Liza M. Walsh
Jessica K. Formichella
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102
(973) 757-1100

Devora W. Allon, P.C. (*phv forthcoming*)
Gilad Bendheim (*phv forthcoming*)
KIRKLAND & ELLIS LLP
601 Lexington Ave.
New York, NY 10022
(212) 446 5967

James R.P. Hileman (*phv forthcoming*)
300 North LaSalle
Chicago, IL 60654
(312) 862-7090

Attorneys for Plaintiff,
Teva Pharmaceuticals USA, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA PHARMACEUTICALS USA, INC., Plaintiff, v. AMARIN PHARMA, INC., AMARIN PHARMARCEUTICALS IRELAND LIMITED, AND AMARIN CORPORATION PLC, Defendants.	Civil Action No. **COMPLAINT** **JURY TRIAL DEMANDED** *REDACTED VERSION - ELECTRONICALLY FILED*

Plaintiff, Teva Pharmaceuticals USA, Inc. ("Teva"), by and through the undersigned attorneys, brings this antitrust lawsuit against Defendants Amarin Pharma, Inc., Amarin

Pharmaceuticals Ireland Limited, and Amarin Corporation plc (collectively, "Amarin" or "Defendants"), and alleges as follows:

INTRODUCTION

1. This action under the Sherman Act and New Jersey law challenges Amarin's anticompetitive conduct to prevent and delay generic competition to its branded Vascepa® (icosapent ethyl) product. Engaging in a methodical decade-long scheme—the effects of which are still being felt in the market—Amarin deliberately locked up the supply of the active pharmaceutical ingredient ("API") icosapent ethyl, in excess of its own needs, in order to reap excessive monopoly profits by thwarting generic competitors from timely bringing more affordable and widely available products to market.

2. Vascepa is a prescription drug product used, among other things, to lower harmful triglycerides, a type of lipid. As Amarin's only marketed product approved by the U.S. Food and Drug Administration ("FDA"), Vascepa sales are the near-exclusive driver of the company's success.

3. From its launch in 2012, Vascepa experienced a dramatic rise in sales and popularity, having been "prescribed over eight million times" and "covered by most major medical insurance plans."[1] In 2013, Amarin reported revenues of $26 million; by 2020—when generic competitors were first permitted to launch—revenues had soared to $607 million, an increase of over 2,200%.[2]

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[1] Amarin Corp., *Vascepa® (Icosapent Ethyl) Shows Significant Cardiovascular Risk Reduction in People with Diabetes in Prespecified and Post Hoc Subgroup Analyses of Landmark Reduce-IT® Study* (June 15, 2020 7:00 AM EDT), https://amarincorp.gcs-web.com/node/19356/pdf.

[2] Amarin Corp. Plc., Annual Report (Form 10-K) (Feb. 27, 2024); Amarin Corp. Plc, Annual Report (Form 10-K) (Feb. 25, 2021).

4. For Amarin, it is Vascepa or bust. The company has no other products and no meaningful pipeline behind Vascepa.[3] Knowing that generic entry would mean an immediate loss of nearly all its Vascepa sales, and a reversal of its meteoric revenue growth, Amarin made concerted and explicit efforts to protect its product from generic competition. Specifically, Amarin embarked on a long, illegal anticompetitive strategy to prevent and delay generic competition and maintain its monopoly power and prices for Vascepa by orchestrating an artificial limit on the amount of API supply available to potential generic competitors, like Teva.

5. Amarin undertook this anticompetitive scheme through a series of exclusive, or de facto exclusive, agreements with different API suppliers. In exchange for agreeing to purchase certain minimum amounts, these API suppliers agreed not to supply API to any other companies—including Teva or any other generic manufacturer. What is more, under some (if not all) of the agreements, Amarin agreed to make a cash payment to maintain exclusivity in the event that Amarin was not able to satisfy the minimum purchase requirement, thus keeping the API supplier in question from contracting with another company, like Teva, despite the API supplier having available, unused capacity. Amarin thus committed to pay suppliers cash in exchange for those suppliers agreeing to limit market supply of Vascepa API, which would allow Amarin to preserve its monopoly and keep charging monopoly prices.

6. Amarin's exclusive agreements with these API suppliers can only be explained as a calculated effort to ensure that no other company could manufacture the generic version of its

[3] *See* Leila Hawkins, *Pharma IQ speaks to Amarin about its unique approach to treating cardiovascular disease and having a country-by-country strategy* (Nov. 30, 2022), https://www.pharma-iq.com/market-access/interviews/pharma-company-with-a-build-as-you-go-approach (quoting Laurent Abuaf, the "SVP and President for Europe at Amarin" as stating that Amarin is "a one-product company, which means it is a high risk for [Amarin]"); Christopher Crocker, *Amarin's Vascepa: Reject the Noise and Accept the Facts*, Seeking Alpha (Nov. 28, 2018 9:30 AM ET), https://seekingalpha.com/article/4225047-amarins-vascepa-reject-noise-and-accept-facts (after the Vascepa clinical studies were over, Amarin's then-"CEO John Thero said Amarin plans to completely cut R&D").

product, or, even if a generic manufacturer could cobble together enough API supply to launch, that it would only be able to supply a tiny fraction of the market demand. Contracting for exclusivity with numerous API suppliers for a single product is inconsistent with the well-established industry practice of drug manufacturers having only one or two API suppliers (even if more are available) because of the considerable cost associated with acquiring and storing API as well as the increased potential for quality issues if sourcing API from multiple suppliers. Deviating from industry practice is especially unusual for a drug that has had no known supply issues. Indeed, Amarin has publicly touted its vast API supply.[4]

7. In fact, Amarin has *admitted* that the purpose of its unique supply arrangements is to protect itself from competition. Its then-CEO made Amarin's anticompetitive goals explicit: "***Amarin's goal [is] 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***."[5]

8. But Amarin has not simply taken advantage of those "barriers to entry"; it created them. By making API supply less available and therefore more costly, Amarin made it nearly impossible for generic manufacturers like Teva to acquire enough supply to enter the market. Even though Teva diligently and timely reached out to API suppliers, those efforts were thwarted by Amarin's exclusive or de facto exclusive agreements. The API suppliers with whom Teva spoke had limited capacity to support Teva's demand needs in connection with a commercial launch. And—likely due to the excess demand for their API as a result of Amarin's lock-up of

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[4] Amarin Corp. plc, *Amarin Provides Preliminary 2017 Results and Provides 2018 Outlook* (Jan. 4, 2018), https://amarincorp.gcs-web.com/static-files/ee8af8cb-e84a-44cb-ae6c-800b16ac88dc.

[5] Amarin Corp., *Amarin Announces Approval of Supplemental New Drug Application for Chemport as Additional Vascepa(R) Active Pharmaceutical Ingredient Supplier* (Apr. 18, 2013), https://amarincorp.gcs-web.com/static-files/c822b3d2-72d5-49e2-a3a0-90d92854fb3f (emphases added).

many other suppliers—even those few suppliers from whom Teva was able to secure API delayed or only partially filled Teva's orders.

9. As a result of Amarin's conduct, Teva could not obtain enough API to launch its generic products until September 2022 (for the 500 mg strength) and December 2022 (for the 1 gram strength). Even then, Teva's launch of each product was on a limited basis because it could not secure enough API to make the amount of product that it had capacity to manufacture, and for which there was ample unmet market demand. But for Amarin's substantial foreclosure of API supply, Teva would have launched much earlier than late 2022, at more robust quantities, and with lower API costs.

10. Amarin's unlawful efforts to lock up API supply also had the effect of artificially increasing the price of API for Teva and other generic manufacturers. By artificially increasing the price of icosapent ethyl API, Amarin made it more likely that Teva and other ANDA filers would be unable to competitively market the product. This, of course, was Amarin's explicit purpose in locking up API supply. As Amarin itself explained, "[i]f generic companies have limited supply capacity, it would be unusual for them to sell their limited supply at a low price as it would further strain their gross margins."[6]

11. Accordingly, Amarin's unlawful conduct prevented Teva and other ANDA filers from vigorously competing using their generic icosapent ethyl drug products, including by offering consumers the ability to buy generic Vascepa at lower prices than brand Vascepa.

12. There is no legitimate business reason for Amarin's conduct, which can be explained only as an anticompetitive strategy to erect "entry barriers" and delay generic

[6] Amarin Corp., *What is Amarin's plan for operations now that generic versions of icosapent ethyl have launched in the United States?*, (June 22, 2021) https://amarincorp.gcs-web.com/static-files/b042df1f-bdf1-45bb-bbee-bb22a2a9b311.

competition to its branded Vascepa, and—once generics could finally launch—to limit the competitive impact on branded Vascepa by engineering higher generic prices. These efforts have harmed, and continue to harm, Teva and consumers.

THE PARTIES

13. Plaintiff Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 400 Interpace Parkway Parsippany, New Jersey 07054.

14. Upon information and belief, Defendant Amarin Pharma, Inc. is a company organized under the laws of Delaware with its principal place of business at 440 Route 22, Suite 330, Bridgewater, New Jersey 08870.

15. Upon information and belief, 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.

16. Upon information and belief, 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, Grand Canal Docklands, Dublin 2, Ireland.

JURISDICTION AND VENUE

17. This action arises under the antitrust laws of the United States, including Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, the New Jersey Antitrust Act, N.J. Stat. § 56:9, and New Jersey common law.

