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20 *Amarin Pharmaceuticals Ireland Limited*

21 **UNITED STATES DISTRICT COURT**
22 **FOR THE DISTRICT OF NEVADA**

23 AMARIN PHARMA, INC. and AMARIN
24 PHARMACEUTICALS IRELAND
25 LIMITED,

26 Plaintiffs,

27 v.

28 TEVA PHARMACEUTICALS USA, INC.
and TEVA PHARMACEUTICAL
INDUSTRIES LIMITED,

Defendants.

Case No.: 2:16-cv-02658

**COMPLAINT FOR PATENT
INFRINGEMENT**

Plaintiffs Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited (collectively,
“Plaintiffs” or “Amarin”), by their attorneys, for their complaint against Teva Pharmaceuticals

1 USA, Inc. (Teva USA) and Teva Pharmaceutical Industries Limited (“Teva Ltd.”) (collectively,
2 “Defendants” or “Teva”) allege as follows:

3 **Nature of the Action**

4 1. This is a civil action for patent infringement arising under the patent laws of the
5 United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(a-c, e) for
6 infringement of U.S. Patent No. 8,293,728 (“the ‘728 Patent”), U.S. Patent No. 8,318,715 (“the
7 ‘715 Patent”), U.S. Patent No. 8,357,677 (“the ‘677 Patent”), U.S. Patent No. 8,367,652 (“the
8 ‘652 Patent”), U.S. Patent No. 8,377,920 (“the ‘920 Patent”), U.S. Patent No. 8,399,446 (“the
9 ‘446 Patent”), U.S. Patent No. 8,415,335 (“the ‘335 Patent”), U.S. Patent No. 8,426,399 (“the
10 ‘399 Patent”), U.S. Patent No. 8,431,560 (“the ‘560 Patent”), U.S. Patent No. 8,440,650 (“the
11 ‘650 Patent”), U.S. Patent No. 8,518,929 (“the ‘929 Patent”), U.S. Patent No. 8,524,698 (“the
12 ‘698 Patent”), U.S. Patent No. 8,546,372 (“the ‘372 Patent”), and U.S. Patent No. 8,617,594
13 (“the ‘594 Patent”). This action relates to an Abbreviated New Drug Application (“ANDA”) No.
14 209525 filed by or for the benefit of Defendants with the United States Food and Drug
15 Administration (“FDA”) for approval to market generic versions of Plaintiffs’ VASCEPA®
16 pharmaceutical products that are sold in the United States, including within this judicial district.
17 This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331
18 and 1338(a).

19 **The Parties**

20 2. Plaintiff Amarin Pharma, Inc. is a company organized and existing under the laws
21 of Delaware with its principal place of business at 1430 Route 206, Bedminster, NJ 07921.

22 3. Plaintiff Amarin Pharmaceuticals Ireland Limited is a company incorporated
23 under the laws of Ireland with registered offices at 88 Harcourt Street, Dublin 2, Dublin, Ireland.

24 4. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. is a
25 company organized and existing under the laws of Delaware with its principal place of business
26 at 425 Privet Road, Horsham, Pennsylvania 19044.

27 5. Upon information and belief, Defendant Teva Pharmaceutical Industries Limited
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1 is a company organized and existing under the laws of Israel with its principal place of business
2 at 5 Basel St., Petach Tikva Israel, 49131.

3 6. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. is a
4 wholly-owned subsidiary of Teva Pharmaceutical Industries Limited.

5 7. Upon information and belief, Teva Ltd. either directly or through one or more of
6 its wholly owned subsidiaries and/or agents, including Teva USA, develops, manufactures,
7 distributes, markets, offers to sell, and sells generic drug products for sale and use throughout
8 the United States, including within this judicial district.

9 8. Upon information and belief, Teva USA with the assistance and/or at the
10 direction of Teva Ltd., develops, manufactures, distributes, markets, offers to sell, and sells
11 generic drug products for sale and use throughout the United States, including within this
12 judicial district.

13 **Jurisdiction and Venue**

14 9. This is a civil action for patent infringement arising under the patent laws of the
15 United States, Title 35 of the U.S. Code, for infringement of the '728 Patent, the '715 Patent, the
16 '677 Patent, the '652 Patent, the '920 Patent, the '446 Patent, the '335 Patent, the '399 Patent,
17 the '560 Patent, the '650 Patent, the '929 Patent, the '698 Patent, the '372 Patent, and the '594
18 Patent.

19 10. This Court has jurisdiction over the subject matter of this action pursuant to 28
20 U.S.C. §§ 1331 and 1338(a).

21 11. On information and belief and as stated in the ANDA Notice Letter, Defendants
22 prepared and filed ANDA No. 209525 with the intention of seeking to market a generic version
23 of Amarin's VASCEPA® product, including within this judicial district.

24 12. Upon information and belief, Defendants regularly conduct business in Nevada,
25 either directly or through one or more of their wholly owned subsidiaries and/or agents. Upon
26 information and belief, wholly-owned subsidiaries of Teva Ltd. are Nevada corporations.

27 13. Upon information and belief, Defendants are licensed to sell generic
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1 pharmaceutical products in Nevada, either directly or through one or more of their wholly
2 owned subsidiaries and/or agents.

3 14. Upon information and belief, Defendants receive Medicaid reimbursements for
4 drugs sold in Nevada, either directly or through one or more of their wholly owned subsidiaries
5 and/or agents.

6 15. Upon information and belief, Defendants plan to sell a generic VASCEPA®
7 product in Nevada, list a generic VASCEPA® product on Nevada's prescription drug formulary,
8 and seek Medicaid reimbursements for sales of a generic VASCEPA® product in Nevada, either
9 directly or through one or more of their wholly owned subsidiaries and/or agents.

