*. with respect to purchases of Vascepa in Hawaii by members of the Damages Class.
 - f. Illinois Antitrust Act, 740 Illinois Compiled Statutes 10/1, *et seq.*, with respect to purchases of Vascepa in Illinois by members of the Damages Class.
 - g. Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Iowa by members of the Damages Class.
 - h. Kansas Stat. Ann. § 50-101 *et seq.*, with respect to purchases of Vascepa and ABrated bioequivalents in Kansas by members of the Damages Class.
 - i. Me. Rev. Stat. Ann. 10, §§ 1102, et seq., with respect to purchases of Vascepa and AB-rated bioequivalents in Maine by consumer members of the Damages Class.

- j. Md. Com'l Law Code Ann. § 11-204(a), et seq., with respect to purchases of Vascepa and AB-rated bioequivalents in Maryland by members of the Damages Class.
- k. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Michigan by members of the Damages Class.
- 1. Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases of Vascepa and AB-rated bioequivalents in Minnesota by members of the Damages Class.
- m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Vascepa and ABrated bioequivalents in Mississippi by members of the Damages Class.
- n. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Vascepa and ABrated bioequivalents in Nebraska by members of the Damages Class.
- o. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Nevada by members of the Damages Class.
- p. N.H. Rev. Stat. Ann. §§ 356.11, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in New Hampshire by members of the Damages Class.
- q. N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to purchases of Vascepa and ABrated bioequivalents in New Mexico by members of the Damages Class.
- r. N.Y. Gen. Bus. Law § 340, *et seq.*, with respect to purchases of Vascepa and ABrated bioequivalents in New York by members of the Damages Class.
- s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Vascepa and ABrated bioequivalents in North Carolina by members of the Damages Class.

- t. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in North Dakota by members of the Damages Class.
- u. Or. Rev. Stat. § 646.730, *et seq.*, with respect to purchases of Vascepa and ABrated bioequivalents in Oregon by members of the Damages Class.
- v. R.I. Gen. Laws §§ 6-36-5 *et seq.*, with respect to purchases of Vascepa and ABrated bioequivalents in Rhode Island by members of the Damages Class.
- w. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in South Dakota by members of the Damages Class.
- x. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Tennessee by members of the Damages Class.
- y. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Utah by members of the Damages Class.
- z. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Vascepa and ABrated bioequivalents in Vermont by consumer members of the Damages Class.
- aa. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in West Virginia by members of the Damages Class.
- bb. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Wisconsin by members of the Damages Class.
- 156. Plaintiffs and members of the Damages Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Vascepa, and (2) paying higher prices for Vascepa and its generic equivalents than they would have paid in the

absence of Defendants' conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

157. Plaintiffs and the Damages Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

THIRD CLAIM FOR RELIEF Unfair or Deceptive Trade Practices (Against All Defendants)

- 158. Plaintiffs incorporate by reference all of the allegations above as though fully set forth herein.
 - 159. Plaintiffs bring this claim on behalf of the Damages Class.
- 160. Defendants engaged in unfair competition, and/or unfair/unconscionable, and/or deceptive acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair and/or unconscionable acts or practices, Plaintiffs and Damages Class members were deprived of the opportunity to purchase a less expensive AB-rated bioequivalent of Vascepa and forced to pay higher prices in violation of the following consumer protection statutes:
 - a. Alaska Stat. Ann. § 45.50.471, et seq., with respect to purchases in Alaska by members of the Damages Class. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce.
 - b. Cal. Bus. & Prof. Code §§ 17200, et seq., with respect to purchases in California by members of the Damages Class. Defendants engaged in business practices that are unfair in that they are immoral, unethical, oppressive, unscrupulous, and substantially injurious to Damages Class members. There are no countervailing