18. The actions complained of occurred in, and substantially affected, interstate commerce. Specifically, Amarin is engaged in interstate commerce and in activities substantially affecting interstate commerce. Amarin's conduct alleged herein has a substantial effect on interstate commerce. Amarin purchases icosapent ethyl API in interstate commerce, and Amarin's

products are marketed and sold in all states and territories of the United States. Drug wholesalers and, ultimately, patients across the country purchase Amarin's drug product, Vascepa.

19. Amarin Pharma, Inc. may be found in, transacts business in, is headquartered in, and is subject to personal jurisdiction in the District of New Jersey.

20. Amarin Pharmaceuticals Ireland Limited transacts business in and is subject to personal jurisdiction in the District of New Jersey.

21. Amarin Corporation plc transacts business in and is subject to personal jurisdiction in the District of New Jersey.

22. This Court has subject-matter jurisdiction based on 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. §§ 15 and 26. This Court has supplemental subject-matter jurisdiction over the New Jersey state-law claims pursuant to 28 U.S.C. § 1367(a).

23. The violations of law alleged in this Complaint took place, in part, and have injured Teva in this judicial district. Venue is therefore proper in the District of New Jersey pursuant to 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391.

STATEMENT OF FACTS

A. Regulatory Framework

24. Under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the "Hatch-Waxman Act," 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 product, as well as any information on applicable patents. The overarching purpose of the Hatch-Waxman Act is to balance the preservation of brand pharmaceutical companies' incentives to innovate with the public interest in access to lower-cost,

high-quality generic drug products through the creation of a carefully calibrated regulatory framework.

25. When the FDA approves a brand pharmaceutical manufacturer's NDA, the manufacturer may list in *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as 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 product before the expiration of the listed patents.

26. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability because it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

27. In addition, to achieve the goal of "get[ting] generic drug products into the hands of patients at reasonable prices—fast,"[7] the Hatch-Waxman Act creates a procedure for generic manufacturers to file Abbreviated New Drug Applications ("ANDAs") with the FDA. An ANDA filer has to show that its drug product is bioequivalent to the "reference listed drug," typically the branded drug product, to demonstrate that the generic product has the same or comparable safety and efficacy as the reference listed drug.

28. The ANDA must contain one of four certifications:

a. That no patent for the brand has been filed with the FDA (a paragraph I certification);

b. That any patent(s) for the brand has/have expired (a paragraph II certification);

[7] *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (internal quotation marks omitted) (quoting *In re Barr Lab'ys., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)).

c. That any patent(s) for the brand will expire on a particular date and the manufacturer does not seek to market its generic before that date (a paragraph III certification); or

d. That any patent(s) for the brand is/are invalid or will not be infringed by the generic manufacturer's proposed product (a paragraph IV certification).[8]

29. If a generic manufacturer files a paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by timely suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA filer (which would enable the manufacturer to market and sell its product) until the earlier of (a) the passage of two and a half years (30 months) or (b) the issuance of a decision by a court that the asserted claims of the patent(s) at issue are invalid or not infringed by the generic manufacturer's ANDA.[9] This period is commonly called a 30-month Hatch-Waxman stay or 30-month stay. Until one of those conditions occurs, the FDA may grant only tentative approval, meaning the ANDA meets all regulatory requirements and is approvable, but for the 30-month stay. Alternatively, the brand/patent holder can choose to sue the generic applicant after 45 days, including waiting until the generic has launched its product. But in that event, the brand cannot take advantage of the 30-month stay of FDA approval and must instead satisfy the showing required to obtain a preliminary or permanent injunction to prevent the generic launch.

30. To encourage manufacturers to seek approval of generic versions of brand drug products, the Hatch-Waxman Act grants the first paragraph IV ANDA filer (the "first-filer") a 180-day exclusivity period to market the generic version of the drug product; the FDA may not

[8] 21 U.S.C. § 355(j)(2)(A)(vii).

[9] 21 U.S.C. § 355(j)(5)(B)(iii).

grant final approval to any other generic manufacturer's ANDA for the same branded drug product during that time.[10] That is, with certain statutory exceptions, when a first-filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book covering the branded drug product are either invalid or not infringed by the generic, the FDA cannot approve a later generic manufacturer's ANDA until that first-filer's generic has been on the market for 180 days.

31. The Hatch-Waxman Act also encourages generic manufacturers to seek approval of generic products for uses that do not infringe valid and enforceable patents. The Hatch-Waxman Act recognizes that a generic drug product manufacturer may infringe one (patented) method of use without infringing another and encourages generics to "carve out" of the generic product label would-be infringing uses (i.e., an FDA-approved indication for a method of treatment covered by a patent) to bring non-infringing products to market quickly.

32. To implement this carve out, an ANDA applicant may submit what is referred to as a "Section viii statement" along with a redacted product label. A Section viii statement asserts that the generic manufacturer will market the drug product for one or more FDA-approved indications (i.e., methods of use) not covered by the brand's valid and enforceable patents.[11] If an ANDA applicant files a Section viii statement and submits a product label that "carves out" the patented method of use or indication, the patent claiming the protected method of use will not serve as a barrier to final ANDA approval.

33. Typically, the Hatch-Waxman Act requires that an ANDA contain "information to show that the labeling proposed for the new [generic] drug is the same as the labeling approved

[10] 21 U.S.C. § 355(j)(5)(B)(iv)(D).

[11] 21 U.S.C. § 355(j)(2)(A)(viii).

for the listed drug[.]"[12] However, FDA regulations also recognize that, by submitting a Section viii statement, an ANDA applicant may omit from the proposed labeling a method of use protected by a listed patent, and therefore need not seek approval for that use.[13]

34. The Supreme Court has explained that the Hatch-Waxman Act, and particularly 21 U.S.C. § 355(j)(2)(A)(viii), authorizes the FDA to approve the marketing of a generic drug product for a particular unpatented use, and under this statutory scheme, a patented use that does not appear on the generic product label will not foreclose marketing a generic drug product for other unpatented uses. [14]

B. Supply and Use of API

35. All drug products are made up of two core components: (i) the active pharmaceutical ingredient ("API"), which is the biologically active component of a drug product and its central ingredient, and (ii) the excipient(s), or other ingredient(s) that, although inactive, may perform a variety of other functional roles in the drug. The API is the part of the drug product that produces the intended effects. Excipients are chemically inactive substances in the drug product, such as lactose or mineral oil.

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12 21 U.S.C. § 355(j)(2)(A)(v).

13 *See* 21 CFR § 314.94(a)(8)(iv) ("Such differences between the applicant's proposed labeling and labeling approved for the reference listed drug may include … omission of an indication or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act."); *see also* 21 CFR § 314.127(a)(7).

14 *Caraco Pharm. Lab'ys., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 415 (2012) ("The statutory scheme, in other words, contemplates that one patented use will not foreclose marketing a generic drug for other unpatented ones."); *see also Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004) (upholding generic manufacturer's right to file a Section viii statement and carve out from labeling method-of-use information protected by a patent); *TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 73 (D.D.C. 2003), *aff'd sub nom. Purepac Pharm. Co. v. Thompson*, 354 F.3d 877 (D.C. Cir. 2004) (same).

36. The API in Vascepa is icosapent ethyl. It is a highly purified ethyl ester of eicosapentaenoic acid, a type of omega-3 fatty acid. Vascepa is the only FDA-approved branded purified icosapent ethyl product.

37. Brand and generic pharmaceutical manufacturers ordinarily purchase the API for their drug products from API suppliers. Drug manufacturers then combine the API with inactive ingredients and formulate the drugs into final dosage forms. The API for a branded drug product and its generic equivalent are the same, and they may come from the same or different suppliers.

38. APIs are subject to stringent regulations and oversight by the FDA. To sell an API in the United States, the API supplier must file a Drug Master File ("DMF") with the FDA. The DMF provides confidential and detailed information about, among other things, the facilities and processes used to manufacture, process, package, and store the API. Because this information is confidential and highly proprietary, API suppliers typically do not share their full DMFs with anyone outside the company, except for the FDA.

39. In its application for FDA approval, a manufacturer must identify its API supplier and that supplier's DMF. More than one manufacturer can reference the DMF of the same API supplier. As part of its review of an NDA or ANDA, the FDA performs a complete review of the technical information contained in the referenced DMF, including, among other things, inspecting the API supplier's facilities.

40. If a manufacturer wants or needs to change its API supplier for a drug product, 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. This supplemental application process is expensive and can take a considerable amount of time. The manufacturer may only market its drug product using the new supplier's API if the FDA approves the change. FDA review and approval of a

change in an API supplier can take six months or more. In addition to the six months or more it takes for FDA review and approval, this process takes at least 12 months of work on the manufacturer's end, including preparing samples, evaluating those samples, preparing batches, and putting the batches on stability. The process can take even longer when, as is the case here, the API is a natural product and thus contains a number of inherent impurities.

41. To avoid delays in the process and to keep costs lower, generic drug product manufacturers typically seek to use API from suppliers that already have a DMF on file, rather than partnering with API suppliers that have not yet filed a DMF. It is common for generic and brand manufacturers to use the same API supplier.