10 16. On information and belief, by virtue of, *inter alia*, Defendants' sales-related
11 activities in Nevada, including but not limited to the substantial, continuous, and systematic
12 distribution, marketing, and/or sales of pharmaceutical products to residents of Nevada
13 described in paragraphs 11–15, this Court has general personal jurisdiction over Teva.

14 17. On information and belief, by virtue of, *inter alia*, Teva's continuous and
15 systematic contacts with Nevada, including but not limited to the contacts described in
16 paragraphs 11–15, this Court has specific personal jurisdiction over Teva. These activities satisfy
17 due process and confer personal jurisdiction over Teva consistent with Nevada law. *See, e.g.,*
18 *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 762–63 (Fed. Cir. 2016) (holding that
19 minimum-contacts requirement for specific personal jurisdiction is established where
20 Defendant's "ANDA filings and its distribution channels establish that [the Defendant] plans to
21 market its proposed drugs in [the State where the complaint was filed] and the lawsuit is about
22 patent constraints on such in-State marketing.").

23 18. On the basis of at least the facts alleged in paragraphs 11–17, venue is proper in
24 this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b). In addition, related actions in
25 which the same patents are asserted are pending in this district. *Amarin Pharma Inc. v. Roxane Labs.*
26 *Inc.*, 2:16-cv-02525-MMD-NJK (D. Nev. filed Oct. 31, 2016); *Amarin Pharma Inc. v. Dr. Reddy's*
27 *Laboratories, Inc.*, 2:16-cv-02562-RCJ-GWF (D. Nev. filed Nov. 4, 2016).

Regulatory Requirements for New and Generic Drugs

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2 19. A person wishing to market a new drug that has not previously been approved by
3 the U.S. Food and Drug Administration (“FDA”) (a “pioneering” drug) must file a New Drug
4 Application (“NDA”) with FDA demonstrating that the drug is safe and effective for its
5 intended use. 21 U.S.C. § 355(b).

6 20. A person wishing to market a generic copy of a drug that previously has been
7 approved by FDA may follow a truncated approval process by filing an Abbreviated New Drug
8 Application (“ANDA”) for a generic version of that drug. In the ANDA, the applicant must
9 demonstrate, among other things, bioequivalence of the generic copy with the pioneering drug.
10 21 U.S.C. § 355(j)(2)(A)(iv).

11 21. Unlike an NDA applicant, an ANDA applicant is not required to include safety
12 and effectiveness data. Instead, the ANDA applicant is permitted to rely on the approval of the
13 NDA applicant’s drug—in essence, piggybacking on the NDA application and safety and
14 effectiveness conclusions. 21 U.S.C. § 355(j).

15 22. Nor does an ANDA applicant establish any new conditions of use for the
16 proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of
17 use that previously have been approved in connection with an approved NDA. 21 U.S.C. §
18 355(j)(2)(A)(i).

The Approved Drug Product

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20 23. Amarin Pharmaceuticals Ireland Limited is the current holder of NDA No.
21 202057, for 1g icosapent ethyl capsules, which was first approved by FDA on July 26, 2012.
22 Amarin Pharma, Inc. is Amarin Pharmaceuticals Ireland Limited’s agent in the United States for
23 purposes of communicating with FDA regarding NDA No. 202057. Amarin Pharmaceuticals
24 Ireland Limited and Amarin Pharma, Inc. market the approved drug product under the
25 tradename VASCEPA®.
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1 24. VASCEPA® is indicated as an adjunct to diet to reduce triglyceride levels in adult
2 patients with severe hypertriglyceridemia. A true, correct, and complete copy of the Prescribing
3 Information for VASCEPA® approved in NDA No. 202057 is attached as Exhibit A.

4 25. FDA has listed the ‘728, ‘715, ‘677, ‘652, ‘920, ‘446, ‘335, ‘399, ‘560, ‘650, ‘929,
5 ‘698, ‘372, and ‘594 Patents in the Orange Book—formally known as Approved Drug Products
6 With Therapeutic Equivalence Evaluations—in connection with NDA No. 202057.

7 26. Amarin Pharmaceuticals Ireland Limited is the owner of the ‘728, ‘715, ‘677, ‘652,
8 ‘920, ‘446, ‘335, ‘399, ‘560, ‘650, ‘929, ‘698, ‘372, and ‘594 Patents.

9 **ANDA No. 209525**

10 27. Upon information and belief, on or before October 7, 2016, Defendants
11 submitted to FDA an ANDA (ANDA No. 209525) with paragraph IV certifications under
12 section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C.
13 § 355(j)(2)(A)(vii)(IV), for 1g icosapent ethyl capsules purportedly bioequivalent to VASCEPA®.
14 The purpose of the ANDA is to obtain approval under section 505(j) of the FDCA to engage in
15 the commercial manufacture and sale of a generic VASCEPA® product.

16 28. Upon information and belief, the indication set forth in the proposed labeling
17 submitted in ANDA No. 209525 for the generic VASCEPA® product is to reduce triglyceride
18 levels in adult patients with severe hypertriglyceridemia, *i.e.*, the same indication as that set forth
19 in the approved labeling for VASCEPA®.

20 29. Upon information and belief, Defendants sent Amarin a letter dated October 7,
21 2016 (the “Notice Letter”). The Notice Letter represented that Defendants had submitted to
22 FDA an ANDA, No. 209525, with a paragraph IV certification for the ‘728, ‘715, ‘677, ‘652,
23 ‘920, ‘446, ‘335, ‘399, ‘560, ‘650, ‘929, ‘698, ‘372, and ‘594 Patents.

