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20 *Amarin Pharmaceuticals Ireland Limited*

21 **UNITED STATES DISTRICT COURT**
22 **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.: 2:17-cv-2641

**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. 8,415,335 (“the
9 ‘335 Patent”), U.S. Patent No. 8,426,399 (“the ‘399 Patent”), U.S. Patent No. 8,440,650 (“the
10 ‘650 Patent”), U.S. Patent No. 8,518,929 (“the ‘929 Patent”), U.S. Patent No. 8,524,698 (“the
11 ‘698 Patent”), U.S. Patent No. 8,546,372 (“the ‘372 Patent”), and U.S. Patent No. 8,617,594
12 (“the ‘594 Patent”). This action relates to an Abbreviated New Drug Application (“ANDA”) No.
13 209525 filed by or for the benefit of Defendants with the United States Food and Drug
14 Administration (“FDA”) for approval to market generic versions of Plaintiffs’ VASCEPA®
15 pharmaceutical products that are sold in the United States, including within this judicial district.
16 This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331
17 and 1338(a).

18 **The Parties**

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

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

23 4. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. is a
24 company organized and existing under the laws of Delaware with its principal place of business
25 at 425 Privet Road, Horsham, Pennsylvania 19044.
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1 5. Upon information and belief, Defendant Teva Pharmaceutical Industries Limited
2 is a company organized and existing under the laws of Israel with its principal place of business
3 at 5 Basel St., Petach Tikva, Israel, 49131.

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

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

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

14 **Jurisdiction and Venue**

15 9. This is a civil action for patent infringement arising under the patent laws of the
16 United States, Title 35 of the U.S. Code, for infringement of the ‘728 Patent, the ‘715 Patent, the
17 ‘677 Patent, the ‘652 Patent, the ‘920 Patent, the ‘335 Patent, the ‘399 Patent, the ‘650 Patent,
18 the ‘929 Patent, the ‘698 Patent, the ‘372 Patent, and the ‘594 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 a letter dated August 29, 2017 sent by
22 Defendants to Amarin (the “August Notice Letter”), Defendants prepared and filed an
23 amendment to ANDA No. 209525 (the “ANDA Amendment”) with the intention of seeking to
24 market a generic version of the 500 mg strength of Amarin’s VASCEPA® product (“generic
25 VASCEPA® 500 mg product”), including within this judicial district.

26 12. Upon information and belief, Defendants regularly conduct business in Nevada,
27 either directly or through one or more of their wholly owned subsidiaries and/or agents. Upon
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1 information and belief, Defendants have wholly-owned subsidiaries incorporated in Nevada,
2 including Teva Branded Pharmaceutical Products R&D, Inc.

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

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

9 15. Upon information and belief, Defendants plan to sell a generic VASCEPA® 500
10 mg product in Nevada, list a generic VASCEPA® 500 mg product on Nevada's prescription
11 drug formulary, and seek Medicaid reimbursements for sales of a generic VASCEPA® 500 mg
12 product in Nevada, either directly or through one or more of their wholly owned subsidiaries
13 and/or agents.

14 16. Upon information and belief, Defendants do business in Nevada through a
15 permanent and continuous presence there. Upon information and belief, Defendants'
16 subsidiaries in Nevada develop, manufacture, and/or market generic and proprietary
17 pharmaceuticals. Upon information and belief, Defendants and/or their subsidiaries actively
18 seek employment of sales representatives to serve Nevada customers, continuously employ sales
19 representatives in Nevada, and regularly market their products in Nevada.

20 17. Teva's outside counsel stated in its October 4, 2017 email to Plaintiffs' counsel
21 that "Teva can agree to personal jurisdiction and venue in the United States District Court for
22 the District of Nevada for purposes of litigation over Teva's 500 mg icosapent ethyl product
23 only." This civil suit concerns Teva's 500 mg icosapent ethyl product that Teva seeks to market.

24 18. On information and belief, by virtue of, *inter alia*, Teva's sales-related activities in
25 Nevada, including but not limited to the substantial, continuous, and systematic distribution,
26 marketing, and/or sales of pharmaceutical products to residents of Nevada described in
27 paragraphs 11–16, this Court has general personal jurisdiction over Teva. In addition, as
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1 described in paragraph 17, Teva has consented to personal jurisdiction of this Court over Teva
2 for the purpose of this litigation.

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

13 20. On the basis of at least the facts alleged in paragraphs 11–19, venue is proper in
14 this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b). In addition, related actions in
15 which the patents asserted in this case are asserted against Teva and other defendants are
16 pending in this district. *Amarin Pharma, Inc. v. Teva Pharmaceuticals USA, Inc.*, 2:16-cv-02658-
17 MMD-NJK (D. Nev. filed Nov. 18, 2016); *Amarin Pharma Inc. v. West-Ward Pharmaceuticals Corp.*,
18 2:16-cv-02525-MMD-NJK (D. Nev. filed Oct. 31, 2016); *Amarin Pharma Inc. v. Dr. Reddy's*
19 *Laboratories, Inc.*, 2:16-cv-02562-MMD-NJK (D. Nev. filed Nov. 4, 2016). Moreover, as described
20 in paragraph 17, Teva has consented to venue in this judicial district for the purpose of this
21 litigation.