42. Because of the costs involved in qualifying an API supplier, as well as the need to ensure quality control by the API supplier, both brand and generic drug product manufacturers typically use only one or two API suppliers to support their drug applications. It is unusual and contrary to industry practice for a brand or generic manufacturer to have multiple, exclusive API supply contracts for a single product, or for a manufacturer to acquire significant excess API supplies, due to, among other things, the costs of acquisition and storage, as well as quality control issues.

43. Generic versions of branded drug products must contain the same API as the brand-name drug product and are determined by the FDA to be just as safe and effective as their brand counterparts. Because the branded drug product and its generics are therapeutically equivalent, the primary basis for competition between a branded product and its generic version, or between multiple generic versions, is price.

44. Without generic competition, branded drug product manufacturers can, and routinely do, sell their drug products for far more than the marginal cost of production, generating

profit margins above 70%. When a generic equivalent enters the market, however, absent other market complexities, it often quickly captures 80% or more of the unit sales from the branded drug product. Over time, and with the addition of additional generics, this so-called generic penetration rate usually reaches 90% or more. When generic entry occurs, the branded drug product manufacturer loses most of the unit sales; the generic manufacturer sells most of the units but at reduced prices, delivering enormous savings to drug purchasers, insurance companies, and patients. When multiple generics compete in the market, that competition drives prices even lower.

C. Amarin's Vascepa® Product

45. Amarin holds approved NDA No. 202057 for Vascepa. Vascepa is available in two strengths: 500 mg and 1 gram. There are currently two approved indications for Vascepa: (a) 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 (i) established cardiovascular disease or (ii) diabetes mellitus and two or more additional risk factors for cardiovascular disease ("the CV Indication"); and (b) as an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia (the "Very High TG Indication").

46. Vascepa was approved for treatment of the Very High TG Indication on July 26, 2012. Vascepa was approved for treatment of the CV Indication on December 13, 2019.

47. Upon information and belief, Amarin has listed at least 61 different patents in the FDA Orange Book in connection with Vascepa. Of those 61 patents, Amarin caused several to be listed that relate to the Very High TG Indication, including, among others, U.S. Patent Nos. 8,293,728, 8,318,715, 8,357,677, 8,367,652, 8,377,920, 8,399,446, 8,415,335, 8,426,399, 8,440,650, and 8,518,929.

48. Amarin listed several other patents in the Orange Book relating to the CV Indication, including, among others, the 9,700,537, 8,642,077, and 10,568,861 patents.

D. Amarin Enters Exclusive Supply Agreements Designed to Harm Competition

49. Upon information and belief, Amarin entered into exclusive agreements with numerous API suppliers—including, but not limited to, Nisshin Seifun Group Inc. ("Nisshin"), BASF SE (formerly Equateq Ltd.) ("BASF"), Chemport, Inc. ("Chemport"), Novasep Inc. ("Novasep"), and Slanmhor Pharmaceutical Inc. ("Slanmhor")—to maintain supply exclusivity and exclude or delay potential competitors from entering the market. This anticompetitive conduct has allowed Amarin to maintain artificially high prices for its product and to delay, hinder, and frustrate robust generic competition.

50. Amarin entered into the first of these exclusive API supply agreements with Japan-based Nisshin in November 2010. Upon information and belief, at the time Amarin contracted with Nisshin, Nisshin had an approved DMF to manufacture the API icosapent ethyl on file with the FDA, and Nisshin was the API supplier included in Amarin's NDA. The terms of that agreement prohibit Nisshin from selling API for commercial use to any competitor. Amarin initially purchased all its API needs from Nisshin.

51. Approximately four months later, in March 2011 (more than a year before Vascepa launched), Amarin signed a second exclusive supply agreement with Chemport. Upon information and belief, when Amarin contracted with Chemport, Chemport had an approved DMF to manufacture the API icosapent ethyl on file with the FDA. Like the Nisshin agreement, the Chemport agreement prohibited Chemport from supplying any competitors so long as Amarin met certain minimum purchase requirements.[15]

[15] Amarin Corp. plc Quarterly Report (Form 15 10-Q), at 9 (Aug. 9, 2011).

52. A mere three months later, in June 2011 (still well before Vascepa launched), the BBC reported that Amarin had entered into a third exclusive supply agreement with Scotland-based Equateq Ltd. ("Equateq").[16] Upon information and belief, when Amarin contracted with Equateq, Equateq had an approved DMF to manufacture the API icosapent ethyl on file with the FDA. Like Amarin's other agreements, Equateq was prohibited from supplying competitors if Amarin met minimum purchase requirements. 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: "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."[17] To lock in Equateq's exclusivity, Amarin also paid Equateq a $1 million "commitment fee" in May 2011.[18] Equateq was acquired by BASF in May 2012.[19]

53. Six months later, in December 2012, Amarin announced it had entered into additional exclusive supply agreements with a consortium of companies led by Canada-based Slanmhor that represented "the world's largest supplier of concentrated omega-3 fatty acid products."[20] Upon information and belief, when Amarin contracted with these companies, they had an approved DMF to manufacture the API icosapent ethyl on file with the FDA. Amarin explained that "Slanmhor, through exclusive agreements, is collaborating with [Royal DSM

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16 BBC News, *Drug firm Equateq secures big US order* (July 4, 2011), https://www.bbc.com/news/uk-scotland-scotland-business-14013747.

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

18 *Id.*

19 NUTRAingredients.com, *BASF completes omega-3 portfolio with Equateq buy* (May 8, 2012), https://www.nutraingredients.com/Article/2012/05/09/BASF-completes-omega-3-portfolio-with-Equateq-buy.

20 Amarin Corp. PLC, "Amarin Announces Additional Vascepa(R) (Icosapent Ethyl) Supplier" (Dec. 11, 2012), https://amarincorp.com/news-and-media/amarin-announces-additional-vascepar-icosapent-ethyl-supplier.

N.V.]/[Ocean Nutrition Canada] for the supply of intermediate omega-3 oil, and Novasep, a global leader in purification technologies and API manufacturing."[21] Together, Amarin said, the companies would work to "reliably source Vascepa."[22] At the same time, Amarin openly admitted that *all* its existing API needs for its expected launch of Vascepa would be "based on product produced by its existing API supplier, Nisshin."[23] Amarin's exclusive agreements with Equateq/BASF, Chemport, and the Slanmhor consortium explicitly locked up API supply that Amarin did not then, and would not foreseeably, need.

54. It was not lost on Amarin that, with the Slanmhor exclusive agreement, it had in essence cornered the market on API for Vascepa. In announcing the agreement, Amarin's then-CEO and Chairman Joseph Zakrzewski boasted that the addition of "this exclusive Slanmhor consortium" to Amarin's existing supply bench meant that Amarin had succeeded in "[p]ooling the resources of four of the world's leading omega-3 API manufacturers" behind brand Vascepa—all before Amarin sold even a single pill.[24]

55. Because Amarin's 2012 FDA approval was based solely on Nisshin as its approved API supplier, Amarin had to seek supplemental approval from the FDA to use any of the three other API suppliers with whom Amarin had gratuitously entered into exclusive dealing arrangements. Having already secured a sufficient supply of API from Nisshin alone, Amarin did not rush to file supplemental new drug applications ("sNDAs") adding these suppliers.

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21 *Id.*

22 *Id.*

23 *Id.*

24 Fierce Pharma, *Amarin Announces Additional Vascepa(R) (icosapent ethyl) Supplier* (Dec. 13, 2012), https://www.fiercepharma.com/supply-chain/amarin-announces-additional-vascepa-r-icosapent-ethyl-supplier.

56. In December 2012, Amarin finally submitted an sNDA for FDA approval to add Chemport as an API supplier—that application was submitted more than a year after Amarin had contracted with Chemport in March 2011.[25]

57. Tellingly, when announcing the Chemport sNDA, Amarin acknowledged that adding superfluous suppliers was part of its generic-delay strategy, admitting that the "submission 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] Amarin announced that the FDA approved the Chemport sNDA in April 2013 (two years after Amarin had contractually locked up Chemport).[27]

58. Similarly, Amarin entered into an exclusive supply agreement with BASF in June of 2011 but waited a year and a half to submit an sNDA for FDA approval to add BASF as an API supplier.[28] In its press release, Amarin doubled down on its disclosure that the acquisition of exclusive API supply agreements was intended to delay generic entry by "protect[ing] the commercial potential of Vascepa" and "***taking advantage of manufacturing barriers to entry***."[29]

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[25] Amarin Corp. PLC, *Amarin Announces Submission of Supplemental New Drug Application for Chemport, Inc. as an Additional Vascepa(R) Active Pharmaceutical Ingredient Supplier* (Dec. 19, 2012), https://amarincorp.gcs-web.com/static-files/98012da0-412f-4582-bfbe-21bba8c533fc.

[26] *Id.* (emphases added).

[27] Amarin Corp. PLC, *Amarin Announces Approval of Supplemental New Drug Application for Chemport as Additional Vascepa® Active Pharmaceutical Ingredient Supplier* (Apr. 18, 2013), https://amarincorp.gcs-web.com/static-files/c822b3d2-72d5-49e2-a3a0-90d92854fb3f.

[28] Amarin Corp. PLC, *Amarin Announces Submission of Supplemental New Drug Application for BASF as an Additional Vascepa(R) Active Pharmaceutical Ingredient Supplier* (Jan. 2, 2013), https://www.globenewswire.com/en/news-release/2013/01/02/514184/18362/en/Amarin-Announces-Submission-of-a-Supplemental-New-Drug-Application-for-BASF-as-Additional-Vascepa-R-Active-Pharmaceutical-Ingredient-Supplier.html?print=1.

