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23 *Amarin Pharmaceuticals Ireland Limited*

24 **UNITED STATES DISTRICT COURT**
25 **DISTRICT OF NEVADA**

26 AMARIN PHARMA, INC. and AMARIN
27 PHARMACEUTICALS IRELAND
28 LIMITED,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, INC. and
DR. REDDY'S LABORATORIES, LTD.,

Defendants.

Case No.: 2:18-cv-01596

**COMPLAINT FOR PATENT
INFRINGEMENT**

1 Plaintiffs Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited (collectively,
2 “Plaintiffs” or “Amarin”), by their attorneys, for their complaint against Dr. Reddy’s
3 Laboratories, Inc. and Dr. Reddy’s Laboratories, Ltd. (collectively, “Defendants” or “DRL”)
4 allege as follows:

5 **Nature of the Action**

6 1. This is a civil action for patent infringement arising under the patent laws of the
7 United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(a-c, e) for
8 infringement of U.S. Patent No. 8,293,728 (“the ‘728 Patent”), U.S. Patent No. 8,318,715 (“the
9 ‘715 Patent”), U.S. Patent No. 8,357,677 (“the ‘677 Patent”), U.S. Patent No. 8,367,652 (“the
10 ‘652 Patent”), U.S. Patent No. 8,377,920 (“the ‘920 Patent”), U.S. Patent No. 8,415,335 (“the
11 ‘335 Patent”), U.S. Patent No. 8,426,399 (“the ‘399 Patent”), U.S. Patent No. 8,440,650 (“the
12 ‘650 Patent”), U.S. Patent No. 8,518,929 (“the ‘929 Patent”), U.S. Patent No. 8,524,698 (“the
13 ‘698 Patent”), U.S. Patent No. 8,546,372 (“the ‘372 Patent”), and U.S. Patent No. 8,617,594
14 (“the ‘594 Patent”). This action relates to an Abbreviated New Drug Application (“ANDA”)
15 No. 209499 filed by or for the benefit of Defendants with the United States Food and Drug
16 Administration (“FDA”) for approval to market generic versions of Plaintiffs’ VASCEPA®
17 pharmaceutical products that are sold in the United States, including within this judicial district.

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 Dr. Reddy’s Laboratories, Inc. is a
24 company organized and existing under the laws of New Jersey with its principal place of
25 business at 107 College Road East, Princeton, New Jersey 08540.

26 5. Upon information and belief, Defendant Dr. Reddy’s Laboratories, Ltd. is a
27 public limited liability company organized and existing under the laws of India and having a
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1 principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Andhra Pradesh
2 500 034, India.

3 6. Upon information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a
4 wholly-owned subsidiary of Dr. Reddy's Laboratories, Ltd.

5 7. Upon information and belief, Defendants either directly or through one or more
6 of their wholly owned subsidiaries and/or agents, develop, manufacture, distribute, market, offer
7 to sell, and sell generic drug products for sale and use throughout the United States, including
8 within this judicial district.

9 8. Upon information and belief, Dr. Reddy's Laboratories, Inc., with the assistance
10 and/or at the direction of Dr. Reddy's Laboratories, Ltd., develops, manufactures, distributes,
11 markets, offers to sell, and sells generic drug products for sale and use throughout the United
12 States, including within this 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 '335 Patent, the '399 Patent, the '650 Patent,
17 the '929 Patent, the '698 Patent, the '372 Patent, and the '594 Patent.

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

20 11. On information and belief and as stated in a letter dated July 11, 2018 sent by
21 Defendants to Amarin (the "July Notice Letter"), Defendants prepared and filed patent
22 certifications with the FDA in support of ANDA No. 209499 with the intention of seeking to
23 market a generic version of the 500 mg strength of Amarin's VASCEPA® product ("generic
24 VASCEPA® 500 mg product"), including within this judicial district.

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

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

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

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

12 16. DRL’s outside counsel stated in an August 15, 2018 email to Plaintiffs’ counsel
13 that “DRL will not object to jurisdiction or venue in the District of Nevada regarding DRL’s
14 500 mg ANDA.” This civil suit concerns the 500 mg icosapent ethyl product that DRL seeks to
15 market.