22 **Regulatory Requirements for New and Generic Drugs**

23 21. A person wishing to market a new drug that has not previously been approved by
24 the U.S. Food and Drug Administration ("FDA") (a "pioneering" drug) must file a New Drug
25 Application ("NDA") with FDA demonstrating that the drug is safe and effective for its
26 intended use. 21 U.S.C. § 355(b).

1 22. A person wishing to market a generic copy of a drug that previously has been
2 approved by FDA may follow a truncated approval process by filing an Abbreviated New Drug
3 Application (“ANDA”) for a generic version of that drug. In the ANDA, the applicant must
4 demonstrate, among other things, bioequivalence of the generic copy with the pioneering drug.
5 21 U.S.C. § 355(j)(2)(A)(iv).

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

10 24. Nor does an ANDA applicant establish any new conditions of use for the
11 proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of
12 use that previously have been approved in connection with an approved NDA. 21 U.S.C. §
13 355(j)(2)(A)(i).

14 **The Approved Drug Product**

15 25. Amarin Pharmaceuticals Ireland Limited is the current holder of NDA No.
16 202057 for 1 g and 500 mg icosapent ethyl capsules. NDA No. 202057 was first approved by
17 FDA on July 26, 2012 for the 1 g strength of icosapent ethyl capsules. A supplement to NDA
18 No. 202057 for the 500 mg strength of icosapent ethyl capsules was approved on February 16,
19 2017. Amarin Pharma, Inc. is Amarin Pharmaceuticals Ireland Limited’s agent in the United
20 States for purposes of communicating with FDA regarding NDA No. 202057. Amarin
21 Pharmaceuticals Ireland Limited and Amarin Pharma, Inc. market both strengths of the
22 approved drug product under the tradename VASCEPA®.

23 26. VASCEPA® is indicated as an adjunct to diet to reduce triglyceride levels in adult
24 patients with severe hypertriglyceridemia. A true, correct, and complete copy of the FDA-
25 approved Prescribing Information for VASCEPA®, covering both the 1 g and 500 mg strengths,
26 is attached as Exhibit A.

1 27. FDA has listed the ‘728, ‘715, ‘677, ‘652, ‘920, ‘335, ‘399, ‘650, ‘929, ‘698, ‘372,
2 and ‘594 Patents in the Orange Book—formally known as Approved Drug Products With
3 Therapeutic Equivalence Evaluations—in connection with NDA No. 202057, including for the
4 500 mg strength of VASCEPA®.

5 28. Amarin Pharmaceuticals Ireland Limited is the owner of the ‘728, ‘715, ‘677, ‘652,
6 ‘920, ‘335, ‘399, ‘650, ‘929, ‘698, ‘372, and ‘594 Patents.

7 **ANDA No. 209525**

8 29. Upon information and belief, on or before October 7, 2016, Defendants
9 submitted to FDA an ANDA (ANDA No. 209525) for 1 g icosapent ethyl capsules purportedly
10 bioequivalent to VASCEPA® with a certification under section 505(j)(2)(A)(vii)(IV) (“paragraph
11 IV certification”) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §
12 355(j)(2)(A)(vii)(IV).

13 30. On November 18, 2016, Plaintiffs filed a complaint against Defendants in this
14 Court alleging that Defendants’ proposed generic 1 g icosapent ethyl capsules infringe Amarin
15 Pharmaceutical Ireland Limited’s patents. *See* 2:16-cv-02658-MMD-NJK, ECF No. 1.

16 31. Upon information and belief, on or before August 29, 2017, Defendants
17 submitted to FDA an ANDA Amendment for 500 mg icosapent ethyl capsules purportedly
18 bioequivalent to VASCEPA® (“Teva’s ANDA Amendment”) with a second paragraph IV
19 certification under section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV).
20 The purpose of the ANDA, as amended, is to obtain approval under section 505(j) of the
21 FDCA to engage in the commercial manufacture and sale of generic versions of both the 1 g
22 and 500 mg strengths of VASCEPA®.

23 32. Upon information and belief, the indication set forth in the proposed labeling
24 submitted in ANDA No. 209525, covering generic versions of the 1 g and 500 mg strengths of
25 VASCEPA®, is to reduce triglyceride levels in adult patients with severe hypertriglyceridemia,
26 *i.e.*, the same indication as that set forth in the approved labeling for VASCEPA®.

1 33. Upon information and belief, Defendants sent Amarin the August Notice Letter
2 dated August 29, 2017. The Notice Letter represented that Defendants had submitted to FDA
3 an ANDA Amendment with a second paragraph IV certification for the ‘728, ‘715, ‘677, ‘652,
4 ‘920, ‘335, ‘399, ‘650, ‘929, ‘698, ‘372, and ‘594 Patents.

5 34. Upon information and belief, the purpose of Teva’s ANDA Amendment and
6 second paragraph IV certification is to obtain approval under section 505(j) of the FDCA to
7 engage in the commercial manufacture and sale of a generic version of the 500 mg strength of
8 VASCEPA® before the expiration of the patents listed in the Orange Book for NDA No.
9 202057. Hence, Defendants’ purpose in submitting Teva’s ANDA Amendment is to market
10 products described therein before expiration of the ‘728, ‘715, ‘677, ‘652, ‘920, ‘335, ‘399, ‘650,
11 ‘929, ‘698, ‘372, and ‘594 Patents.

12 35. This case is an exceptional one, and Plaintiffs are entitled to an award of their
13 reasonable attorneys’ fees under 35 U.S.C. § 285.