[29] *Id.* (emphasis added).

Amarin announced that the sNDA was approved on April 30, 2013 (nearly two years after contractually locking up BASF).[30]

59. Similarly, Amarin submitted an sNDA for FDA approval to add Novasep, (one of the companies in the Slanmhor consortium), as an additional icosapent ethyl API supplier in August 2013 (even though it had announced the Slanmhor agreement in 2012). The Novasep sNDA was likewise described as a way to "protect" Vascepa and utilize "manufacturing barriers to entry."

60. Amarin's delay in submitting sNDAs for each of these suppliers demonstrates the anticompetitive nature of the agreements. Amarin could not manufacture Vascepa using API from these suppliers until the FDA approved the sNDAs. But, because Amarin had sufficient API supply already, without these additional suppliers, it was in no hurry to file the sNDAs. The agreements were intended to lock up the market, not to expand Amarin's API supply.

61. To incentivize suppliers to forego other opportunities, Amarin agreed to highly lucrative terms. Amarin's agreements with these API suppliers contain expensive minimum purchase requirements in exchange for exclusivity. For example, on information and belief, Amarin's minimum purchasing requirements with BASF cost Amarin between $10 and $20 million per year to maintain exclusivity.

62. Some of the agreements also require Amarin to make additional cash payments—beyond the minimum purchasing requirements—to lock in the suppliers' exclusivity. For example, in 2011, Amarin disclosed that, pursuant to its deal with Chemport, Amarin was required to "make minimum annual purchases from Chemport ranging from approximately $7.5 to $15

[30] Amarin Corp. PLC, *Amarin Announces Approval of Supplemental New Drug Application for BASF as an Additional Vascepa(R) Active Pharmaceutical Ingredient Supplier* (Apr. 30, 2013), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-approval-supplemental-new-drug-application-basf.

million" and "make a minority share equity investment in Chemport of up to $3.3 million."[31] Similarly, Amarin agreed to pay Equateq/BASF a one time $1 million commitment fee.[32]

63. Some of these agreements also include provisions that protect Amarin's exclusivity—and ensure that its competitors cannot access these suppliers—by requiring Amarin to make large cash payments in the event it does not satisfy the minimum purchase requirement for the suppliers. Amarin knew that it had locked up far more API supply than it would actually be willing or able to use in connection with its bona fide sales, so it had to agree to these naked payments in exchange for supply restrictions that would maintain its exclusivity and disadvantage its competitors.

64. Amarin has no legitimate business justification for its collection of exclusive API supply agreements. Amarin started locking up API suppliers in 2011 before it had even begun recognizing revenue in 2014. And it reached exclusive supply agreements with five API suppliers before 2016, when it recognized only $81 million in sales. To maintain dominance over the icosapent ethyl API market, upon information and belief, Amarin made a concerted and continuing effort to keep its number of API suppliers higher than necessary to support its commercial needs. For example, when Amarin's exclusive supply agreement with BASF terminated in February 2014, Amarin entered into a new exclusive supply agreement with Finorga SAS (Novasep) in June 2015 and then yet another supply agreement with KD Pharma in December 2017.[33] There was (and remains) no legitimate reason for Amarin to obtain so many exclusive supply agreements

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[31] Amarin Corp., *Amarin Announces Global Supply Network for AMR101* (May 31, 2011, 2:00 AM EDT) https://amarincorp.gcs-web.com/static-files/910a3e7f-c8d2-485c-a2f7-929c65b7e9db.

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

[33] Amarin Corp. plc, Form 10-K (Mar. 1, 2017), *available at* https://www.annualreports.com/HostedData/AnnualReportArchive/a/NASDAQ_AMRN_2016.pdf; ECF No. 142 at 5, *Dr. Reddy's Laboratories Inc. v. Amarin Pharms, Inc.*, 21-cv-10309 (ZNQ)(TJB) (D.N.J. Jan. 12, 2024).

when Amarin experienced no or very low demand for Vascepa at the time. And Amarin has never announced any supply issues with suppliers or publicly disclosed any other reasons why it would increase its API purchasing obligations so significantly.

65. Rather, the purpose of Amarin securing multiple exclusive API supply agreements was to foreclose future generic competition. Amarin did not hide the intent of these agreements: the purpose of the "minimum annual purchase levels [is] to enable [itself] to maintain certain supply exclusivity," rather than to ensure sufficient capacity to keep up with demand.[34] According to Amarin's then-CEO, the company was making a concerted "effort to prevent a generic launch (if an ANDA approval is obtained)" and to erect artificial "barriers to competition" for generic competitors.[35]

66. Amarin actively tracked and reported to its investors on generic companies' unsuccessful efforts to obtain API supply. For example, John Thero, Amarin's then-President and CEO boasted: "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***[.]"[36] There would be no reason for Amarin to report to investors such feedback from suppliers except for the fact that it was part and parcel of Amarin's strategy to stymie competition, and that Amarin knew that reduced competition meant increased Amarin profits and share value, all at Teva's and consumers' expense.

E. Teva Applies for FDA Approval to Compete with Amarin

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[34] Amarin Corp. plc, Form 10-Q (September 30, 2018), *available at* https://www.sec.gov/Archives/edgar/data/897448/000156459018025979/amrn-10q_20180930 htm.

[35] *Amarin Comments on Ruling in Vascepa® ANDA Litigation*, GlobeNewsWire (March 30, 2020), https://www.globenewswire.com/news-release/2020/03/30/2008763/0/en/Amarin-Comments-on-Ruling-in-VASCEPA-ANDA-Litigation html.

[36] Amarin Corporation plc Q1 2020 Earnings Call Transcript (April 13, 2020), *available at* https://www.fool.com/earnings/call-transcripts/2020/04/13/amarin-corporation-plc-amrn-q1-2020-earnings-call.aspx (emphasis added).

67. On July 26, 2016, Teva submitted ANDA No. 209525 with the FDA seeking approval to launch a 1 gram generic version of Vascepa, with a paragraph IV certification. On or around the same date, Hikma Pharmaceuticals USA Inc. ("Hikma") and Dr. Reddy's Laboratories Inc. ("DRL") also submitted their respective ANDAs seeking approval to launch their generic versions of Vascepa, each with a paragraph IV certification. As a result of the concurrent filing, Teva, Hikma, and DRL are joint first filers.

68. Upon information and belief, Apotex, Inc. ("Apotex") also submitted an ANDA application with the FDA in or around July 2016, seeking approval to launch its generic version of Vascepa. Upon information and belief, Apotex's application also contained a Paragraph IV certification.

69. Shortly after these ANDA applications were filed, Amarin initiated lawsuits against Teva, Hikma, and DRL, alleging that their respective ANDA products would infringe Amarin's patents. Specifically, Amarin filed suit against Hikma on October 31, 2016, against DRL on November 4, 2016, and against Teva on November 18, 2016. These lawsuits were consolidated into a single action (the "Nevada Litigation"). Amarin did not file suit against Apotex in 2016.

70. Teva subsequently amended ANDA No. 209525 to include a 500 mg generic version of Vascepa. On October 11, 2017, Amarin filed another lawsuit against Teva, alleging that its 500 mg ANDA product would infringe several of Amarin's patents. This lawsuit related to Teva's 500 mg ANDA product was also consolidated with the Nevada Litigation.

71. On May 24, 2018, Teva and Amarin entered into a settlement agreement (the "Settlement Agreement") resolving the patent litigation against Teva's ANDA seeking FDA approval of 500 mg and 1 gram icosapent ethyl products. [redacted]

[redacted]

72. But Teva's launch of generic Vascepa was still subject to FDA approval of its ANDA as well as procurement of supply of icosapent ethyl API in adequate quantities to support a commercial launch. [redacted]

73. On June 16, 2020, Apotex also entered into a settlement agreement with Amarin, pursuant to which Apotex received an entry date of August 9, 2029, or "earlier under certain customary circumstances," including if Amarin's then-pending appeal of the Nevada Litigation against Hikma and DRL, discussed below, failed.[37]

74. Amarin continued to litigate the Nevada Litigation against Hikma and DRL and, on March 30, 2020, the court ruled in favor of Hikma and DRL and issued an order invalidating Amarin's asserted patents for obviousness.[38] Amarin appealed the invalidity judgment to the United States Court of Appeals for the Federal Circuit, which summarily affirmed the Nevada court's invalidity judgment on September 3, 2020.[39] Because the decision of the Federal Circuit could not be appealed as of right, [redacted]

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[37] Press Release, Amarin Corp. PLC, "Amarin Announces Patent Litigation Settlement Agreement with Apotex Inc." (June 16, 2020), https://www.globenewswire.com/news-release/2020/06/16/2049162/0/en/Amarin-Announces-Patent-Litigation-Settlement-Agreement-with-Apotex-Inc html.

[38] *Amarin Pharma, Inc. v. Hikma Pharm. USA*, 449 F. Supp. 3d 967 (D. Nev. 2020).

[39] *Amarin Pharma, Inc. v. Hikma Pharm. USA*, 819 F. App'x 932 (Fed. Cir. 2020).