- benefits to Damages Class members and any utility of defendants' conduct is outweighed by the consequences to Damages Class members.
- c. Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Damages Class.
- d. Mo. Rev. Stat. §§ 407.020 et seq., with respect to purchases in Missouri by consumer members of the Damages Class.
- e. Mont. Code Ann. §§ 30-14-101, et seq., with respect to purchases in Montana by consumer members of the Damages Class. Defendants engaged in unfair and deceptive acts and practices.
- f. S.C. Code Ann. §§ 39-5-20, et seq., with respect to purchases in South Carolina by Damages Class members. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce. Defendants' conduct is offensive to public policy and immoral, unethical, and oppressive.
- g. Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by consumer members of the Damages Class. Defendants engaged in unfair methods of competition, unfair practices, and deceptive practices in the conduct of trade and commerce.
- 161. Plaintiffs and members of the Damages Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair/unconscionable, and/or deceptive acts or practices alleged in this Count. Their injury consists of paying higher prices for Vascepa and/or AB-rated generic bioequivalents than they would have paid in the absence of these

violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

FOURTH CLAIM FOR RELIEF Unjust Enrichment Under State Law (Against All Defendants)

- 162. Plaintiffs incorporate by reference all of the allegations above as though fully set forth herein.
 - 163. Plaintiffs bring this claim on behalf of the Damages Class.
- 164. To the extent required, this claim is pleaded in the alternative to the other claims in this complaint.
- 165. As a result of their unlawful conduct described above, Defendants have and will continue to be unjustly enriched. Defendants have been unjustly enriched by the receipt of, at a minimum, unlawfully inflated prices and unlawful profits on Vascepa.
- 166. Defendants' financial benefits are traceable to Plaintiffs' and Damages Class members' overpayments for Vascepa.
- 167. Plaintiffs and Damages Class members have conferred and continue to confer an economic benefit upon Defendants in the nature of profits resulting from the unlawful overcharges described herein, to the economic detriment of Plaintiffs and Damages Class members.
- 168. Defendants have benefited from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of the ill-gotten gains resulting from the overpayments made by Plaintiffs and the members of the Damages Class for Vascepa manufactured by Defendants during the Class Period.
- 169. It would be futile for Plaintiffs and Damages Class members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly

purchased Vascepa, as those intermediaries are not liable and would not compensate Plaintiffs and Damages Class members for Defendants' unlawful conduct.

- 170. The economic benefit Defendants derived from overcharging Plaintiffs and Damages Class members for Vascepa is a direct and proximate result of Defendants' unlawful and anticompetitive practices.
- 171. The financial benefits Defendants derived are ill-gotten gains that rightfully belong to Plaintiffs and Damages Class members, who paid and continue to pay artificially inflated prices that inured to Defendants' benefit.
- 172. It would be inequitable under unjust enrichment principles under the laws of the states described below for Defendants to retain any of the overcharges Plaintiffs and Damages Class members paid for Vascepa that were derived from Defendants' unfair, anticompetitive, and unlawful methods, acts, and trade practices.
- 173. Defendants are aware of and appreciate the benefits that Plaintiffs and the Damages Class members have bestowed upon them.
- 174. Defendants should be ordered to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of Plaintiffs and Damages Class members, who collectively have no adequate remedy at law.
- 175. A constructive trust should be imposed upon all unlawful or inequitable sums Defendants received, which arise from overpayments for branded and generic versions of Vascepa by Plaintiffs and the Damages Class members.
 - 176. Plaintiffs and Damages Class members have no adequate remedy at law.
- 177. By engaging in the foregoing unlawful or inequitable conduct, which deprived Plaintiffs and the Damages Class members of the opportunity to purchase lower-priced generic

versions of Vascepa and forced them to pay higher prices for branded and generic versions of Vascepa, Defendants have been unjustly enriched in violation of the common law of various states and commonwealths, as outlined below:

Alabama

- 178. Defendants unlawfully overcharged end-payers who made purchases of or reimbursements for branded and generic versions of Vascepa in Alabama at prices that were more than they would have been but for Defendants' actions.
- 179. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 180. Defendants accepted and retained the benefits bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to Plaintiffs and Damages Class members.
- 181. Defendants have benefitted at the expense of Plaintiffs and Damages Class members from revenue resulting from unlawful overcharges for branded and generic versions of Vascepa.