14 **Count I: Patent Infringement of the ‘728 Patent**

15 36. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 35
16 above.

17 37. United States Patent No. 8,293,728, entitled “METHODS OF TREATING
18 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and
19 Trademark Office on October 23, 2012. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
20 owner of the ‘728 Patent. A true and complete copy of the ‘728 Patent is attached hereto as
21 Exhibit B.

22 38. Upon information and belief, Defendants submitted Teva’s ANDA Amendment
23 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale
24 of a generic version of the 500 mg strength of VASCEPA® before the expiration of the ‘728
25 Patent.

26 39. Defendants’ manufacture, use, offer for sale, or sale of such product would
27 infringe the claims of the ‘728 Patent under 35 U.S.C. § 271(a), (b), and/or (c).
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1 40. Upon information and belief, if approved, the generic VASCEPA® 500 mg
2 product for which approval is sought in Defendants' ANDA No. 209525 will be administered to
3 human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
4 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
5 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
6 '728 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
7 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
8 marketing, and distribution of their generic VASCEPA® 500 mg product as an adjunct to diet
9 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
10 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
11 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs'
12 rights under the '728 Patent.

13 41. Defendants' manufacture, use, offer for sale, or sale in the United States, or
14 importation into the United States, of the generic VASCEPA® 500 mg product for which
15 approval is sought in ANDA No. 209525 would actively induce and contribute to infringement
16 of the '728 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
17 and/or (c).

18 42. Upon information and belief, as part of the ANDA filing, Defendants
19 purportedly provided written certification to FDA that the claims of the '728 Patent are invalid
20 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
21 VASCEPA® 500 mg product.

22 43. Defendants gave written notice of their certification of invalidity and/or non-
23 infringement of the '728 Patent, alleging that claims of the '728 Patent are invalid and/or that
24 certain claims would not be infringed by Defendants' generic VASCEPA® 500 mg product, and
25 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
26 use, and sale of a product bioequivalent to the 500 mg strength of VASCEPA® prior to the
27 expiration of the '728 Patent.

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1 44. Defendants have infringed the ‘728 Patent under 35 U.S.C. § 271(e)(2)(A) by
2 virtue of submitting ANDA No. 209525 and Teva’s ANDA Amendment with a paragraph IV
3 certification, and seeking FDA approval of ANDA No. 209525 to market a generic version of
4 the 500 mg strength of VASCEPA® prior to the expiration of the ‘728 Patent. Moreover, if
5 Defendants commercially use, offer for sale, or sell their generic VASCEPA® 500 mg product,
6 or induce or contribute to such conduct, they would further infringe the ‘728 Patent under 35
7 U.S.C. § 271(a), (b), and/or (c).

8 45. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
9 infringing or actively inducing or contributing to infringement of the ‘728 Patent. Plaintiffs do
10 not have an adequate remedy at law.

11 **Count II: Patent Infringement of the ‘715 Patent**

12 46. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 45
13 above.

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

19 48. Upon information and belief, Defendants submitted Teva’s ANDA Amendment
20 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale
21 of a generic version of the 500 mg strength of VASCEPA® before the expiration of the ‘715
22 Patent.

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

25 50. Upon information and belief, if approved, the generic VASCEPA® 500 mg
26 product for which approval is sought in Defendants’ ANDA No. 209525 will be administered to
27 human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
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1 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
2 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
3 ‘715 Patent. Upon information and belief, this infringement will occur at Defendants’ behest,
4 with their intent, knowledge, and encouragement as a result of, for example, Defendants’ sales,
5 marketing, and distribution of their generic VASCEPA® 500 mg product as an adjunct to diet
6 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
7 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
8 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs’
9 rights under the ‘715 Patent.

10 51. Defendants’ manufacture, use, offer for sale, or sale in the United States, or
11 importation into the United States, of the generic VASCEPA® 500 mg product for which
12 approval is sought in ANDA No. 209525 would actively induce and contribute to infringement
13 of the ‘715 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
14 and/or (c).

15 52. Upon information and belief, as part of the ANDA filing, Defendants
16 purportedly provided written certification to FDA that the claims of the ‘715 Patent are invalid
17 and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic
18 VASCEPA® 500 mg product.

19 53. Defendants gave written notice of their certification of invalidity and/or non-
20 infringement of the ‘715 Patent, alleging that claims of the ‘715 Patent are invalid and/or that
21 certain claims would not be infringed by Defendants’ generic VASCEPA® 500 mg product, and
22 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
23 use, and sale of a product bioequivalent to the 500 mg strength of VASCEPA® prior to the
24 expiration of the ‘715 Patent.

25 54. Defendants have infringed the ‘715 Patent under 35 U.S.C. § 271(e)(2)(A) by
26 virtue of submitting ANDA No. 209525 and Teva’s ANDA Amendment with a paragraph IV
27 certification, and seeking FDA approval of ANDA No. 209525 to market a generic
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1 VASCEPA® 500 mg product prior to the expiration of the ‘715 Patent. Moreover, if
2 Defendants commercially use, offer for sale, or sell their generic VASCEPA® 500 mg product,
3 or induce or contribute to such conduct, they would further infringe the ‘715 Patent under 35
4 U.S.C. § 271(a), (b), and/or (c).