[redacted]

75. Amarin continued litigating by requesting a rehearing, but the Federal Circuit denied that request as well.[40] On February 11, 2021, Amarin petitioned for a writ of certiorari from the Supreme Court of the United States.[41] On June 21, 2021, the Supreme Court denied the request for certiorari.[42]

76. On May 21, 2020, the FDA granted final approval of Hikma's ANDA. On August 7, 2020, the FDA granted final approval of DRL's ANDA for its 1gram product (and tentative approval for its 500 mg product). On September 11, 2020, the FDA granted final approval of Teva's ANDA for both its 500mg and 1gram products.

77. These final approvals cleared all remaining regulatory impediments for Teva—and, on information and belief, DRL and Hikma—to launch a generic version of Vascepa for the Very High TG Indication. As discussed above, Vascepa was approved for a second indication (the CV Indication) in 2019, but Teva's (as well as Hikma's, and DRL's) ANDA carved out the 2019 indication from its label pursuant to Section viii statements, as permitted by the FDCA.[43]

78. Accordingly, after the Federal Circuit's September 3, 2020 denial of Amarin's appeal and the FDA's September 11, 2020 final approval of Teva's ANDA, Teva had cleared all regulatory, contractual, and patent hurdles to commercializing its 500 mg and 1 gram icosapent ethyl products.

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40 *Amarin Pharma, Inc. v. Hikma Pharms. USA*, *reh'g denied*, 2020-1723, D.I. 90 (Fed. Cir. Nov. 4, 2020).

41 *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, No 20-1119 (2021).

42 *Id.*

43 The Nevada litigation expressly recognized that Hikma and DRL's labels carved out the 2019 indication consistent with the FDCA's requirements. *Amarin Pharma, Inc. v. Hikma Pharm. USA*, 449 F. Supp. 3d 967 (D. Nev. 2020). Teva's label contains an identical carve-out.

F. Teva's API Supply-Constraint Shock

79. However, Teva's efforts to commercialize its icosapent ethyl products were frustrated by Amarin's exclusive API supply agreements.

80. Upon information and belief, Amarin, under these agreements, maintained a hold over the majority of the icosapent ethyl API market in 2020, and Amarin has continued to foreclose a significant share of the API market to this date. Amarin's majority hold of the icosapent ethyl API market prevents generic companies like Teva from competing effectively.

81. In 2020, only a few API suppliers (such as Nisshin, Chemport, and Novasep) had sufficient preexisting capacity to support large volume manufacturing of icosapent ethyl API. Amarin foreclosed generic companies from sourcing API from these established suppliers because Amarin locked up these suppliers with exclusive supply agreements, as described above. Making matters worse, despite its self-professed abundant API supply, Amarin continued to seek out new supply agreements with additional suppliers once they had achieved commercial manufacturing capacity (e.g., KD Pharma), further diminishing the pool of available API supply for Amarin's competitors.

82. Instead, generic companies had to source API from other suppliers that had approved DMFs but did not have the experience or capacity to support manufacturing of icosapent ethyl API in commercial quantities. Because these manufacturers needed substantial time to build manufacturing expertise and capacity, generic companies could not make timely commercial launches of their generic Vascepa products.

83. Amarin's conduct also forced all the generic companies to compete against each other for the same, small subset of API suppliers that Amarin had not locked up, which was insufficient to supply the demands of all the generic companies. Moreover, the size of the API market is constrained by regulatory requirements. Any potential API supplier must have an

approved DMF for icosapent ethyl API on file with the FDA. Due to the time and cost involved in filing and obtaining approval for a DMF, it is not feasible for generic companies to source API supply from a supplier without an approved DMF. As a result, generic companies have been forced to compete for a small and largely fixed pool of API supply. Even if Amarin did not succeed in locking up every ounce of API, by taking exclusive control over most of the market's supply, it left an insufficient amount of API for its generic competitors to effectively compete against Amarin in the market for branded and generic Vascepa.

84. Teva's experience in preparing for the launch of its icosapent ethyl products demonstrates the anticompetitive effects of Amarin's conduct. In preparation for its commercial launch of its icosapent ethyl products, Teva contacted a number of companies with an approved DMF to manufacture the icosapent ethyl API.

85. [redacted]

86. [redacted]

87. [redacted]

88. [redacted]

89. [redacted]

[redacted]

90. The other API manufacturers that Teva contacted had limited manufacturing capacity and needed time to expand their capacity to meet Teva's API supply requirements.

91. [redacted]

92. Because of Amarin's exclusive agreements and efforts to lock up icosapent ethyl API, Teva was unable to secure the minimum necessary supply of icosapent ethyl to make a competitive entry into the Vascepa market, despite Teva's best efforts to find alternative API suppliers.

93. Teva was only able to launch its 500 mg icosapent ethyl product in September 2022, and its 1 gram icosapent ethyl product in December 2022—more than two years after it had received final approval of both products in September 2020. Even then, Teva's launch of its products in late 2022 was on a limited basis due to Teva's limited API supply. Teva expected demand for its products far in excess of these limited volumes, and on that basis had planned

sufficient manufacturing capacity to support a full commercial launch of its icosapent ethyl products in much higher quantities. However, because Teva could not obtain sufficient API to supply a full launch, Teva was forced to scale back its production of icosapent ethyl products and launch on a limited basis.

94. Had Teva been able timely to secure adequate API supply to support a commercial launch, Teva would have launched its 500 mg and 1 gram products earlier than September 2022 and December 2022, and Teva would have conducted a full commercial launch of its products that reflected its manufacturing capacity and product demand.

MARKET SHARE EROSION AFTER GENERIC ENTRY

95. Not only did Amarin's conduct delay generic entry but it also worked to inflate Amarin's market share even when generics finally entered the market (on a limited basis).

96. For an uncomplicated product market like the icosapent ethyl market at issue here, it is typical for the branded drug product's share to quickly drop, and continue to drop further, as additional generic competitors enter.

97. But here, and even after two generic manufacturers entered the market, Amarin's chokehold on API supply allowed it to maintain roughly 80%–85% of the sales. Even after Teva entered the market in late 2022, Amarin held a 62% share of the market. And with four generic drug products on the market, at the end of 2023, Amarin has maintained approximately 57% market share.

98. This unusual behavior can only be explained by Amarin's exclusive API agreements and efforts to lock up icosapent ethyl API.

99. Amarin itself said that "[m]arket dynamics for payors and patients are likely to be unusual relating to these generic [Vascepa] products," pointing specifically to the anticipated "limited supply" of the generics.[44]

100. Indeed, in August 2020, as Amarin was anxiously awaiting the Federal Circuit's decision on its appeal of its trial loss to Hikma and DRL, Amarin's then-CEO comforted his investors, stating that even if generics could find "supply capacity to support tens of millions of dollars in revenue [in the near term] . . . such level would only be a small portion of Amarin's total revenue and even a smaller portion of Vascepa's potential."[45]

101. And in a February 6, 2023 investor presentation, Amarin admitted that this trend of Amarin maintaining a large market share is "***exceptional for any drug facing two years of generic competition***."[46]

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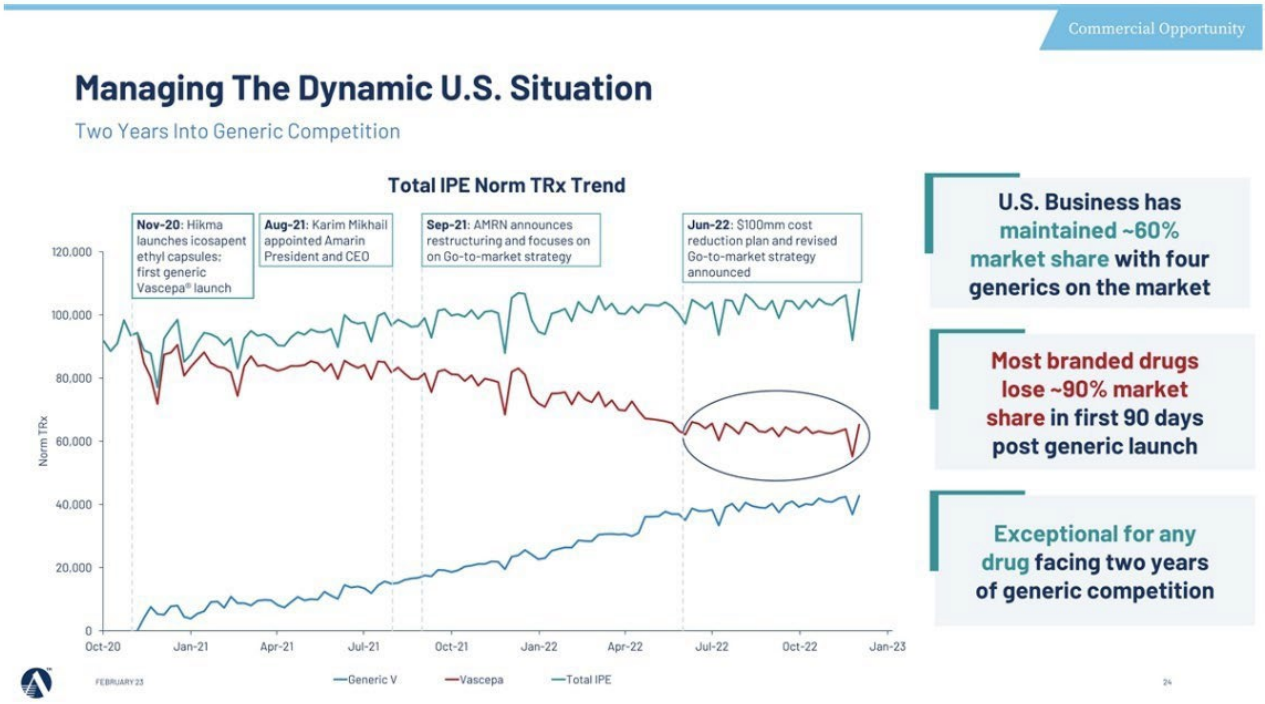
[44] Press Release, Amarin Corp. plc, "Amarin's Commercial Plans" (June 22, 2021), https://investor.amarincorp.com/static-files/21b859d2-0823-4fd5-9c14-91678feb8447 (emphasis added).