Alaska

- 182. Defendants unlawfully overcharged end-payers who made purchases of or reimbursements for branded and generic versions of Vascepa in Alaska at prices that were more than they would have been but for Defendants' actions.
- 183. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.

- 184. Defendants appreciated the benefits bestowed upon them by Plaintiffs and Damages Class members.
- 185. Defendants accepted and retained the benefits bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to Plaintiffs and Damages Class members.
- 186. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.
- 187. Defendants have benefitted at the expense of Plaintiffs and Damages Class members from revenue resulting from unlawful overcharges for branded and generic versions of Vascepa.

Arizona

- 188. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Arizona at prices that were more than they would have been but for Defendants' actions.
- 189. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Vascepa.
- 190. Plaintiffs have been impoverished by the overcharges for branded and generic versions of Vascepa resulting from Defendants' unlawful conduct.
- 191. Defendants' enrichment and Plaintiffs' impoverishment are connected. Defendants have paid no consideration to any other person for any benefits they received from Plaintiffs and Damages Class Members.
- 192. There is no justification for Defendants' receipt of the benefits causing their enrichment and Plaintiffs' impoverishment, because Plaintiffs paid anticompetitive prices that

inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.

193. Plaintiffs and Damages Class members have no remedy at law.

Arkansas

- 194. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Arkansas at prices that were more than they would have been but for Defendants' actions.
- 195. Defendants received money from Plaintiffs and Damages Class members as a direct result of the unlawful overcharges and have retained this money.
- 196. Defendants have paid no consideration to any other person in exchange for this money.
- 197. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.

California

- 198. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in California at prices that were more than they would have been but for Defendants' actions.
- 199. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Class members.
- 200. Defendants retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of Plaintiffs and Damages Class members.

Colorado

- 201. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Colorado at prices that were more than they would have been but for Defendants' actions.
- 202. Defendants have received a benefit from Plaintiffs and Damages Class members in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants.
- 203. Defendants have benefitted at the expense of Plaintiffs and Damages Class members.
- 204. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.

Connecticut

- 205. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Connecticut at prices that were more than they would have been but for Defendants' actions.
- 206. Defendants were benefitted in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 207. Defendants have paid no consideration to any other person in exchange for this benefit.
- 208. Defendants retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of Plaintiffs and Damages Class members.

Delaware

209. Defendants unlawfully overcharged end-payers, who made purchases of or

reimbursements for branded and generic versions of Vascepa in Delaware at prices that were more than they would have been but for Defendants' actions.

- 210. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Vascepa.
- 211. Plaintiffs and Damages Class members have been impoverished by the overcharges for branded and generic versions of Vascepa resulting from Defendants' unlawful conduct.
 - 212. Defendants' enrichment and Plaintiffs' impoverishment are connected.
- 213. There is no justification for Defendants' receipt of the benefits causing their enrichment, because Plaintiffs and Damages Class members paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.
 - 214. Plaintiffs and Damages Class members have no remedy at law.

Florida

- 215. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Florida at prices that were more than they would have been but for Defendants' actions.
- 216. Plaintiffs and the Damages Class Members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and the Damages Class members.
- 217. Defendants appreciated the benefits bestowed upon them by Plaintiffs and the Damages Class members.
- 218. It is inequitable for Defendants to accept and retain the benefits received without compensating Plaintiffs and the Damages Class members.

Georgia

- 219. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Georgia at prices that were more than they would have been but for Defendants' actions.
- 220. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 221. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.

Hawaii

- 222. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Hawaii at prices that were more than they would have been but for Defendants' actions.
- 223. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Class members.
- 224. It is unjust for Defendants to retain the benefits received without compensating Plaintiffs and Damages Class members.

Idaho

225. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Idaho at prices that were more than they would have been but for Defendants' actions.

- 226. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 227. Defendants appreciated the benefit conferred upon them by Plaintiffs and Damages Class members.
- 228. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.

Illinois

- 229. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Illinois at prices that were more than they would have been but for Defendants' actions.
- 230. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 231. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiffs and Damages Class members.
- 232. It is unjust and inequitable for Defendants to retain the benefits received without compensating Plaintiffs and Damages Class members.