5 55. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
6 infringing or actively inducing or contributing to infringement of the ‘715 Patent. Plaintiffs do
7 not have an adequate remedy at law.

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

9 56. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 55
10 above.

11 57. United States Patent No. 8,357,677, entitled “METHODS OF TREATING
12 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and
13 Trademark Office on January 22, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
14 owner of the ‘677 Patent. A true and complete copy of the ‘677 Patent is attached hereto as
15 Exhibit D.

16 58. Upon information and belief, Defendants submitted Teva’s ANDA Amendment
17 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale
18 of a generic VASCEPA® 500 mg product before the expiration of the ‘677 Patent.

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

21 60. Upon information and belief, if approved, the generic VASCEPA® 500 mg
22 product for which approval is sought in Defendants’ ANDA No. 209525 will be administered to
23 human 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 ‘677 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 generic VASCEPA® 500 mg product as an adjunct to diet
2 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
3 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
4 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs'
5 rights under the '677 Patent.

6 61. Defendants' manufacture, use, offer for sale, or sale in the United States, or
7 importation into the United States, of the generic VASCEPA® 500 mg product for which
8 approval is sought in ANDA No. 209525 would actively induce and contribute to infringement
9 of the '677 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
10 and/or (c).

11 62. Upon information and belief, as part of the ANDA filing, Defendants
12 purportedly provided written certification to FDA that the claims of the '677 Patent are invalid
13 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
14 VASCEPA® 500 mg product.

15 63. Defendants gave written notice of their certification of invalidity and/or non-
16 infringement of the '677 Patent, alleging that claims of the '677 Patent are invalid and/or that
17 certain claims would not be infringed by Defendants' generic VASCEPA® 500 mg product, and
18 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
19 use, and sale of a product bioequivalent to the 500 mg strength of VASCEPA® prior to the
20 expiration of the '677 Patent.

21 64. Defendants have infringed the '677 Patent under 35 U.S.C. § 271(e)(2)(A) by
22 virtue of submitting ANDA No. 209525 and Teva's ANDA Amendment with a paragraph IV
23 certification, and seeking FDA approval of ANDA No. 209525 to market a generic
24 VASCEPA® 500 mg product prior to the expiration of the '677 Patent. Moreover, if
25 Defendants commercially use, offer for sale, or sell their generic VASCEPA® 500 mg product,
26 or induce or contribute to such conduct, they would further infringe the '677 Patent under 35
27 U.S.C. § 271(a), (b), and/or (c).

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1 65. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
2 infringing or actively inducing or contributing to infringement of the '677 Patent. Plaintiffs do
3 not have an adequate remedy at law.

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

5 66. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 65
6 above.

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

12 68. Upon information and belief, Defendants submitted Teva's ANDA Amendment
13 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale
14 of a generic VASCEPA® 500 mg product before the expiration of the '652 Patent.

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

17 70. Upon information and belief, if approved, the generic VASCEPA® 500 mg
18 product for which approval is sought in Defendants' ANDA No. 209525 will be administered to
19 human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
20 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
21 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
22 '652 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
23 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
24 marketing, and distribution of their generic VASCEPA® 500 mg product as an adjunct to diet
25 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
26 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
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1 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs’
2 rights under the ‘652 Patent.

3 71. Defendants’ manufacture, use, offer for sale, or sale in the United States, or
4 importation into the United States, of the generic VASCEPA® 500 mg product for which
5 approval is sought in ANDA No. 209525 would actively induce and contribute to infringement
6 of the ‘652 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
7 and/or (c).

8 72. Upon information and belief, as part of the ANDA filing, Defendants
9 purportedly provided written certification to FDA that the claims of the ‘652 Patent are invalid
10 and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic
11 VASCEPA® 500 mg product.

12 73. Defendants gave written notice of their certification of invalidity and/or non-
13 infringement of the ‘652 Patent, alleging that claims of the ‘652 Patent are invalid and/or that
14 certain claims would not be infringed by Defendants’ generic VASCEPA® 500 mg product, and
15 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
16 use, and sale of a product bioequivalent to the 500 mg strength of VASCEPA® prior to the
17 expiration of the ‘652 Patent.

18 74. Defendants have infringed the ‘652 Patent under 35 U.S.C. § 271(e)(2)(A) by
19 virtue of submitting ANDA No. 209525 and Teva’s ANDA Amendment with a paragraph IV
20 certification, and seeking FDA approval of ANDA No. 209525 to market a generic
21 VASCEPA® 500 mg product prior to the expiration of the ‘652 Patent. Moreover, if
22 Defendants commercially use, offer for sale, or sell their generic VASCEPA® 500 mg product,
23 or induce or contribute to such conduct, they would further infringe the ‘652 Patent under 35
24 U.S.C. § 271(a), (b), and/or (c).

25 75. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
26 infringing or actively inducing or contributing to infringement of the ‘652 Patent. Plaintiffs do
27 not have an adequate remedy at law.
28

Count V: Patent Infringement of the '920 Patent

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2 76. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 75
3 above.

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

9 78. Upon information and belief, Defendants submitted Teva's ANDA Amendment
10 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale
11 of a generic VASCEPA® 500 mg product before the expiration of the '920 Patent.