[45] Seeking Alpha, *Amarin Corporation plc's (AMRN) CEO John Thero on Q2 2020 Results – Earnings Call Transcript* (Aug. 4, 2020), https://seekingalpha.com/article/ 4364297-amarin-corporation-plcs-amrn-ceo-john-theroon-q2-2020-results-earnings-call-transcript.

[46] Amarin Corp., Schedule 14A at 23 (Feb. 6, 2023), *available at* https://edgar.secdatabase.com/132/119312523025756/filing-main html (emphasis added).



102. Amarin's enduring and "exceptional" market share, which persists to this date, is a result of its unlawful conduct in maintaining exclusive supply agreements that limited the supply of icosapent ethyl API.

103. Amarin's market share is also unusual for another reason. Since November 2020, at least four generics have launched at various times. However, the generic share of the market has not experienced any steep increases, as is usually the case upon generic entry in the absence of anticompetitive conduct.

104. The only explanation for this muted generic penetration is that generic companies have not been able to supply enough icosapent ethyl product to meet demand for its products, as a result of Amarin's foreclosure of the icosapent ethyl API market. Rather, the generic share has only gradually increased over time as a result of generic companies' efforts to obtain more API supply.

105. But for Amarin's unlawful conduct, Amarin's market share would be lower and Teva's and other generic's market share would be higher. Thus, to this date, more than one and a half years after Teva's launch, Teva's commercial sales continue to be constrained and frustrated because of Amarin's conduct.

MONOPOLY POWER AND RELEVANT MARKETS

106. At all relevant times, Amarin has maintained monopoly power and market power in the markets for (a) branded (*i.e.*, Amarin's Vascepa) and generic FDA-approved icosapent ethyl drug products (collectively, "icosapent ethyl Drug Products") and (b) the purchase of icosapent ethyl API (the "icosapent ethyl API Market"). Amarin's monopoly power and market power in the market for icosapent ethyl Drug Products (the "icosapent ethyl Drug Market") and the icosapent ethyl API Market include monopoly power and market power over any narrower markets within them.

107. Icosapent ethyl Drug Products include AB-rated generic equivalents. The FDA deems AB-rated generic equivalents to be therapeutically equivalent to the branded drug product.

108. Amarin's monopoly power and market power include the ability to control prices and exclude competitors.

109. In the icosapent ethyl Drug Products Market, with respect to Amarin's ability to profitably raise prices, a small but significant non-transitory price increase in the price of Vascepa has never resulted in a significant loss of sales, nor would a future small but significant non-transitory price increase result in lost sales. In fact, despite Amarin's consistent price increases for Vascepa over the years, the demand for icosapent ethyl Drug Products continues. As for Amarin's ability to exclude competitors, direct evidence shows that generic versions of icosapent ethyl Drug Products would have more quickly entered the market at substantial discounts to the branded version but for Amarin's anticompetitive exclusionary conduct.

110. Similarly, in the icosapent ethyl API Market, with respect to Amarin's ability to control prices, a small but significant non-transitory decrease in the purchase price of icosapent ethyl API does not and will not result in suppliers of icosapent ethyl API switching to the supply of a different API, including APIs for drugs in the same therapeutic class as icosapent ethyl Drug Products. As for Amarin's ability to exclude competitors, direct evidence shows that Amarin, through several exclusive or de facto exclusive agreements, successfully precluded generic manufacturers of icosapent ethyl Drug Products, including Teva, from purchasing sufficient icosapent ethyl API to commercially launch their generic icosapent ethyl Drug Products.

111. Amarin did not and does not need to control or influence pricing for any other pharmaceutical product to maintain its monopoly power and market power over icosapent ethyl Drug Products and the purchase of icosapent ethyl API, as there are no reasonable substitutes for either product.

112. Amarin has sold and continues to sell icosapent ethyl Drug Products at a price greater than any measurement of competitive pricing and above Amarin's marginal cost. On information and belief, Amarin has experienced atypically high profit margins for icosapent ethyl Drug Products, which have been increasing over the years.

113. In addition to direct evidence of monopoly power and market power, indirect evidence also establishes monopoly power and market power. Icosapent ethyl Drug Products exhibit high barriers to entry, including the high cost of entry and expansion due to Amarin's conduct limiting supply of icosapent ethyl, and compliance with regulatory requirements. Icosapent ethyl API similarly exhibits high barriers to entry, including the costs of developing the API, patent protection, the high cost of entry and expansion, and regulatory requirements.

114. Until November 2020, Amarin controlled 100% of the icosapent ethyl Drug Market. Even after the first generic launched with limited quantities in November 2020, due to the limited nature of the launch, Amarin's market share did not decrease significantly and continued to remain above 85% and remains near 60% through present. For example, Amarin's then-CEO commented that even if generics could find "supply capacity to support tens of millions of dollars in revenue [in the near term] . . . such level would only be a small portion of Amarin's total revenue and even a smaller portion of Vascepa's potential."[47]

115. Similarly, until November 2020, Amarin controlled nearly 100% of the icosapent ethyl API Market because the volume of icosapent ethyl API that generic manufacturers used for their regulatory submissions is negligible compared to the commercial volume that Amarin purchased. Generics' inability to obtain sufficient API to support and maintain a more robust launch forced each to launch in limited quantities, gaining less than 40% of the of the icosapent ethyl Drug Market.

116. Icosapent ethyl Drug Products are not reasonably interchangeable with any other drugs except for AB-rated generic versions of icosapent ethyl Drug Products.

117. Icosapent ethyl API is not reasonably interchangeable with any other API.

118. The existence of other FDA-approved treatments for severe (≥ 500 mg/dL) hypertriglyceridemia has not significantly constrained Amarin, and Amarin has been increasing the prices for Vascepa over the years. For example, Lovaza (omega-3-acid ethyl esters) is indicated for the reduction of triglyceride ("TG") levels in adults with severe (≥ 500 mg/dL) hypertriglyceridemia. Not only did Amarin not reduce the price of Vascepa upon the entry of

[47] Seeking Alpha, *Amarin Corporation plc's (AMRN) CEO John Thero on Q2 2020 Results – Earnings Call Transcript* (Aug. 4, 2020), https://seekingalpha.com/article/4364297-amarin-corporation-plcs-amrn-ceo-john-theroon-q2-2020-results-earnings-call-transcript.

generic omega-3-acid ethyl esters drug products in 2014 but it continued to increase Vascepa prices in the following years despite generic omega-3-acid ethyl esters drug products' price erosion over time. Even though Vascepa prices were and continue to be higher than the price of generic omega-3-acid ethyl esters drug products, demand for Lovaza and generic omega-3-acid ethyl esters drug products decreased over time whereas demand for icosapent ethyl Drug Products increased over time.

119. The existence of other purchasers of fish oil-based API has not significantly constrained Amarin, and Amarin has maintained exclusive or de facto exclusive agreements for the supply of icosapent ethyl API with the leading suppliers of fish oil-based API for several years.

120. Manufacturers differentiate branded drug products like Vascepa based on features and benefits (including safety and efficacy), and not based on price. Doctors and patients are generally price-insensitive when prescribing and taking prescription drug products like Vascepa. This is due in part to institutional features of the pharmaceutical marketplace such as the presence of insurance that bears much of the cost of prescriptions. Different patients may respond differently to different drug products, and even drug products within its same therapeutic class do not constrain the price of Vascepa.

121. Unlike many consumer products where consumers are provided with a choice of functionally similar products at the point of sale and make purchasing decisions primarily based on price, the prescribing decision for prescription drug products is made by the prescriber, not consumers of these products.

122. The United States and its territories are the relevant geographic market.

ANTITRUST IMPACT

123. Amarin's anticompetitive strategy to maintain its monopoly in the icosapent ethyl Drug Market and icosapent ethyl API Market through exclusive or de facto exclusive agreements

with numerous API suppliers has denied and, unless remedied, will continue to deny consumers the benefits of full and robust generic competition for Vascepa as contemplated by the Hatch-Waxman Act. Amarin illegally maintained and extended its monopoly power through exclusionary conduct completely unrelated to its ability to compete on a level playing field.

124. Amarin's anticompetitive conduct has achieved its purpose of delaying, hindering, and frustrating generic competition to Amarin's Vascepa product. By engaging in this conduct, Amarin effectively foreclosed a substantial share of icosapent ethyl API supply. The lack of API supply hinders ANDA filers like Teva from robustly competing with their generic icosapent ethyl drug products, including by offering consumers the ability to buy generic Vascepa at lower prices than brand Vascepa.