Iowa

233. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Iowa at prices that were more than they would have been but for Defendants' actions.

- 234. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Vascepa, which revenue resulted from anticompetitive prices paid by Plaintiffs and the Damages Class members, which inured to Defendants' benefit.
- 235. Defendants' enrichment has occurred at the expense of Plaintiffs and Damages Class members.
- 236. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

Kansas

- 237. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Kansas at prices that were more than they would have been but for Defendants' actions.
- 238. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 239. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiffs and Damages Class members.
- 240. Defendants were unjustly enriched at the expense of Plaintiffs and Damages Class members.

Kentucky

241. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Kentucky at prices that were more than they would have been but for Defendants' actions.

- 242. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 243. Defendants appreciated the benefit conferred upon them by Plaintiffs and Damages Class members.
- 244. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintifs and Damages Class members.

Louisiana

- 245. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Louisiana at prices that were more than they would have been but for Defendants' actions.
- 246. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Vascepa.
- 247. Plaintiffs and Damages Class members have been impoverished by the overcharges for branded and generic versions of Vascepa resulting from Defendants' unlawful conduct.
 - 248. Defendants' enrichment and Plaintiffs' impoverishment are connected.
- 249. There is no justification for Defendants' receipt of the benefits causing their enrichment, because Plaintiffs and Damages Class members paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.
 - 250. Plaintiffs and Damages Class members have no other remedy at law.

Maine

251. Defendants unlawfully overcharged end-payers, who made purchases of or

reimbursements for branded and generic versions of Vascepa in Maine at prices that were more than they would have been but for Defendants' actions.

- 252. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 253. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiffs and Damages Class members.
- 254. Defendants were aware of and appreciated the benefit bestowed upon them by Plaintiffs and Damages Class members.
- 255. Defendants were unjustly enriched at the expense of Plaintiffs and Damages Class members.

Maryland

- 256. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Maryland at prices that were more than they would have been but for Defendants' actions.
- 257. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 258. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiffs and Damages Class members.
- 259. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.

Massachusetts

- 260. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Massachusetts at prices that were more than they would have been but for Defendants' actions.
- 261. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 262. Defendants were aware of or appreciated the benefit conferred upon them by Plaintiffs and Damages Class members.
- 263. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members. Fairness and good conscience require that Defendants not be permitted to retain the revenue resulting from their unlawful overcharges at the expense of Plaintiffs and Damages Class members.

Michigan

- 264. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Michigan at prices that were more than they would have been but for Defendants' actions.
- 265. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 266. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiffs and Damages Class members.

267. Defendants were unjustly enriched at the expense of Plaintiffs and Damages Class members.

Minnesota

- 268. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Minnesota at prices that were more than they would have been but for Defendants' actions.
- 269. Defendants appreciated and knowingly accepted the benefits bestowed upon them by Plaintiffs and Damages Class members. Defendants have paid no consideration to any other person for any of the benefits they have received from Plaintiffs and Damages Class members.
- 270. It is inequitable for Defendants to accept and retain the benefits received without compensating Plaintiffs and Damages Class members.

Mississippi

- 271. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Mississippi at prices that were more than they would have been but for Defendants' actions.
- 272. Defendants retain the benefit of overcharges received on the sales of branded and generic versions of Vascepa, which in equity and good conscience belong to Plaintiffs and Damages Class members on account of Defendants' anticompetitive conduct.

Missouri

273. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Missouri at prices that were more than they would have been but for Defendants' actions.

- 274. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 275. Defendants appreciated the benefit bestowed upon them by Plaintiffs and Damages Class members.
- 276. Defendants accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to Plaintiffs and Damages Class members.

Montana

- 277. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Montana at prices that were more than they would have been but for Defendants' actions.
- 278. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 279. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.

Nebraska

280. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Nebraska at prices that were more than they would have been but for Defendants' actions.

- 281. Defendants received money from Plaintiffs and Damages Class members as a direct result of the unlawful overcharges, and have retained this money. Defendants have paid no consideration to any other person in exchange for this money.
- 282. In justice and fairness, Defendants should disgorge such money and remit the overcharged payments back to Plaintiffs and Damages Class members.