24 30. Upon information and belief, the purpose of the ANDA and paragraph IV
25 certifications is to obtain approval under section 505(j) of the FDCA to engage in the
26 commercial manufacture and sale of a generic version of VASCEPA® before the expiration of
27 the patents listed in the Orange Book for NDA No. 202057. Hence, Defendants’ purpose in
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1 submitting ANDA No. 209525 is to market products described therein before expiration of the
2 '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 Patents.

3 31. This case is an exceptional one, and Plaintiffs are entitled to an award of their
4 reasonable attorneys' fees under 35 U.S.C. § 285.

5 **Count I: Patent Infringement of the '728 Patent**

6 32. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 31
7 above.

8 33. United States Patent No. 8,293,728, entitled "METHODS OF TREATING
9 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and
10 Trademark Office on October 23, 2012. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
11 owner of the '728 Patent. A true and complete copy of the '728 Patent is attached hereto as
12 Exhibit B.

13 34. Upon information and belief, Defendants submitted ANDA No. 209525 to FDA
14 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
15 generic version of VASCEPA® before the expiration of the '728 Patent.

16 35. Defendants' manufacture, use, offer for sale, or sale of such product would
17 infringe the claims of the '728 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

18 36. Upon information and belief, if approved, the generic VASCEPA® product for
19 which approval is sought in Defendants' ANDA No. 209525 will be administered to human
20 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
21 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
22 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
23 '728 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
24 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
25 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
26 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
27 Defendants will actively induce, encourage, aid, and abet administration of the generic
28

1 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
2 '728 Patent.

3 37. Defendants' manufacture, use, offer for sale, or sale in the United States, or
4 importation into the United States, of the generic VASCEPA® product for which approval is
5 sought in ANDA No. 209525 would actively induce and contribute to infringement of the '728
6 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

7 38. Upon information and belief, as part of the ANDA filing, Defendants
8 purportedly provided written certification to FDA that the claims of the '728 Patent are invalid
9 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of
10 VASCEPA®.

11 39. Defendants gave written notice of their certification of invalidity and/or non-
12 infringement of the '728 Patent, alleging that claims of the '728 Patent are invalid and/or that
13 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and
14 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
15 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '728
16 Patent.

17 40. Defendants have infringed the '728 Patent under 35 U.S.C. § 271(e)(2)(A) by
18 virtue of submitting ANDA No. 209525 with a paragraph IV certification and seeking FDA
19 approval of ANDA No. 209525 to market a generic version of VASCEPA® prior to the
20 expiration of the '728 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
21 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
22 further infringe the '728 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

23 41. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
24 infringing or actively inducing or contributing to infringement of the '728 Patent. Plaintiffs do
25 not have an adequate remedy at law.

26 **Count II: Patent Infringement of the '715 Patent**

27 42. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 41
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1 above.

2 43. United States Patent No. 8,318,715, entitled “METHODS OF TREATING
3 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and
4 Trademark Office on November 27, 2012. Plaintiff Amarin Pharmaceuticals Ireland Limited is
5 the owner of the ‘715 Patent. A true and complete copy of the ‘715 Patent along with the
6 certificate of correction is attached hereto as Exhibit C.

7 44. Upon information and belief, Defendants submitted ANDA No. 209525 to FDA
8 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
9 generic version of VASCEPA® before the expiration of the ‘715 Patent.

10 45. Defendants’ manufacture, use, offer for sale, or sale of such product would
11 infringe the claims of the ‘715 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

12 46. Upon information and belief, if approved, the generic VASCEPA® product for
13 which approval is sought in Defendants’ ANDA No. 209525 will be administered to human
14 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
15 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
16 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
17 ‘715 Patent. Upon information and belief, this infringement will occur at Defendants’ behest,
18 with their intent, knowledge, and encouragement as a result of, for example, Defendants’ sales,
19 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
20 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
21 Defendants will actively induce, encourage, aid, and abet administration of the generic
22 VASCEPA® product with knowledge that it is in contravention of Plaintiffs’ rights under the
23 ‘715 Patent.

24 47. Defendants’ manufacture, use, offer for sale, or sale in the United States, or
25 importation into the United States, of the generic VASCEPA® product for which approval is
26 sought in ANDA No. 209525 would actively induce and contribute to infringement of the ‘715
27 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

1 48. Upon information and belief, as part of the ANDA filing, Defendants
2 purportedly provided written certification to FDA that the claims of the ‘715 Patent are invalid
3 and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic version of
4 VASCEPA®.

5 49. Defendants gave written notice of their certification of invalidity and/or non-
6 infringement of the ‘715 Patent, alleging that claims of the ‘715 Patent are invalid and/or that
7 certain claims would not be infringed by Defendants’ generic version of VASCEPA®, and
8 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
9 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the ‘715
10 Patent.

11 50. Defendants have infringed the ‘715 Patent under 35 U.S.C. § 271(e)(2)(A) by
12 virtue of submitting ANDA No. 209525 with a paragraph IV certification and seeking FDA
13 approval of ANDA No. 209525 to market a generic version of VASCEPA® prior to the
14 expiration of the ‘715 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
15 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
16 further infringe the ‘715 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

17 51. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
18 infringing or actively inducing or contributing to infringement of the ‘715 Patent. Plaintiffs do
19 not have an adequate remedy at law.

20 **Count III: Patent Infringement of the ‘677 Patent**

21 52. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 51
22 above.