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

14 80. Upon information and belief, if approved, the generic VASCEPA® 500 mg
15 product for which approval is sought in Defendants' ANDA No. 209525 will be administered to
16 human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
17 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
18 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
19 '920 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
20 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
21 marketing, and distribution of their generic VASCEPA® 500 mg product as an adjunct to diet
22 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
23 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
24 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs'
25 rights under the '920 Patent.

26 81. Defendants' manufacture, use, offer for sale, or sale in the United States, or
27 importation into the United States, of the generic VASCEPA® 500 mg product for which
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1 approval is sought in ANDA No. 209525 would actively induce and contribute to infringement
2 of the '920 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
3 and/or (c).

4 82. Upon information and belief, as part of the ANDA filing, Defendants
5 purportedly provided written certification to FDA that the claims of the '920 Patent are invalid
6 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
7 VASCEPA® 500 mg product.

8 83. Defendants gave written notice of their certification of invalidity and/or non-
9 infringement of the '920 Patent, alleging that claims of the '920 Patent are invalid and/or that
10 certain claims would not be infringed by Defendants' generic VASCEPA® 500 mg product, and
11 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
12 use, and sale of a product bioequivalent to the 500 mg strength of VASCEPA® prior to the
13 expiration of the '920 Patent.

14 84. Defendants have infringed the '920 Patent under 35 U.S.C. § 271(e)(2)(A) by
15 virtue of submitting ANDA No. 209525 and Teva's ANDA Amendment with a paragraph IV
16 certification, and seeking FDA approval of ANDA No. 209525 to market a generic
17 VASCEPA® 500 mg product prior to the expiration of the '920 Patent. Moreover, if
18 Defendants commercially use, offer for sale, or sell their generic VASCEPA® 500 mg product,
19 or induce or contribute to such conduct, they would further infringe the '920 Patent under 35
20 U.S.C. § 271(a), (b), and/or (c).

21 85. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
22 infringing or actively inducing or contributing to infringement of the '920 Patent. Plaintiffs do
23 not have an adequate remedy at law.

24 **Count VI: Patent Infringement of the '335 Patent**

25 86. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 85
26 above.

1 87. United States Patent No. 8,415,335, entitled “METHODS OF TREATING
2 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and
3 Trademark Office on April 9, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
4 owner of the ‘335 Patent. A true and complete copy of the ‘335 Patent is attached hereto as
5 Exhibit G.

6 88. Upon information and belief, Defendants submitted Teva’s ANDA Amendment
7 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale
8 of a generic VASCEPA® 500 mg product before the expiration of the ‘335 Patent.

9 89. Defendants’ manufacture, use, offer for sale, or sale of such product would
10 infringe the claims of the ‘335 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

11 90. Upon information and belief, if approved, the generic VASCEPA® 500 mg
12 product for which approval is sought in Defendants’ ANDA No. 209525 will be administered to
13 human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
14 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
15 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
16 ‘335 Patent. Upon information and belief, this infringement will occur at Defendants’ behest,
17 with their intent, knowledge, and encouragement as a result of, for example, Defendants’ sales,
18 marketing, and distribution of their generic VASCEPA® 500 mg product as an adjunct to diet
19 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
20 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
21 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs’
22 rights under the ‘335 Patent.

23 91. Defendants’ manufacture, use, offer for sale, or sale in the United States, or
24 importation into the United States, of the generic VASCEPA® 500 mg product for which
25 approval is sought in ANDA No. 209525 would actively induce and contribute to infringement
26 of the ‘335 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
27 and/or (c).

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1 92. Upon information and belief, as part of the ANDA filing, Defendants
2 purportedly provided written certification to FDA that the claims of the ‘335 Patent are invalid
3 and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic
4 VASCEPA® 500 mg product.

5 93. Defendants gave written notice of their certification of invalidity and/or non-
6 infringement of the ‘335 Patent, alleging that claims of the ‘335 Patent are invalid and/or that
7 certain claims would not be infringed by Defendants’ generic VASCEPA® 500 mg product, and
8 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
9 use, and sale of a product bioequivalent to the 500 mg strength of VASCEPA® prior to the
10 expiration of the ‘335 Patent.

11 94. Defendants have infringed the ‘335 Patent under 35 U.S.C. § 271(e)(2)(A) by
12 virtue of submitting ANDA No. 209525 and Teva’s ANDA Amendment with a paragraph IV
13 certification, and seeking FDA approval of ANDA No. 209525 to market a generic
14 VASCEPA® 500 mg product prior to the expiration of the ‘335 Patent. Moreover, if
15 Defendants commercially use, offer for sale, or sell their generic VASCEPA® 500 mg product,
16 or induce or contribute to such conduct, they would further infringe the ‘335 Patent under 35
17 U.S.C. § 271(a), (b), and/or (c).

18 95. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
19 infringing or actively inducing or contributing to infringement of the ‘335 Patent. Plaintiffs do
20 not have an adequate remedy at law.

21 **Count VII: Patent Infringement of the ‘399 Patent**

22 96. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 95
23 above.

24 97. United States Patent No. 8,426,399, entitled “METHODS OF TREATING
25 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and
26 Trademark Office on April 23, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
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1 owner of the '399 Patent. A true and complete copy of the '399 Patent along with the certificate
2 of correction is attached hereto as Exhibit H.

3 98. Upon information and belief, Defendants submitted Teva's ANDA Amendment
4 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale
5 of a generic VASCEPA® 500 mg product before the expiration of the '399 Patent.