Nevada

- 283. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Nevada at prices that were more than they would have been but for Defendants' actions.
- 284. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants in the nature of revenue resulting from unlawful overcharges for branded and generic versions of Vascepa.
- 285. Defendants appreciated the benefits bestowed upon them by Plaintiffs and Damages Class members, for which they have paid no consideration to any other person.
- 286. Defendants have knowingly accepted and retained the benefits bestowed upon them by Plaintiffs and Damages Class members.
- 287. The circumstances under which Defendants have accepted and retained the benefits bestowed upon them by Plaintiffs and Damages Class members are inequitable in that they result from Defendants' unlawful overcharges for branded and generic versions of Vascepa.

New Hampshire

288. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in New Hampshire at prices that were more than they would have been but for Defendants' actions.

- 289. Defendants have received a benefit from Plaintiffs in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants.
- 290. Under the circumstances, it would be unconscionable for Defendants to retain such benefits.

New Jersey

- 291. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in New Jersey at prices that were more than they would have been but for Defendants' actions.
- 292. Defendants have received a benefit from Plaintiffs and Damages Class members in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants.
- 293. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to Plaintiffs and Damages Class members.
- 294. Defendants have paid no consideration to any other person for any of the unlawful benefits they received from Plaintiffs and Damages Class members with respect to Defendants' sales of branded and generic versions of Vascepa.
- 295. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.

New Mexico

296. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in New Mexico at prices that were

more than they would have been but for Defendants' actions.

297. Defendants have knowingly benefitted at the expense of Plaintiffs and Damages Class members from revenue resulting from unlawful overcharges for branded and generic versions of Vascepa.

298. To allow Defendants to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured to Defendants' benefit and because Defendants have paid no consideration to any other person for any of the benefits they received.

New York

- 299. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in New York at prices that were more than they would have been but for Defendants' actions.
- 300. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Vascepa, which revenue resulted from anticompetitive prices paid by Plaintiffs and Damages Class members, which inured to Defendants' benefit.
- 301. Defendants' enrichment has occurred at the expense of Plaintiffs and Damages Class members.
- 302. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

North Carolina

303. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in North Carolina at prices that were more than they would have been but for Defendants' actions.

- 304. Plaintiffs and Damages Class Members have conferred an economic benefit upon Defendants in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 305. Plaintiffs did not interfere with Defendants' affairs in any manner that conferred these benefits upon Defendants.
- 306. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from Defendants' actions to delay entry of generic versions of Vascepa to the market.
- 307. The benefits conferred upon Defendants are measurable, in that the revenue Defendants have earned due to unlawful overcharges are ascertainable by review of sales records and documents relating to Defendants' anticompetitive conduct.
- 308. Defendants consciously accepted the benefits and continue to do so as of the date of this filing.

North Dakota

- 309. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in North Dakota at prices that were more than they would have been but for Defendants' actions.
- 310. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Vascepa.
- 311. Plaintiffs have been impoverished by the overcharges for branded and generic versions of Vascepa resulting from Defendants' unlawful conduct.

- 312. Defendants' enrichment and Plaintiffs' impoverishment are connected. Defendants have paid no consideration to any other person for any benefits they received directly or indirectly from Plaintiffs and Damages Class members.
- 313. There is no justification for Defendants' receipt of the benefits causing their enrichment, because Plaintiffs paid anticompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.
 - 314. Plaintiffs and Damages Class members have no remedy at law.

Oklahoma

- 315. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Oklahoma at prices that were more than they would have been but for Defendants' actions.
- 316. Defendants received money from Plaintiffs and Damages Class members as a direct result of the unlawful overcharges and have retained this money.
- 317. Defendants have paid no consideration to any other person in exchange for this money.
 - 318. Plaintiffs and Damages Class members have no remedy at law.
- 319. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

Oregon

320. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Oregon at prices that were more than they would have been but for Defendants' actions.