23 53. United States Patent No. 8,357,677, entitled “METHODS OF TREATING
24 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and
25 Trademark Office on January 22, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
26 owner of the ‘677 Patent. A true and complete copy of the ‘677 Patent is attached hereto as
27 Exhibit D.
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1 54. Upon information and belief, Defendants submitted ANDA No. 209525 to FDA
2 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
3 generic version of VASCEPA® before the expiration of the ‘677 Patent.

4 55. Defendants’ manufacture, use, offer for sale, or sale of such product would
5 infringe the claims of the ‘677 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

6 56. Upon information and belief, if approved, the generic VASCEPA® product for
7 which approval is sought in Defendants’ ANDA No. 209525 will be administered to human
8 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
9 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
10 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
11 ‘677 Patent. Upon information and belief, this infringement will occur at Defendants’ behest,
12 with their intent, knowledge, and encouragement as a result of, for example, Defendants’ sales,
13 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
14 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
15 Defendants will actively induce, encourage, aid, and abet administration of the generic
16 VASCEPA® product with knowledge that it is in contravention of Plaintiffs’ rights under the
17 ‘677 Patent.

18 57. Defendants’ manufacture, use, offer for sale, or sale in the United States, or
19 importation into the United States, of the generic VASCEPA® product for which approval is
20 sought in ANDA No. 209525 would actively induce and contribute to infringement of the ‘677
21 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

22 58. Upon information and belief, as part of the ANDA filing, Defendants
23 purportedly provided written certification to FDA that the claims of the ‘677 Patent are invalid
24 and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic version of
25 VASCEPA®.

26 59. Defendants gave written notice of their certification of invalidity and/or non-
27 infringement of the ‘677 Patent, alleging that claims of the ‘677 Patent are invalid and/or that
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1 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and
2 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
3 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '677
4 Patent.

5 60. Defendants have infringed the '677 Patent under 35 U.S.C. § 271(e)(2)(A) by
6 virtue of submitting ANDA No. 209525 with a paragraph IV certification and seeking FDA
7 approval of ANDA No. 209525 to market a generic version of VASCEPA® prior to the
8 expiration of the '677 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
9 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
10 further infringe the '677 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

11 61. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
12 infringing or actively inducing or contributing to infringement of the '677 Patent. Plaintiffs do
13 not have an adequate remedy at law.

14 **Count IV: Patent Infringement of the '652 Patent**

15 62. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 61
16 above.

17 63. United States Patent No. 8,367,652, entitled "METHODS OF TREATING
18 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and
19 Trademark Office on February 5, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
20 owner of the '652 Patent. A true and complete copy of the '652 Patent is attached hereto as
21 Exhibit E.

22 64. Upon information and belief, Defendants submitted ANDA No. 209525 to FDA
23 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
24 generic version of VASCEPA® before the expiration of the '652 Patent.

25 65. Defendants' manufacture, use, offer for sale, or sale of such product would
26 infringe the claims of the '652 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

27 66. Upon information and belief, if approved, the generic VASCEPA® product for
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1 which approval is sought in Defendants' ANDA No. 209525 will be administered to human
2 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
3 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
4 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
5 '652 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
6 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
7 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
8 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
9 Defendants will actively induce, encourage, aid, and abet administration of the generic
10 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
11 '652 Patent.

12 67. Defendants' manufacture, use, offer for sale, or sale in the United States, or
13 importation into the United States, of the generic VASCEPA® product for which approval is
14 sought in ANDA No. 209525 would actively induce and contribute to infringement of the '652
15 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

16 68. Upon information and belief, as part of the ANDA filing, Defendants
17 purportedly provided written certification to FDA that the claims of the '652 Patent are invalid
18 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of
19 VASCEPA®.

20 69. Defendants gave written notice of their certification of invalidity and/or non-
21 infringement of the '652 Patent, alleging that claims of the '652 Patent are invalid and/or that
22 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and
23 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
24 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '652
25 Patent.

26 70. Defendants have infringed the '652 Patent under 35 U.S.C. § 271(e)(2)(A) by
27 virtue of submitting ANDA No. 209525 with a paragraph IV certification and seeking FDA
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1 approval of ANDA No. 209525 to market a generic version of VASCEPA® prior to the
2 expiration of the '652 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
3 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
4 further infringe the '652 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

5 71. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
6 infringing or actively inducing or contributing to infringement of the '652 Patent. Plaintiffs do
7 not have an adequate remedy at law.

8 **Count V: Patent Infringement of the '920 Patent**

9 72. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 71
10 above.

11 73. United States Patent No. 8,377,920, entitled "METHODS OF TREATING
12 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and
13 Trademark Office on February 19, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
14 owner of the '920 Patent. A true and complete copy of the '920 Patent is attached hereto as
15 Exhibit F.

16 74. Upon information and belief, Defendants submitted ANDA No. 209525 to FDA
17 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
18 generic version of VASCEPA® before the expiration of the '920 Patent.

19 75. Defendants' manufacture, use, offer for sale, or sale of such product would
20 infringe the claims of the '920 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

21 76. Upon information and belief, if approved, the generic VASCEPA® product for
22 which approval is sought in Defendants' ANDA No. 209525 will be administered to human
23 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
24 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
25 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
26 '920 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
27 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
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1 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
2 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
3 Defendants will actively induce, encourage, aid, and abet administration of the generic
4 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
5 '920 Patent.

6 77. Defendants' manufacture, use, offer for sale, or sale in the United States, or
7 importation into the United States, of the generic VASCEPA® product for which approval is
8 sought in ANDA No. 209525 would actively induce and contribute to infringement of the '920
9 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

10 78. Upon information and belief, as part of the ANDA filing, Defendants
11 purportedly provided written certification to FDA that the claims of the '920 Patent are invalid
12 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of
13 VASCEPA®.