6 99. Defendants' manufacture, use, offer for sale, or sale of such product would
7 infringe the claims of the '399 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

8 100. Upon information and belief, if approved, the generic VASCEPA® 500 mg
9 product for which approval is sought in Defendants' ANDA No. 209525 will be administered to
10 human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
11 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
12 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
13 '399 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
14 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
15 marketing, and distribution of their generic VASCEPA® 500 mg product as an adjunct to diet
16 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
17 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
18 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs'
19 rights under the '399 Patent.

20 101. Defendants' manufacture, use, offer for sale, or sale in the United States, or
21 importation into the United States, of the generic VASCEPA® 500 mg product for which
22 approval is sought in ANDA No. 209525 would actively induce and contribute to infringement
23 of the '399 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
24 and/or (c).

25 102. Upon information and belief, as part of the ANDA filing, Defendants
26 purportedly provided written certification to FDA that the claims of the '399 Patent are invalid
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1 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
2 VASCEPA® 500 mg product.

3 103. Defendants gave written notice of their certification of invalidity and/or non-
4 infringement of the '399 Patent, alleging that claims of the '399 Patent are invalid and/or that
5 certain claims would not be infringed by Defendants' generic VASCEPA® 500 mg product, and
6 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
7 use, and sale of a product bioequivalent to the 500 mg strength of VASCEPA® prior to the
8 expiration of the '399 Patent.

9 104. Defendants have infringed the '399 Patent under 35 U.S.C. § 271(e)(2)(A) by
10 virtue of submitting ANDA No. 209525 and Teva's ANDA Amendment with a paragraph IV
11 certification, and seeking FDA approval of ANDA No. 209525 to market a generic
12 VASCEPA® 500 mg product prior to the expiration of the '399 Patent. Moreover, if
13 Defendants commercially use, offer for sale, or sell their generic VASCEPA® 500 mg product,
14 or induce or contribute to such conduct, they would further infringe the '399 Patent under 35
15 U.S.C. § 271(a), (b), and/or (c).

16 105. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
17 infringing or actively inducing or contributing to infringement of the '399 Patent. Plaintiffs do
18 not have an adequate remedy at law.

19 **Count VIII: Patent Infringement of the '650 Patent**

20 106. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
21 105 above.

22 107. United States Patent No. 8,440,650, entitled "METHODS OF TREATING
23 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and
24 Trademark Office on May 14, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
25 owner of the '650 Patent. A true and complete copy of the '650 Patent is attached hereto as
26 Exhibit I.

1 108. Upon information and belief, Defendants submitted Teva's ANDA Amendment
2 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale
3 of a generic VASCEPA® 500 mg product before the expiration of the '650 Patent.

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

6 110. Upon information and belief, if approved, the generic VASCEPA® 500 mg
7 product for which approval is sought in Defendants' ANDA No. 209525 will be administered to
8 human 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 '650 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 generic VASCEPA® 500 mg product as an adjunct to diet
14 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
15 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
16 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs'
17 rights under the '650 Patent.

18 111. Defendants' manufacture, use, offer for sale, or sale in the United States, or
19 importation into the United States, of the generic VASCEPA® 500 mg product for which
20 approval is sought in ANDA No. 209525 would actively induce and contribute to infringement
21 of the '650 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
22 and/or (c).

23 112. Upon information and belief, as part of the ANDA filing, Defendants
24 purportedly provided written certification to FDA that the claims of the '650 Patent are invalid
25 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
26 VASCEPA® 500 mg product.

1 113. Defendants gave written notice of their certification of invalidity and/or non-
2 infringement of the '650 Patent, alleging that claims of the '650 Patent are invalid and/or that
3 certain claims would not be infringed by Defendants' generic VASCEPA® 500 mg product, and
4 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
5 use, and sale of a product bioequivalent to the 500 mg strength of VASCEPA® prior to the
6 expiration of the '650 Patent.

7 114. Defendants have infringed the '650 Patent under 35 U.S.C. § 271(e)(2)(A) by
8 virtue of submitting ANDA No. 209525 and Teva's ANDA Amendment with a paragraph IV
9 certification, and seeking FDA approval of ANDA No. 209525 to market a generic
10 VASCEPA® 500 mg product prior to the expiration of the '650 Patent. Moreover, if
11 Defendants commercially use, offer for sale, or sell their generic VASCEPA® 500 mg product,
12 or induce or contribute to such conduct, they would further infringe the '650 Patent under 35
13 U.S.C. § 271(a), (b), and/or (c).

14 115. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
15 infringing or actively inducing or contributing to infringement of the '650 Patent. Plaintiffs do
16 not have an adequate remedy at law.

17 **Count IX: Patent Infringement of the '929 Patent**

18 116. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
19 115 above.

20 117. United States Patent No. 8,518,929, entitled "METHODS OF TREATING
21 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and
22 Trademark Office on August 27, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
23 owner of the '929 Patent. A true and complete copy of the '929 Patent is attached hereto as
24 Exhibit J.

25 118. Upon information and belief, Defendants submitted Teva's ANDA Amendment
26 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale
27 of a generic VASCEPA® 500 mg product before the expiration of the '929 Patent.
28

1 119. Defendants' manufacture, use, offer for sale, or sale of such product would
2 infringe the claims of the '929 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

3 120. Upon information and belief, if approved, the generic VASCEPA® 500 mg
4 product for which approval is sought in Defendants' ANDA No. 209525 will be administered to
5 human 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 '929 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 generic VASCEPA® 500 mg product as an adjunct to diet
11 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
12 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
13 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs'
14 rights under the '929 Patent.