- 321. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 322. Defendants were aware of the benefit bestowed upon them by Plaintiffs and Damages Class members.
- 323. It would be inequitable and unjust for Defendants to retain any of the overcharges for Vascepa derived from Defendants' unfair conduct without compensating Plaintiffs and Class members.

Pennsylvania

- 324. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Pennsylvania at prices that were more than they would have been but for Defendants' actions.
- 325. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 326. Defendants appreciated the benefit bestowed upon them by Plaintiffs and Damages Class members.
- 327. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.

Rhode Island

328. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Rhode Island at prices that were more than they would have been but for Defendants' actions.

- 329. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 330. Defendants were aware of and/or recognized the benefit bestowed upon them by Plaintiffs and the Damages Class members.
- 331. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.

South Carolina

- 332. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in South Carolina at prices that were more than they would have been but for Defendants' actions.
- 333. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges to Plaintiffs and Damages Class members.
- 334. Defendants realized value from the benefit bestowed upon them by Plaintiffs and Damages Class members.
- 335. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.

South Dakota

336. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in South Dakota at prices that were more than they would have been but for Defendants' actions.

- 337. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 338. Defendants were aware of the benefit bestowed upon them by Plaintiffs and Damages Class members.
- 339. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits without reimbursing Plaintiffs and Damages Class members.

Tennessee

- 340. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Tennessee at prices that were more than they would have been but for Defendants' actions.
- 341. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 342. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiffs and Damages Class members.
- 343. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.
- 344. It would be futile for Plaintiffs and Damages Class members to exhaust all remedies against the entities with which Plaintiffs and Damages Class members have privity of contract because Plaintiffs and Damages Class members did not purchase branded or generic versions of Vascepa directly from any Defendant.

Texas

- 345. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Texas at prices that were more than they would have been but for Defendants' actions.
- 346. Defendants have received a benefit from Plaintiffs and Damages Class members in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants.
- 347. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiffs and Damages Class members.
- 348. The circumstances under which Defendants have retained the benefits bestowed upon them by Plaintiffs and Damages Class members are inequitable in that they result from Defendants' unlawful overcharges for branded and generic versions of Vascepa.
 - 349. Plaintiffs and Damages Class members have no remedy at law

Utah

- 350. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Utah at prices that were more than they would have been but for Defendants' actions.
- 351. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 352. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiffs and Damages Class members.

353. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.

Vermont

- 354. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Vermont at prices that were more than they would have been but for Defendants' actions.
- 355. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 356. Defendants accepted the benefit bestowed upon them by Plaintiffs and Damages Class members.
- 357. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.

Virginia

- 358. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Virginia at prices that were more than they would have been but for Defendants' actions.
- 359. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
 - 360. Defendants were aware of the benefit bestowed upon them.
- 361. Defendants should reasonably have expected to repay Plaintiffs and Damages Class members.

- 362. The benefits conferred upon Defendants were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from Defendants' illegal and unfair actions to inflate the prices of branded and generic versions of Vascepa.
- 363. Defendants have paid no consideration to any other person for any of the benefits they have received from Plaintiffs and Damages Class members.

Washington

- 364. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Washington at prices that were more than they would have been but for Defendants' actions.
- 365. Plaintiffs and the Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 366. Defendants were aware of or appreciated the benefit conferred upon them by Plaintiffs and Damages Class members.
- 367. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.

West Virginia

- 368. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in West Virginia at prices that were more than they would have been but for Defendants' actions.
- 369. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.

- 370. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiffs and Damages Class members.
- 371. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.

Wisconsin

- 372. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Wisconsin at prices that were more than they would have been but for Defendants' actions.
- 373. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 374. Defendants appreciated the benefit bestowed upon them by Plaintiffs and Damages Class members.
- 375. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.

Wyoming

- 376. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Wyoming at prices that were more than they would have been but for Defendants' actions.
- 377. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
 - 378. Defendants accepted, used and enjoyed the benefits bestowed upon them by

Plaintiffs and Damages Class members.

379. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and Damages Class members.

District of Columbia

- 380. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in the District of Columbia at prices that were more than they would have been but for Defendants' actions.
- 381. Plaintiffs and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiffs and Damages Class members.
- 382. Defendants accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to Plaintiffs and Damages Class members.
- 383. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits.