14 79. Defendants gave written notice of their certification of invalidity and/or non-
15 infringement of the '920 Patent, alleging that claims of the '920 Patent are invalid and/or that
16 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and
17 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
18 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '920
19 Patent.

20 80. Defendants have infringed the '920 Patent under 35 U.S.C. § 271(e)(2)(A) by
21 virtue of submitting ANDA No. 209525 with a paragraph IV certification and seeking FDA
22 approval of ANDA No. 209525 to market a generic version of VASCEPA® prior to the
23 expiration of the '920 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
24 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
25 further infringe the '920 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

26 81. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
27 infringing or actively inducing or contributing to infringement of the '920 Patent. Plaintiffs do
28

1 not have an adequate remedy at law.

2 **Count VI: Patent Infringement of the '446 Patent**

3 82. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 81
4 above.

5 83. United States Patent No. 8,399,446, entitled "METHODS OF TREATING
6 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and
7 Trademark Office on March 19, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
8 owner of the '446 Patent. A true and complete copy of the '446 Patent is attached hereto as
9 Exhibit G.

10 84. Upon information and belief, Defendants submitted ANDA No. 209525 to FDA
11 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
12 generic version of VASCEPA® before the expiration of the '446 Patent.

13 85. Defendants' manufacture, use, offer for sale, or sale of such product would
14 infringe the claims of the '446 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

15 86. Upon information and belief, if approved, the generic VASCEPA® product for
16 which approval is sought in Defendants' ANDA No. 209525 will be administered to human
17 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
18 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
19 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
20 '446 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
21 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
22 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
23 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
24 Defendants will actively induce, encourage, aid, and abet administration of the generic
25 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
26 '446 Patent.

27 87. Defendants' manufacture, use, offer for sale, or sale in the United States, or
28

1 importation into the United States, of the generic VASCEPA® product for which approval is
2 sought in ANDA No. 209525 would actively induce and contribute to infringement of the ‘446
3 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

4 88. Upon information and belief, as part of the ANDA filing, Defendants
5 purportedly provided written certification to FDA that the claims of the ‘446 Patent are invalid
6 and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic version of
7 VASCEPA®.

8 89. Defendants gave written notice of their certification of invalidity and/or non-
9 infringement of the ‘446 Patent, alleging that claims of the ‘446 Patent are invalid and/or that
10 certain claims would not be infringed by Defendants’ generic version of VASCEPA®, and
11 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
12 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the ‘446
13 Patent.

14 90. Defendants have infringed the ‘446 Patent under 35 U.S.C. § 271(e)(2)(A) by
15 virtue of submitting ANDA No. 209525 with a paragraph IV certification and seeking FDA
16 approval of ANDA No. 209525 to market a generic version of VASCEPA® prior to the
17 expiration of the ‘446 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
18 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
19 further infringe the ‘446 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

20 91. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
21 infringing or actively inducing or contributing to infringement of the ‘446 Patent. Plaintiffs do
22 not have an adequate remedy at law.

23 **Count VII: Patent Infringement of the ‘335 Patent**

24 92. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 91
25 above.

26 93. United States Patent No. 8,415,335, entitled “METHODS OF TREATING
27 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and
28

1 Trademark Office on April 9, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
2 owner of the '335 Patent. A true and complete copy of the '335 Patent is attached hereto as
3 Exhibit H.

4 94. Upon information and belief, Defendants submitted ANDA No. 209525 to FDA
5 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
6 generic version of VASCEPA® before the expiration of the '335 Patent.

7 95. Defendants' manufacture, use, offer for sale, or sale of such product would
8 infringe the claims of the '335 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

9 96. Upon information and belief, if approved, the generic VASCEPA® product for
10 which approval is sought in Defendants' ANDA No. 209525 will be administered to human
11 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
12 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
13 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
14 '335 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
15 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
16 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
17 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
18 Defendants will actively induce, encourage, aid, and abet administration of the generic
19 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
20 '335 Patent.

21 97. Defendants' manufacture, use, offer for sale, or sale in the United States, or
22 importation into the United States, of the generic VASCEPA® product for which approval is
23 sought in ANDA No. 209525 would actively induce and contribute to infringement of the '335
24 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

25 98. Upon information and belief, as part of the ANDA filing, Defendants
26 purportedly provided written certification to FDA that the claims of the '335 Patent are invalid
27 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of
28

1 VASCEPA®.

2 99. Defendants gave written notice of their certification of invalidity and/or non-
3 infringement of the '335 Patent, alleging that claims of the '335 Patent are invalid and/or that
4 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and
5 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
6 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '335
7 Patent.

8 100. Defendants have infringed the '335 Patent under 35 U.S.C. § 271(e)(2)(A) by
9 virtue of submitting ANDA No. 209525 with a paragraph IV certification and seeking FDA
10 approval of ANDA No. 209525 to market a generic version of VASCEPA® prior to the
11 expiration of the '335 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
12 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
13 further infringe the '335 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

14 101. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
15 infringing or actively inducing or contributing to infringement of the '335 Patent. Plaintiffs do
16 not have an adequate remedy at law.

17 **Count VIII: Patent Infringement of the '399 Patent**

18 102. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
19 101 above.

20 103. United States Patent No. 8,426,399, entitled "METHODS OF TREATING
21 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and
22 Trademark Office on April 23, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
23 owner of the '399 Patent. A true and complete copy of the '399 Patent along with the certificate
24 of correction is attached hereto as Exhibit I.