15 121. Defendants' manufacture, use, offer for sale, or sale in the United States, or
16 importation into the United States, of the generic VASCEPA® 500 mg product for which
17 approval is sought in ANDA No. 209525 would actively induce and contribute to infringement
18 of the '929 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
19 and/or (c).

20 122. Upon information and belief, as part of the ANDA filing, Defendants
21 purportedly provided written certification to FDA that the claims of the '929 Patent are invalid
22 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
23 VASCEPA® 500 mg product.

24 123. Defendants gave written notice of their certification of invalidity and/or non-
25 infringement of the '929 Patent, alleging that claims of the '929 Patent are invalid and/or that
26 certain claims would not be infringed by Defendants' generic VASCEPA® 500 mg product, and
27 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
28

1 use, and sale of a product bioequivalent to the 500 mg strength of VASCEPA® prior to the
2 expiration of the '929 Patent.

3 124. Defendants have infringed the '929 Patent under 35 U.S.C. § 271(e)(2)(A) by
4 virtue of submitting ANDA No. 209525 and Teva's ANDA Amendment with a paragraph IV
5 certification, and seeking FDA approval of ANDA No. 209525 to market a generic
6 VASCEPA® 500 mg product prior to the expiration of the '929 Patent. Moreover, if
7 Defendants commercially use, offer for sale, or sell their generic VASCEPA® 500 mg product,
8 or induce or contribute to such conduct, they would further infringe the '929 Patent under 35
9 U.S.C. § 271(a), (b), and/or (c).

10 125. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
11 infringing or actively inducing or contributing to infringement of the '929 Patent. Plaintiffs do
12 not have an adequate remedy at law.

13 **Count X: Patent Infringement of the '698 Patent**

14 126. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
15 125 above.

16 127. United States Patent No. 8,524,698, entitled "METHODS OF TREATING
17 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and
18 Trademark Office on September 3, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is
19 the owner of the '698 Patent. A true and complete copy of the '698 Patent along with the
20 certificate of correction is attached hereto as Exhibit K.

21 128. Upon information and belief, Defendants submitted Teva's ANDA Amendment
22 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale
23 of a generic VASCEPA® 500 mg product before the expiration of the '698 Patent.

24 129. Defendants' manufacture, use, offer for sale, or sale of such product would
25 infringe the claims of the '698 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

26 130. Upon information and belief, if approved, the generic VASCEPA® 500 mg
27 product for which approval is sought in Defendants' ANDA No. 209525 will be administered to
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1 human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
2 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
3 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
4 '698 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
5 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
6 marketing, and distribution of their generic VASCEPA® 500 mg product as an adjunct to diet
7 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
8 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
9 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs'
10 rights under the '698 Patent.

11 131. Defendants' manufacture, use, offer for sale, or sale in the United States, or
12 importation into the United States, of the generic VASCEPA® 500 mg product for which
13 approval is sought in ANDA No. 209525 would actively induce and contribute to infringement
14 of the '698 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
15 and/or (c).

16 132. Upon information and belief, as part of the ANDA filing, Defendants
17 purportedly provided written certification to FDA that the claims of the '698 Patent are invalid
18 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
19 VASCEPA® 500 mg product.

20 133. Defendants gave written notice of their certification of invalidity and/or non-
21 infringement of the '698 Patent, alleging that claims of the '698 Patent are invalid and/or that
22 certain claims would not be infringed by Defendants' generic VASCEPA® 500 mg product, and
23 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
24 use, and sale of a product bioequivalent to the 500 mg strength of VASCEPA® prior to the
25 expiration of the '698 Patent.

26 134. Defendants have infringed the '698 Patent under 35 U.S.C. § 271(e)(2)(A) by
27 virtue of submitting ANDA No. 209525 and Teva's ANDA Amendment with a paragraph IV
28

1 certification, and seeking FDA approval of ANDA No. 209525 to market a generic
2 VASCEPA® 500 mg product prior to the expiration of the ‘698 Patent. Moreover, if
3 Defendants commercially use, offer for sale, or sell their generic VASCEPA® 500 mg product,
4 or induce or contribute to such conduct, they would further infringe the ‘698 Patent under 35
5 U.S.C. § 271(a), (b), and/or (c).

6 135. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
7 infringing or actively inducing or contributing to infringement of the ‘698 Patent. Plaintiffs do
8 not have an adequate remedy at law.

9 **Count XI: Patent Infringement of the ‘372 Patent**

10 136. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
11 135 above.

12 137. United States Patent No. 8,546,372, entitled “METHODS OF TREATING
13 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and
14 Trademark Office on October 1, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
15 owner of the ‘372 Patent. A true and complete copy of the ‘372 Patent is attached hereto as
16 Exhibit L.

17 138. Upon information and belief, Defendants submitted Teva’s ANDA Amendment
18 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale
19 of a generic VASCEPA® 500 mg product before the expiration of the ‘372 Patent.