Puerto Rico

- 384. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for branded and generic versions of Vascepa in Puerto Rico at prices that were more than they would have been but for Defendants' actions.
- 385. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Vascepa.
- 386. Plaintiffs have been impoverished by the overcharges for branded and generic versions of Vascepa resulting from Defendants' unlawful conduct.

- 387. Defendants' enrichment and Plaintiffs' impoverishment are connected.
- 388. There is no justification for Defendants' receipt of the benefits causing their enrichment and Plaintiffs' impoverishment, because Plaintiffs paid anticompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.
 - 389. Plaintiffs and Damages Class members have no remedy at law.

FIFTH CLAIM FOR RELIEF

Violation of Section 1 of the Sherman Act: Contract, Combination, and Conspiracy in Restraint of Trade (Against All Defendants)

- 390. Plaintiffs incorporate by reference all of the allegations above as though fully set forth herein.
 - 391. Plaintiffs bring this claim on behalf of the Injunctive Relief Class.
- 392. Defendants violated 15 U.S.C. § 1 by entering into a series of exclusive contracts that were intended to and did lock up supply of Vascepa API, thereby constraining competition in the market for branded and generic Vascepa.
- 393. The agreements between Amarin and each of the API-supplier defendants substantially, unreasonable, and unduly restrained trade in the relevant market, the purpose and effect of which was to:
 - a. prevent generic competitors from obtaining the API necessary to manufacture
 Vascepa;
 - b. delay the entry of generic versions of Vascepa;
 - c. hamper the ability of generic competitors to meet demand for their generic Vascepa product; and

- d. raise and maintain the prices that Plaintiffs and the Injunction Class members would pay for Vascepa to and at supra-competitive levels.
- 394. There is no legitimate, non-pretextual, procompetitive business justification for the exclusive contracts between Amarin and the API-supplier defendants.
- 395. The agreements between Amarin and each of the API-supplier defendants harmed competition in the relevant market.
- 396. As a direct and proximate result of Defendants' violation of Sherman Act § 1, Plaintiffs and the Injunction Class have been injured in their business and property throughout the Class Period.
- 397. Plaintiffs and the Injunction Class are entitled to injunctive and other equitable relief, pursuant to 15 U.S.C. § 26.

SIXTH CLAIM FOR RELIEF Violation of Section 2 of the Sherman Act: Monopolization (Against Amarin)

- 398. Plaintiffs incorporate by reference all of the allegations above as though fully set forth herein.
 - 399. Plaintiffs bring this claim on behalf of the Injunctive Relief Class.
- 400. As described above, throughout the relevant time period Amarin possessed monopoly power nationwide and in each of the United States and its territories in the market for Vascepa. No other manufacturer sold a competing version of Vascepa during the relevant time period.
- 401. At all relevant times, Amarin possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Amarin possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

- 402. Through their overarching anticompetitive scheme, as alleged above, Amarin willfully maintained their monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or a historic accident, and thereby injured Plaintiffs and the Injunctive Relief Class. Amarin's anticompetitive conduct was done with the specific intent to maintain their monopoly in the market for Vascepa in the United States and its territories.
- 403. Amarin knowingly and intentionally engaged in this anticompetitive scheme to monopolize the market for Vascepa and its generic equivalents as described above. Amarin accomplished this scheme by, *inter alia*, (1) entering into exclusive supply agreements with at least four different icosapent ethyl API suppliers; (2) otherwise foreclosing the supply of icosapent ethyl API; and (3) raising and maintaining prices so that Plaintiffs and Class members would pay for Vascepa at supracompetitive prices.
- 404. The goal, purpose, and effect of Amarin's scheme was to prevent, delay, and limit the sale of generic Vascepa in the United States at prices significantly below Amarin's prices for Vascepa, thereby effectively preventing the average market price of Vascepa and its generic equivalents from declining dramatically while maintaining and extending its monopoly power with respect to Vascepa.
- 405. Plaintiffs and members of the Injunctive Relief Class purchased substantial amounts of Vascepa indirectly from Amarin.
- 406. As a result of Amarin's illegal conduct, Plaintiffs and members of the Injunctive Relief Class were compelled to pay, and did pay, more than they would have paid for their requirements of Vascepa and its generic equivalents absent Amarin's illegal conduct. But for

Amarin's illegal conduct, competitors would have begun selling generic Vascepa during the relevant period, and prices for Vascepa and its generic equivalents would have been lower, sooner.