25 104. Upon information and belief, Defendants submitted ANDA No. 209525 to FDA
26 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
27 generic version of VASCEPA® before the expiration of the '399 Patent.
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1 105. Defendants' manufacture, use, offer for sale, or sale of such product would
2 infringe the claims of the '399 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

3 106. Upon information and belief, if approved, the generic VASCEPA® product for
4 which approval is sought in Defendants' ANDA No. 209525 will be administered to human
5 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
6 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
7 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
8 '399 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
9 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
10 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
11 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
12 Defendants will actively induce, encourage, aid, and abet administration of the generic
13 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
14 '399 Patent.

15 107. Defendants' manufacture, use, offer for sale, or sale in the United States, or
16 importation into the United States, of the generic VASCEPA® product for which approval is
17 sought in ANDA No. 209525 would actively induce and contribute to infringement of the '399
18 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

19 108. Upon information and belief, as part of the ANDA filing, Defendants
20 purportedly provided written certification to FDA that the claims of the '399 Patent are invalid
21 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of
22 VASCEPA®.

23 109. Defendants gave written notice of their certification of invalidity and/or non-
24 infringement of the '399 Patent, alleging that claims of the '399 Patent are invalid and/or that
25 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and
26 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
27 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '399
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1 Patent.

2 110. Defendants have infringed the '399 Patent under 35 U.S.C. § 271(e)(2)(A) by
3 virtue of submitting ANDA No. 209525 with a paragraph IV certification and seeking FDA
4 approval of ANDA No. 209525 to market a generic version of VASCEPA® prior to the
5 expiration of the '399 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
6 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
7 further infringe the '399 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

8 111. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
9 infringing or actively inducing or contributing to infringement of the '399 Patent. Plaintiffs do
10 not have an adequate remedy at law.

11 **Count IX: Patent Infringement of the '560 Patent**

12 112. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
13 111 above.

14 113. United States Patent No. 8,431,560, entitled "METHODS OF TREATING
15 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and
16 Trademark Office on April 30, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
17 owner of the '560 Patent. A true and complete copy of the '560 Patent is attached hereto as
18 Exhibit J.

19 114. Upon information and belief, Defendants submitted ANDA No. 209525 to FDA
20 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
21 generic version of VASCEPA® before the expiration of the '560 Patent.

22 115. Defendants' manufacture, use, offer for sale, or sale of such product would
23 infringe the claims of the '560 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

24 116. Upon information and belief, if approved, the generic VASCEPA® product for
25 which approval is sought in Defendants' ANDA No. 209525 will be administered to human
26 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
27 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
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1 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
2 '560 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
3 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
4 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
5 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
6 Defendants will actively induce, encourage, aid, and abet administration of the generic
7 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
8 '560 Patent.

9 117. Defendants' manufacture, use, offer for sale, or sale in the United States, or
10 importation into the United States, of the generic VASCEPA® product for which approval is
11 sought in ANDA No. 209525 would actively induce and contribute to infringement of the '560
12 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

13 118. Upon information and belief, as part of the ANDA filing, Defendants
14 purportedly provided written certification to FDA that the claims of the '560 Patent are invalid
15 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of
16 VASCEPA®.

17 119. Defendants gave written notice of their certification of invalidity and/or non-
18 infringement of the '560 Patent, alleging that claims of the '560 Patent are invalid and/or that
19 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and
20 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
21 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '560
22 Patent.

23 120. Defendants have infringed the '560 Patent under 35 U.S.C. § 271(e)(2)(A) by
24 virtue of submitting ANDA No. 209525 with a paragraph IV certification and seeking FDA
25 approval of ANDA No. 209525 to market a generic version of VASCEPA® prior to the
26 expiration of the '560 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
27 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
28

1 further infringe the '560 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

2 121. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
3 infringing or actively inducing or contributing to infringement of the '560 Patent. Plaintiffs do
4 not have an adequate remedy at law.

5 **Count X: Patent Infringement of the '650 Patent**

6 122. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
7 121 above.

8 123. United States Patent No. 8,440,650, entitled "METHODS OF TREATING
9 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and
10 Trademark Office on May 14, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
11 owner of the '650 Patent. A true and complete copy of the '650 Patent is attached hereto as
12 Exhibit K.

13 124. Upon information and belief, Defendants submitted ANDA No. 209525 to FDA
14 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
15 generic version of VASCEPA® before the expiration of the '650 Patent.

16 125. Defendants' manufacture, use, offer for sale, or sale of such product would
17 infringe the claims of the '650 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

18 126. Upon information and belief, if approved, the generic VASCEPA® product for
19 which approval is sought in Defendants' ANDA No. 209525 will be administered to human
20 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
21 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
22 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
23 '650 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
24 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
25 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
26 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
27 Defendants will actively induce, encourage, aid, and abet administration of the generic
28

1 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
2 '650 Patent.

3 127. Defendants' manufacture, use, offer for sale, or sale in the United States, or
4 importation into the United States, of the generic VASCEPA® product for which approval is
5 sought in ANDA No. 209525 would actively induce and contribute to infringement of the '650
6 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

7 128. Upon information and belief, as part of the ANDA filing, Defendants
8 purportedly provided written certification to FDA that the claims of the '650 Patent are invalid
9 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of
10 VASCEPA®.

11 129. Defendants gave written notice of their certification of invalidity and/or non-
12 infringement of the '650 Patent, alleging that claims of the '650 Patent are invalid and/or that
13 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and
14 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
15 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '650
16 Patent.