125. This is exactly what Amarin intended to, and did, cause through its unlawful conduct. As Amarin itself has explained, "if generic companies have limited supply capacity, it would be unusual for them to sell their limited supply at a low price as it would further strain their gross margins."[48] During these periods of delay and constraint, consumers are deprived of lower-priced generic icosapent ethyl drug products and are forced to pay higher prices than they would but for Amarin's conduct.

126. Since generic drug products are therapeutically equivalent to brand-name drugs, generic manufacturers compete by offering their drug products at lower prices. Drugs like icosapent ethyl have an uncomplicated distribution system in which entry of a single generic typically results in steep price reductions for purchases, and entry of several generics typically drives the price down close to marginal manufacturing costs. In a market unconstrained by supply

[48] Amarin Corp., *What is Amarin's plan for operations now that generic versions of icosapent ethyl have launched in the United States?* (June 22, 2021), https://amarincorp.gcs-web.com/static-files/b042df1f-bdf1-45bb-bbee-bb22a2a9b311#:~:text=In%20the%20United%20States%2C%20Amarin,to%20go%20to%20generic%20manufacturers.

issues, most branded drug products lose 82% of their market share within 12 months of generic launch due to substitution at the pharmacy level.[49] Automatic substitution practices allow pharmacies to fill prescriptions with generic drug products rather than branded drugs unless the prescribing physician specifically writes that a generic should not be substituted.

127. Amarin's foreclosure of the icosapent ethyl API Market, however, created a highly unusual circumstance for an otherwise uncomplicated market. By Amarin's own admission, "Amarin retained approximately 89% of the icosapent ethyl market in the first half of 2021, with approximately eight months of generic presence in the market."[50] And, by Amarin's own admission, this situation continued, and—rather than *losing* 82% of its market share, as would be expected with normal generic competition—"Amarin *retained* approximately 83% and 87% of the icosapent ethyl market in the three and nine months ended September 30, 2021, respectively, with approximately one year of generic presence in the market."[51] More recently, Amarin announced that in 2023, "the Amarin team continued to retain its [icosapent ethyl] market share leadership in the U.S. at 57%," and that as it enters 2024, Amarin's "U.S. business continues to retain IPE market leadership."[52]

128. Amarin's anticompetitive conduct has had a direct, substantial, and adverse effect on Teva and competition by monopolizing and maintaining monopoly power, artificially creating

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[49] Grabowski, Henry, *Continuing Trends In U.S. Brand-Name And Generic Drug Competition*, JOURNAL OF MEDICAL ECONOMICS, Vol. 24 (July 5, 2021).

[50] Amarin Corp., *Amarin Reports Second Quarter and Six Month 2021 Financial Results and Provides Business Update* (Aug. 5, 2021), https://amarincorp.com/news-and-media/amarin-reports-second-quarter-and-six-month-2021-financial.

[51] Amarin Corp., *Amarin Reports Third Quarter 2021 Financial Results and Provides Business Update* (Nov. 3, 2021 6:00 AM EDT), https://amarincorp.com/news-and-media/amarin-reports-third-quarter-2021-financial-results-and-provides (emphasis added).

[52] Amarin Corp., *Amarin Provides Preliminary Fourth Quarter 2023 Selected Financials and Outlines Key Priorities for 2024* (Jan. 10, 2024), https://amarincorp.com/news-and-media/amarin-provides-preliminary-fourth-quarter-2023-selected.

barriers to entry, and foreclosing competition in the icosapent ethyl Drug Market and icosapent ethyl API Market. But for Amarin's conduct, Teva would have been able to obtain a sufficient supply of API to make a full-scale launch of its generic icosapent ethyl drug products upon or shortly after receiving final FDA approval. However, because of Amarin's conduct, Teva's launch was at limited quantities below market demand and with artificially inflated API costs.

129. Amarin's anticompetitive conduct has impeded and continues to impede the sale of generic icosapent ethyl drug products. Amarin's anticompetitive conduct impacted Teva's pricing and market share and, therefore, stifled robust generic competition. Unless restrained by this Court, Amarin will continue to maintain and extend its monopoly power in the relevant markets and continue to sell Vascepa at artificially inflated monopoly prices.

130. This conduct has harmed the competitive process and allowed Amarin to perpetuate supracompetitive prices against wholesalers, retailers, and consumers. But for Amarin's anticompetitive conduct, consumers and federal, state, and private payors would have enjoyed the benefits of lower-priced generic competition earlier. Instead, Amarin's strategies to thwart generic entry forced and continues to force consumers and federal, state, and private payors to pay monopoly rents for Amarin's branded Vascepa. The impact of Amarin's conduct is felt throughout the healthcare industry, impacting pharmaceutical competitors, healthcare providers, insurers and direct purchasers, intermediaries, and consumers.

AMARIN'S CONDUCT HAS NO LEGITIMATE BUSINESS PURPOSE

131. There is no valid procompetitive business justification for Amarin's anticompetitive conduct, and even if Amarin offers one, it is pretextual and not cognizable, and any procompetitive benefits of Amarin's conduct do not outweigh its anticompetitive harms.

132. Amarin's multiple exclusive, or de facto exclusive API supply contracts have no legitimate procompetitive business purpose and are contrary to industry practice. It is industry

practice for a manufacturer, including a brand manufacturer like Amarin, to have one or two API suppliers, even though more may be available, because it is costly and takes time and resources to qualify and ensure quality control at the API suppliers. It is also industry practice not to have exclusive agreements with multiple API suppliers for a single product. Thus, Amarin's agreements with at least five suppliers are contrary to industry practice and economically irrational.

133. Indeed, Amarin's several exclusive or de facto exclusive agreements with suppliers since 2012 cannot be justified by the usual rationale for manufacturers to enter exclusive supply contracts—i.e., to ensure adequate supplies. The additional exclusive contracts also cannot be explained by the 2019 indication or other market events.

134. Amarin has not been silent on its API supply. In fact, it has made repeated public statements about its API supply and the suppliers with whom it has entered agreements.[53] Amarin never once mentioned a supply issue. Indeed, Amarin boasted about its abundant supply. Amarin's public statements in January 2018 confirmed that it had "capacity to provide supply to support the potential of over $1 billion in product revenues in 2019."[54] Accordingly, without any evidence of supply concerns, Amarin has no legitimate justification for entering into the exclusive or de facto exclusive agreements with suppliers.

135. And despite having an oversupply relative to its needs, Amarin has committed to paying suppliers to maintain exclusivity even when Amarin does not meet minimum purchase requirements. In a public statement, Amarin stated:

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[53] *See*, *e.g.*, Press Release, Amarin Corp. plc, "Amarin Receives FDA Approval of VASCEPA® (icosapent ethyl) to Reduce Cardiovascular Risk" (Dec. 13, 2019), https://amarincorp.gcs-web.com/node/18451/pdf; Press Release, Amarin Corp. plc, "Amarin Announces Patent Litigation Settlement Agreement with Apotex Inc." (June 16, 2020), https://www.globenewswire.com/news-release/2020/06/16/2049162/0/en/Amarin-AnnouncesPatent-Litigation-Settlement-Agreement-with-Apotex-Inc.html; Press Release, Amarin Corp. plc, "Amarin Provides Update Following Ruling in Vascepa® ANDA Patent Litigation" (Sep. 3, 2020), https://amarincorp.gcs-web.com/node/19871/pdf.

[54] *Id.* at 83.

> We have agreements with API suppliers which include minimum purchase levels to enable us to maintain certain exclusivity with each respective supplier and certain agreements require any shortfall in such purchase levels to be paid in cash.[55]

136. Amarin's practice of agreeing to cover any shortfall in Amarin's minimum purchase commitments in cash payments is unnecessary given that Amarin faces no short- or long-run supply constraints on its access to icosapent ethyl. Rather, the true purpose for these agreements is made clear by Amarin's own public statements. In a public statement, Amarin said:

> [A]greements with our [API] 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. 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 [API] from our suppliers to our potential competitors would make our competitors' entry into the market easier and more attractive.[56]

As is clear from this statement, Amarin entered into exclusivity agreements and agreed to cover any shortfalls in its minimum purchase commitments with cash payments in order to constrain the availability of icosapent ethyl API supply to its competitors, with the explicit aim of deterring generic competitors from manufacturing and marketing generic icosapent ethyl drug products.

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[55] Amarin Corp. plc, *Amarin Provides Preliminary 2017 Results and Provides 2018 Outlook* (Jan. 4, 2018), https://amarincorp.gcs-web.com/static-files/ee8af8cb-e84a-44cb-ae6c-800b16ac88dc.

[56] Amarin Corp. PLC, Annual Report (Form 10-K), at 40 (Feb. 27, 2014).

COUNT I
(Sherman Act Section I – Conspiracy)

137. Teva repeats, realleges, and incorporates by reference the allegations in paragraphs 1–136.

138. The relevant markets are icosapent ethyl Drug Products and the icosapent ethyl API Market. These markets are characterized by significant barriers to entry.

139. Amarin possesses monopoly power in the relevant markets as the sole brand manufacturer authorized by the FDA.

140. This claim arises under the Sherman Act, 15 U.S.C. § 1, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Amarin has violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by conspiring, combining, and/or agreeing to restrain trade in the relevant markets.