- 407. Had manufacturers of generic Vascepa entered the market and lawfully competed with Amarin earlier, Plaintiffs and other members of the Injunctive Relief Class would have substituted lower-priced generic Vascepa for the higher-priced brand-name Vascepa for some or all of their requirements of Vascepa and its generic equivalents, and/or would have paid lower net prices on their remaining Vascepa and/or AB-rated bioequivalent purchases
- 408. Plaintiffs and members of the Injunctive Relief Class will continue to suffer injury, in the form of overcharges paid for Vascepa, if Amarin's unlawful conduct is not enjoined.
- 409. Plaintiffs and the members of the Injunctive Relief Class therefore seek equitable and injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable laws, to correct for the anticompetitive market effects caused by Amarin's unlawful conduct, and to assure that similar anticompetitive conduct and effects do not continue or reoccur in the future

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on their own behalf and on behalf of the proposed Classes, prays for judgment against Defendants and that this Court:

- 1. Determine that this action may be maintained as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Classes, and appoint Plaintiffs as the named representative of the Classes;
- 2. Award Plaintiffs and the Damages Class treble damages (*i.e.*, three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;

- 3. Grant Plaintiffs and the Injunctive Relief Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;
- 4. Award Plaintiffs and the Classes their costs of suit, including reasonable attorneys' fees as provided by law;
- 5. Permanently enjoin Defendants both from continuing the unlawful conduct alleged here, and from engaging in similar or related conduct in the future; and
- 6. Award such other and further relief as the Court deems just and proper.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs, on behalf of themselves and the proposed Classes, demand a trial by jury of all issues so triable.

Dated: June 2, 2021 /s/ James E. Cecchi

James E. Cecchi Lindsey H. Taylor

CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO, P.C.

5 Becker Farm Road Roseland, NJ 07068 Telephone: (973) 994-1700

Fax: (973) 994-1744 jcecchi@carellabyrne.com ltaylor@carellabyrne.com

Lee Albert Brian Murray Greg Linkh Brian Brooks

GLANCY PRONGAY & MURRAY LLP

230 Park Avenue, Suite 358 New York, NY 10169

Telephone: (212) 682-5340 Facsimile: (212) 884-0988 bmurray@glancylaw.com lalbert@glancylaw.com glinkh@glancylaw.com bbrooks@glancylaw.com Roberta D. Liebenberg
Adam J. Pessin
Fine, Kaplan and Black R.P.C.
1 S. Broad St., 23rd Floor
Philadelphia, PA 19107
Telephone: (215) 567-6565
rliebenberg@finekaplan.com
apessin@finekaplan.com

Joseph H. Meltzer
Terence S. Ziegler
Ethan J. Barlieb
Lauren M. McGinley
KESSLER TOPAZ
MELTZER & CHECK, LLP
280 King of Prussia Road
Radnor, PA 19087
Telephone: (610) 667-7706
jmeltzer@ktmc.com
tziegler@ktmc.com
lmcginley@ktmc.com

Michael E. Criden Kevin B. Love Lindsey C. Grossman CRIDEN & LOVE, P.A. 7301 S.W. 57th Court, Suite 515 South Miami, Florida 33143 Telephone: (305) 357-9000 Fax: (305) 357-9050 mcriden@cridenlove.com klove@cridenlove.com lgrossman@cridenlove.com

Counsel for Uniformed Fire Officers Association Family Protection Plan Local 854 and the Uniformed Fire Officers Association for Retired Fire Officers Family Protection Plan

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: <u>Amarin Pharma Led 'Scheme' to Suppress Competition for Hyperglyceridemia Treatment Vascepa, Class Action Alleges</u>