17 130. Defendants have infringed the '650 Patent under 35 U.S.C. § 271(e)(2)(A) by
18 virtue of submitting ANDA No. 209525 with a paragraph IV certification and seeking FDA
19 approval of ANDA No. 209525 to market a generic version of VASCEPA® prior to the
20 expiration of the '650 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
21 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
22 further infringe the '650 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

23 131. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
24 infringing or actively inducing or contributing to infringement of the '650 Patent. Plaintiffs do
25 not have an adequate remedy at law.

26 **Count XI: Patent Infringement of the '929 Patent**

27 132. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
28

1 131 above.

2 133. United States Patent No. 8,518,929, entitled “METHODS OF TREATING
3 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and
4 Trademark Office on August 27, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
5 owner of the ‘929 Patent. A true and complete copy of the ‘929 Patent is attached hereto as
6 Exhibit L.

7 134. Upon information and belief, Defendants submitted ANDA No. 209525 to FDA
8 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
9 generic version of VASCEPA® before the expiration of the ‘929 Patent.

10 135. Defendants’ manufacture, use, offer for sale, or sale of such product would
11 infringe the claims of the ‘929 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

12 136. Upon information and belief, if approved, the generic VASCEPA® product for
13 which approval is sought in Defendants’ ANDA No. 209525 will be administered to human
14 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
15 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
16 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
17 ‘929 Patent. Upon information and belief, this infringement will occur at Defendants’ behest,
18 with their intent, knowledge, and encouragement as a result of, for example, Defendants’ sales,
19 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
20 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
21 Defendants will actively induce, encourage, aid, and abet administration of the generic
22 VASCEPA® product with knowledge that it is in contravention of Plaintiffs’ rights under the
23 ‘929 Patent.

24 137. Defendants’ manufacture, use, offer for sale, or sale in the United States, or
25 importation into the United States, of the generic VASCEPA® product for which approval is
26 sought in ANDA No. 209525 would actively induce and contribute to infringement of the ‘929
27 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

1 138. Upon information and belief, as part of the ANDA filing, Defendants
2 purportedly provided written certification to FDA that the claims of the ‘929 Patent are invalid
3 and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic version of
4 VASCEPA®.

5 139. Defendants gave written notice of their certification of invalidity and/or non-
6 infringement of the ‘929 Patent, alleging that claims of the ‘929 Patent are invalid and/or that
7 certain claims would not be infringed by Defendants’ generic version of VASCEPA®, and
8 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
9 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the ‘929
10 Patent.

11 140. Defendants have infringed the ‘929 Patent under 35 U.S.C. § 271(e)(2)(A) by
12 virtue of submitting ANDA No. 209525 with a paragraph IV certification and seeking FDA
13 approval of ANDA No. 209525 to market a generic version of VASCEPA® prior to the
14 expiration of the ‘929 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
15 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
16 further infringe the ‘929 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

17 141. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
18 infringing or actively inducing or contributing to infringement of the ‘929 Patent. Plaintiffs do
19 not have an adequate remedy at law.

20 **Count XII: Patent Infringement of the ‘698 Patent**

21 142. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
22 141 above.

23 143. United States Patent No. 8,524,698, entitled “METHODS OF TREATING
24 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and
25 Trademark Office on September 3, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is
26 the owner of the ‘698 Patent. A true and complete copy of the ‘698 Patent along with the
27 certificate of correction is attached hereto as Exhibit M.

1 144. Upon information and belief, Defendants submitted ANDA No. 209525 to FDA
2 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
3 generic version of VASCEPA® before the expiration of the ‘698 Patent.

4 145. Defendants’ manufacture, use, offer for sale, or sale of such product would
5 infringe the claims of the ‘698 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

6 146. Upon information and belief, if approved, the generic VASCEPA® product for
7 which approval is sought in Defendants’ ANDA No. 209525 will be administered to human
8 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
9 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
10 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
11 ‘698 Patent. Upon information and belief, this infringement will occur at Defendants’ behest,
12 with their intent, knowledge, and encouragement as a result of, for example, Defendants’ sales,
13 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
14 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
15 Defendants will actively induce, encourage, aid, and abet administration of the generic
16 VASCEPA® product with knowledge that it is in contravention of Plaintiffs’ rights under the
17 ‘698 Patent.

18 147. Defendants’ manufacture, use, offer for sale, or sale in the United States, or
19 importation into the United States, of the generic VASCEPA® product for which approval is
20 sought in ANDA No. 209525 would actively induce and contribute to infringement of the ‘698
21 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

22 148. Upon information and belief, as part of the ANDA filing, Defendants
23 purportedly provided written certification to FDA that the claims of the ‘698 Patent are invalid
24 and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic version of
25 VASCEPA®.

26 149. Defendants gave written notice of their certification of invalidity and/or non-
27 infringement of the ‘698 Patent, alleging that claims of the ‘698 Patent are invalid and/or that
28

1 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and
2 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
3 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '698
4 Patent.

5 150. Defendants have infringed the '698 Patent under 35 U.S.C. § 271(e)(2)(A) by
6 virtue of submitting ANDA No. 209525 with a paragraph IV certification and seeking FDA
7 approval of ANDA No. 209525 to market a generic version of VASCEPA® prior to the
8 expiration of the '698 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
9 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
10 further infringe the '698 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

11 151. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
12 infringing or actively inducing or contributing to infringement of the '698 Patent. Plaintiffs do
13 not have an adequate remedy at law.

14 **Count XIII: Patent Infringement of the '372 Patent**

15 152. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
16 151 above.

17 153. United States Patent No. 8,546,372, entitled "METHODS OF TREATING
18 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and
19 Trademark Office on October 1, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
20 owner of the '372 Patent. A true and complete copy of the '372 Patent is attached hereto as
21 Exhibit N.