141. Through the foregoing acts, Amarin, unlawfully and in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, has acted pursuant to a contract, combination, or conspiracy in order to, and with the likely effect of, unreasonably restraining trade in each of the relevant markets.

142. Amarin knowingly and intentionally engaged in anticompetitive conduct designed to unlawfully delay and suppress the full launch and commercialization of Teva's generic version of Vascepa and maintain its monopoly power. Amarin did this by entering into exclusive supply agreements with the leading suppliers of API icosapent ethyl. Amarin's conduct has no procompetitive, legitimate business justification. Amarin's conduct can only be explained by anticompetitive motives to foreclose competition in the relevant markets.

143. Amarin's conduct has had a substantial effect on interstate commerce.

144. Amarin's anticompetitive and exclusionary conduct has directly and proximately caused injury to Teva's business and property as well as to consumers, as set forth above. This is the type of injury the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

145. Teva is entitled to a judgment that Amarin has violated Section 1 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Amarin's continued violations.

COUNT II
(Sherman Act Section 2 – Monopolization)

146. Teva repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1–145.

147. The relevant markets are icosapent ethyl Drug Products and the icosapent ethyl API Market. These markets are characterized by significant barriers to entry.

148. Amarin possesses monopoly power in the relevant markets as the sole brand manufacturer authorized by the FDA.

149. This claim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Amarin has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by monopolizing the markets through exclusionary acts.

150. Through the foregoing acts, Amarin, unlawfully and in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, has used, is using. and, if not restrained by this Court, will continue to use, its power in the relevant markets.

151. Amarin knowingly and intentionally engaged in anticompetitive conduct designed to unlawfully delay and suppress the full launch and commercialization of Teva's generic version of Vascepa and maintain its monopoly power. Amarin did this by entering into exclusive supply agreements with the leading suppliers of icosapent ethyl, and by ensuring generic competitors could not successfully enter the market. Amarin's conduct has no procompetitive, legitimate

business justification. Amarin's conduct can only be explained by anticompetitive motives to foreclose competition in the relevant markets.

152. By its conduct, Amarin intentionally and wrongfully maintained monopoly power in the relevant markets in violation of Section 2 of the Sherman Act. As a result of Amarin's unlawful maintenance of monopoly power, Teva has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

153. Amarin's conduct has had a substantial effect on interstate commerce.

154. Amarin's anticompetitive and exclusionary conduct has directly and proximately caused injury to Teva's business and property and consumers, as set forth above. This is the type of injury the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

155. Amarin's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Teva and consumers will suffer immediate and irreparable injury for which Teva is without an adequate remedy at law.

156. Teva is entitled to a judgment that Amarin has violated Section 2 of the Sherman Act; to the damages it suffered because of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Amarin's continued violations.

COUNT III
(Sherman Act Section 2 – Attempt to Monopolize)

157. Teva repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1–156.

158. The relevant markets are icosapent ethyl Drug Products and the icosapent ethyl API Market. These markets are characterized by significant barriers to entry.

159. Amarin possesses monopoly power in the relevant markets and is the sole brand manufacturer authorized by the FDA.

160. This claim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Amarin has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by attempting to monopolize U.S. patient market for FDA-approved pure icosapent ethyl drugs.

161. Through the foregoing acts, Amarin, unlawfully and in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, has used, is using, and, if not restrained by this Court, will continue to use, its power in the U.S. patient market for FDA-approved pure icosapent ethyl drugs to attempt to monopolize the market.

162. Amarin knowingly and intentionally engaged in anticompetitive conduct designed to unlawfully delay and suppress the full launch and commercialization of Teva's generic version of Vascepa and to attempt to create monopoly power. Amarin did this by entering into exclusive supply agreements with the leading suppliers of icosapent ethyl. Amarin's conduct has no procompetitive, legitimate business justification. Amarin's conduct can only be explained by anticompetitive motives to foreclose competition in the relevant markets.

163. Amarin engaged in this conduct with the specific intent to monopolize the relevant markets.

164. By its conduct, Amarin intentionally and wrongfully attempted to maintain monopoly power in the relevant markets in violation of Section 2 of the Sherman Act. As a result of Amarin's unlawful attempt to maintain monopoly power, Teva has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

165. Amarin's conduct has had a substantial effect on interstate commerce.

166. Amarin's anticompetitive and exclusionary conduct has directly and proximately caused injury to Teva's business and property and consumers, as set forth above. This is the type of injury the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

167. Amarin's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Teva will suffer immediate and irreparable injury for which Teva is without an adequate remedy at law.

168. Teva is entitled to a judgment that Amarin has violated Section 2 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Amarin's continued violations.

COUNT IV
(The New Jersey Antitrust Act, Sections 56:9-3 and 56:9-4)

169. Teva repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1–168.

170. The relevant markets are icosapent ethyl Drug Products and the icosapent ethyl API Market. These markets are characterized by significant barriers to entry.

171. Amarin possesses monopoly power in the relevant markets and is the sole brand manufacturer authorized by the FDA.

172. This claim arises under the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9 *et seq.*, and seeks a judgment that Amarin has violated New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-3 and 56:9-4.

173. Amarin's conduct as alleged herein constitutes monopolization, attempted monopolization, and conspiracy to monopolize, in violation of N.J. Stat. Ann. § 56:9-4.

174. Amarin knowingly and intentionally engaged in anticompetitive conduct designed to unlawfully delay and suppress the full launch and commercialization of Teva's generic version of Vascepa and to attempt to create monopoly power. Amarin did this by entering into exclusive supply agreements with the leading suppliers of icosapent ethyl. Amarin's conduct has no procompetitive, legitimate business justification. Amarin's conduct can only be explained by anticompetitive motives to foreclose competition in the relevant markets.

175. Amarin's conduct as alleged herein constitutes a contract, combination, or conspiracy in restraint of trade or commerce in violation of N.J. Stat. Ann. § 56:9-3.

176. Amarin knowingly and intentionally engaged in exclusive or de facto exclusive agreements with at least BASF, Slanmhor, Novasep, Chemport, Nisshin, and KD Pharma to unlawfully delay the launch of Teva's generic version of Vascepa.

177. Amarin's anticompetitive and exclusionary conduct has directly and proximately caused injury to Teva's business and property and consumers, as set forth above. This is the type of injury the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

COUNT V
(Common Law of the State of New Jersey – Unfair Competition)

178. Teva repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1–177 of its claims.

179. Through the same foregoing unlawful, predatory, and anticompetitive acts as alleged, Amarin has engaged in unfair competition and unfair trade practices in violation of the common law of the State of New Jersey.

180. As a result of the foregoing, Amarin has injured Teva in its business and property and Teva is entitled to damages, attorneys' fees, costs of suit, and other appropriate relief.

JURY DEMAND

181. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Teva demands a trial by jury as to all issues of right to a jury.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully requests that this Court enter judgment in its favor and grant the following relief:

a. Permanent injunctive relief under 15 U.S.C. § 26, Fed. R. Civ. P. 65, and N.J. Stat. Ann. § 56:9-10, restraining Amarin, its affiliates, successors, transferees, assignees as well as its officers, directors, partners, agents, and employees, from continuing or renewing the conduct, contract, conspiracy, or combination alleged or from engaging in any other conduct, contract, conspiracy, or combination with a similar purpose or effect;

b. Compensatory damages for Teva's lost sales of generic icosapent ethyl, and profits on those sales, caused by Amarin's actions, and caused by Amarin's actions in foreclosing the other suppliers;

c. Treble damages under 15 U.S.C. § 15 and N.J. Stat. Ann. § 56:9-12;

d. Pre- and post-judgment interest as available by law;

e. Attorneys' fees and costs under 28 U.S.C. § 15 and N.J. Stat. Ann. § 56:9-12; and

f. Any other further relief as the Court deems just and proper.

Dated: March 28, 2024

/s/ Liza M. Walsh

Liza M. Walsh
Jessica K. Formichella
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102

(973) 757-1100

Devora W. Allon, P.C. (*phv forthcoming*)
Gilad Bendheim (*phv forthcoming*)
KIRKLAND & ELLIS LLP
601 Lexington Ave.
New York, NY 10022
(212) 446 5967
devora.allon@kirkland.com
gilad.bendheim@kirkland.com

James R.P. Hileman (*phv forthcoming*)
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
(312) 862-7090
james.hileman@kirkland.com

Attorneys for Plaintiff,
Teva Pharmaceuticals USA, Ltd.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, the matter in controversy is the subject of four pending matters in this District: *Hikma Pharms. USA Inc. v. Amarin Pharms. Inc.*, 23-cv-01016 (RK/TJB); *Dr. Reddy's Laboratories Inc. v. Amarin Pharms, Inc.*, 21-cv-10309 (RK/TJB); *In re Vascepa Antitrust Litigation Indirect Purchaser Plaintiffs*, 21-cv-12061 (RK/TJB); and *In re Vascepa Antitrust Litigation Direct Purchaser Plaintiffs*, 21-cv-12747(RK/TJB). Teva is not aware of any other action pending in any court or any pending arbitration or administrative proceeding related to this matter.

s/ Liza M. Walsh
Liza M. Walsh

Dated: March 28, 2024

LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

Dated: March 28, 2024

/s/ Liza M. Walsh
Liza M. Walsh