20 139. Defendants’ manufacture, use, offer for sale, or sale of such product would
21 infringe the claims of the ‘372 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

22 140. Upon information and belief, if approved, the generic VASCEPA® 500 mg
23 product for which approval is sought in Defendants’ ANDA No. 209525 will be administered to
24 human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
25 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
26 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
27 ‘372 Patent. Upon information and belief, this infringement will occur at Defendants’ behest,
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1 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
2 marketing, and distribution of their generic VASCEPA® 500 mg product as an adjunct to diet
3 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
4 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
5 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs'
6 rights under the '372 Patent.

7 141. Defendants' manufacture, use, offer for sale, or sale in the United States, or
8 importation into the United States, of the generic VASCEPA® 500 mg product for which
9 approval is sought in ANDA No. 209525 would actively induce and contribute to infringement
10 of the '372 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
11 and/or (c).

12 142. Upon information and belief, as part of the ANDA filing, Defendants
13 purportedly provided written certification to FDA that the claims of the '372 Patent are invalid
14 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
15 VASCEPA® 500 mg product.

16 143. Defendants gave written notice of their certification of invalidity and/or non-
17 infringement of the '372 Patent, alleging that claims of the '372 Patent are invalid and/or that
18 certain claims would not be infringed by Defendants' generic VASCEPA® 500 mg product, and
19 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
20 use, and sale of a product bioequivalent to the 500 mg strength of VASCEPA® prior to the
21 expiration of the '372 Patent.

22 144. Defendants have infringed the '372 Patent under 35 U.S.C. § 271(e)(2)(A) by
23 virtue of submitting ANDA No. 209525 and Teva's ANDA Amendment with a paragraph IV
24 certification, and seeking FDA approval of ANDA No. 209525 to market a generic
25 VASCEPA® 500 mg product prior to the expiration of the '372 Patent. Moreover, if
26 Defendants commercially use, offer for sale, or sell their generic VASCEPA® 500 mg product,
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1 or induce or contribute to such conduct, they would further infringe the '372 Patent under 35
2 U.S.C. § 271(a), (b), and/or (c).

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

6 **Count XII: Patent Infringement of the '594 Patent**

7 146. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
8 145 above.

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

14 148. Upon information and belief, Defendants submitted Teva's ANDA Amendment
15 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale
16 of a generic VASCEPA® 500 mg product before the expiration of the '594 Patent.

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

19 150. Upon information and belief, if approved, the generic VASCEPA® 500 mg
20 product for which approval is sought in Defendants' ANDA No. 209525 will be administered to
21 human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
22 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
23 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
24 '594 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
25 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
26 marketing, and distribution of their generic VASCEPA® 500 mg product as an adjunct to diet
27 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
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1 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
2 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs'
3 rights under the '594 Patent.

4 151. Defendants' manufacture, use, offer for sale, or sale in the United States, or
5 importation into the United States, of the generic VASCEPA® 500 mg product for which
6 approval is sought in ANDA No. 209525 would actively induce and contribute to infringement
7 of the '594 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
8 and/or (c).

9 152. Upon information and belief, as part of the ANDA filing, Defendants
10 purportedly provided written certification to FDA that the claims of the '594 Patent are invalid
11 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
12 VASCEPA® 500 mg product.

13 153. Defendants gave written notice of their certification of invalidity and/or non-
14 infringement of the '594 Patent, alleging that claims of the '594 Patent are invalid and/or that
15 certain claims would not be infringed by Defendants' generic VASCEPA® 500 mg product, and
16 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
17 use, and sale of a product bioequivalent to the 500 mg strength of VASCEPA® prior to the
18 expiration of the '594 Patent.

19 154. Defendants have infringed the '594 Patent under 35 U.S.C. § 271(e)(2)(A) by
20 virtue of submitting ANDA No. 209525 and Teva's ANDA Amendment with a paragraph IV
21 certification, and seeking FDA approval of ANDA No. 209525 to market a generic
22 VASCEPA® 500 mg product prior to the expiration of the '594 Patent. Moreover, if
23 Defendants commercially use, offer for sale, or sell their generic VASCEPA® 500 mg product,
24 or induce or contribute to such conduct, they would further infringe the '594 Patent under 35
25 U.S.C. § 271(a), (b), and/or (c).

1 155. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
2 infringing or actively inducing or contributing to infringement of the '594 Patent. Plaintiffs do
3 not have an adequate remedy at law.

4 **Prayer for Relief**

5 WHEREFORE, Plaintiffs seek the following relief:

6 A. A judgment that Defendants have infringed the '728, '715, '677, '652, '920, '335,
7 '399, '650, '929, '698, '372, and '594 Patents under 35 U.S.C. § 271(e)(2)(A);

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

13 C. A permanent injunction restraining and enjoining Defendants and their officers,
14 agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active
15 concert or participation with any of them, from making, using, selling, offering to sell, or
16 importing any product that infringes the '728, '715, '677, '652, '920, '335, '399, '650, '929, '698,
17 '372, and '594 Patents, including the product described in ANDA No. 209525;

18 D. A judgment declaring that making, using, selling, offering to sell, or importing the
19 product described in ANDA No. 209525, or inducing or contributing to such conduct, would
20 constitute infringement of the '728, '715, '677, '652, '920, '335, '399, '650, '929, '698, '372, and
21 '594 Patents by Defendants pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

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

24 F. Costs and expenses in this action; and
25
26
27
28

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

2 DATED: October 11, 2017

Respectfully submitted,

3
4 /s/ Nicholas J. Santoro

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

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