22 154. Upon information and belief, Defendants submitted ANDA No. 209525 to FDA
23 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
24 generic version of VASCEPA® before the expiration of the '372 Patent.

25 155. Defendants' manufacture, use, offer for sale, or sale of such product would
26 infringe the claims of the '372 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

27 156. Upon information and belief, if approved, the generic VASCEPA® product for
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1 which approval is sought in Defendants' ANDA No. 209525 will be administered to human
2 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
3 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
4 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
5 '372 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
6 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
7 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
8 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
9 Defendants will actively induce, encourage, aid, and abet administration of the generic
10 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
11 '372 Patent.

12 157. Defendants' manufacture, use, offer for sale, or sale in the United States, or
13 importation into the United States, of the generic VASCEPA® product for which approval is
14 sought in ANDA No. 209525 would actively induce and contribute to infringement of the '372
15 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

16 158. Upon information and belief, as part of the ANDA filing, Defendants
17 purportedly provided written certification to FDA that the claims of the '372 Patent are invalid
18 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of
19 VASCEPA®.

20 159. Defendants gave written notice of their certification of invalidity and/or non-
21 infringement of the '372 Patent, alleging that claims of the '372 Patent are invalid and/or that
22 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and
23 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
24 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '372
25 Patent.

26 160. Defendants have infringed the '372 Patent under 35 U.S.C. § 271(e)(2)(A) by
27 virtue of submitting ANDA No. 209525 with a paragraph IV certification and seeking FDA
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1 approval of ANDA No. 209525 to market a generic version of VASCEPA® prior to the
2 expiration of the '372 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
3 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
4 further infringe the '372 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

5 161. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
6 infringing or actively inducing or contributing to infringement of the '372 Patent. Plaintiffs do
7 not have an adequate remedy at law.

8 **Count XIV: Patent Infringement of the '594 Patent**

9 162. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
10 161 above.

11 163. United States Patent No. 8,617,594, entitled "STABLE PHARMACEUTICAL
12 COMPOSITION AND METHODS OF USING SAME," was duly and legally issued by the
13 United States Patent and Trademark Office on December 31, 2013. Plaintiff Amarin
14 Pharmaceuticals Ireland Limited is the owner of the '594 Patent. A true and complete copy of
15 the '594 Patent is attached hereto as Exhibit O.

16 164. Upon information and belief, Defendants submitted ANDA No. 209525 to FDA
17 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
18 generic version of VASCEPA® before the expiration of the '594 Patent.

19 165. Defendants' manufacture, use, offer for sale, or sale of such product would
20 infringe the claims of the '594 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

21 166. Upon information and belief, if approved, the generic VASCEPA® product for
22 which approval is sought in Defendants' ANDA No. 209525 will be administered to human
23 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
24 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
25 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
26 '594 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
27 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
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1 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
2 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
3 Defendants will actively induce, encourage, aid, and abet administration of the generic
4 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
5 '594 Patent.

6 167. Defendants' manufacture, use, offer for sale, or sale in the United States, or
7 importation into the United States, of the generic VASCEPA® product for which approval is
8 sought in ANDA No. 209525 would actively induce and contribute to infringement of the '594
9 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

10 168. Upon information and belief, as part of the ANDA filing, Defendants
11 purportedly provided written certification to FDA that the claims of the '594 Patent are invalid
12 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of
13 VASCEPA®.

14 169. Defendants gave written notice of their certification of invalidity and/or non-
15 infringement of the '594 Patent, alleging that claims of the '594 Patent are invalid and/or that
16 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and
17 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
18 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '594
19 Patent.

20 170. Defendants have infringed the '594 Patent under 35 U.S.C. § 271(e)(2)(A) by
21 virtue of submitting ANDA No. 209525 with a paragraph IV certification and seeking FDA
22 approval of ANDA No. 209525 to market a generic version of VASCEPA® prior to the
23 expiration of the '594 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
24 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
25 further infringe the '594 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

26 171. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
27 infringing or actively inducing or contributing to infringement of the '594 Patent. Plaintiffs do
28

1 not have an adequate remedy at law.

2 **Prayer for Relief**

3 WHEREFORE, Plaintiffs seek the following relief:

4 A. A judgment that Defendants have infringed the '728, '715, '677, '652, '920, '446,
5 '335, '399, '560, '650, '929, '698, '372, and '594 Patents under 35 U.S.C. § 271(e)(2)(A);

6 B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of
7 any FDA approval of ANDA No. 209525 is not earlier than the expiration date of the '728, '715,
8 '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 Patents, or any later
9 expiration of exclusivity for the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698,
10 '372, and '594 Patents to which Plaintiffs are or become entitled;

11 C. A permanent injunction restraining and enjoining Defendants and their officers,
12 agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active
13 concert or participation with any of them, from making, using, selling, offering to sell, or
14 importing any product that infringes the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650,
15 '929, '698, '372, and '594 Patents, including the product described in ANDA No. 209525;

16 D. A judgment declaring that making, using, selling, offering to sell, or importing the
17 product described in ANDA No. 209525, or inducing or contributing to such conduct, would
18 constitute infringement of the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698,
19 '372, and '594 Patents by Defendants pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

20 E. A finding that this is an exceptional case, and an award of attorneys' fees in this
21 action pursuant to 35 U.S.C. § 285;

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1 F. Costs and expenses in this action; and

2 G. Such further and other relief as this Court determines to be just and proper.

3 DATED: November 18, 2016

Respectfully submitted,

4
5 /s/ Nicholas J. Santoro

Nicholas J. Santoro (Nev. Bar No. 532)

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