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

20 18. Upon information and belief, by virtue of, *inter alia*, Defendants’ continuous and
21 systematic contacts with Nevada, including but not limited to the contacts described in
22 paragraphs 11–15, this Court has specific personal jurisdiction over Defendants. These activities
23 satisfy due process and confer personal jurisdiction over Defendants consistent with Nevada law.
24 *See, e.g., Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 762–63 (Fed. Cir. 2016)
25 (holding that minimum-contacts requirement for specific personal jurisdiction is established
26 where the defendant’s “ANDA filings and its distribution channels establish that [the defendant]
27 plans to market its proposed drugs in [the State where the complaint was filed] and the lawsuit is
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1 about patent constraints on such in-State marketing.”). In addition, as described in paragraph 16,
2 DRL does not object to the Court’s exercise of personal jurisdiction over DRL for the purpose
3 of this litigation.

4 19. On the basis of at least the facts alleged in paragraphs 11–18, venue is proper in
5 this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b). In addition, related actions in
6 which the patents asserted in this case are asserted against DRL and other defendants are
7 pending in this district. *Amarin Pharma Inc. v. Hikma Pharmaceuticals USA Inc.*, 2:16-cv-02525-
8 MMD-NJK (D. Nev. filed Oct. 31, 2016); *Amarin Pharma Inc. v. Dr. Reddy’s Laboratories, Inc.*, 2:16-
9 cv-02562-MMD-NJK (D. Nev. filed Nov. 4, 2016). Moreover, as described in paragraph 16,
10 DRL does not object to venue in this judicial district for the purpose of this litigation.

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

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

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

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

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

3 The Approved Drug Product

4 24. Amarin Pharmaceuticals Ireland Limited is the current holder of NDA No.
5 202057 for 1 g and 500 mg icosapent ethyl capsules. NDA No. 202057 was first approved by
6 the FDA on July 26, 2012 for the 1 g strength of icosapent ethyl capsules. A supplement to
7 NDA No. 202057 for the 500 mg strength of icosapent ethyl capsules was approved on
8 February 16, 2017. Amarin Pharma, Inc. is Amarin Pharmaceuticals Ireland Limited's agent in
9 the United States for purposes of communicating with the FDA regarding NDA No. 202057.
10 Amarin Pharmaceuticals Ireland Limited and Amarin Pharma, Inc. market both strengths of the
11 approved drug product under the tradename VASCEPA®.

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

16 26. FDA has listed the '728, '715, '677, '652, '920, '335, '399, '650, '929, '698, '372,
17 and '594 Patents in the Orange Book—formally known as Approved Drug Products With
18 Therapeutic Equivalence Evaluations—in connection with NDA No. 202057, including for the
19 500 mg strength of VASCEPA®.

20 27. Amarin Pharmaceuticals Ireland Limited is the owner of the '728, '715, '677, '652,
21 '920, '335, '399, '650, '929, '698, '372, and '594 Patents.

22 ANDA No. 209499

23 28. Upon information and belief, on or before September 22, 2016, Defendants,
24 through Dr. Reddy's Laboratories, Inc., submitted to the FDA ANDA No. 209499, for 1 g
25 icosapent ethyl capsules purportedly bioequivalent to VASCEPA®, along with a certification
26 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C.
27 § 355(j)(2)(A)(vii)(IV) (the "first paragraph IV certification").
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1 29. On November 4, 2016, Plaintiffs filed a complaint against Defendants in this
2 Court alleging that Defendants’ proposed generic 1 g icosapent ethyl capsules infringe Amarin
3 Pharmaceuticals Ireland Limited’s patents. *See* 2:16-cv-02562-MMD-NJK, ECF No. 1.

4 30. Upon information and belief, on or before July 11, 2018, Defendants, through Dr.
5 Reddy’s Laboratories, Inc., submitted to the FDA a second paragraph IV certification under
6 § 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), in support ANDA No.
7 209499, for 500 mg icosapent ethyl capsules purportedly bioequivalent to VASCEPA® (the
8 “second paragraph IV certification”).

9 31. Upon information and belief, the indication set forth in the proposed labeling
10 submitted in ANDA No. 209499, covering generic versions of the 1 g and 500 mg strengths of
11 VASCEPA®, is to reduce triglyceride levels in adult patients with severe hypertriglyceridemia,
12 *i.e.*, the same indication as that set forth in the approved labeling for VASCEPA®.

13 32. Upon information and belief, the July Notice Letter represented that Defendants
14 had submitted to the FDA a second paragraph IV certification in support of ANDA No.
15 209499 for the ‘728, ‘715, ‘677, ‘652, ‘920, ‘335, ‘399, ‘650, ‘929, ‘698, ‘372, and ‘594 Patents.

16 33. Upon information and belief, the purpose of ANDA No. 209499 and DRL’s
17 paragraph IV certifications is to obtain approval under section 505(j) of the FDCA to engage in
18 the commercial manufacture and sale of generic versions of both the 1 g and 500 mg strengths
19 of VASCEPA® before the expiration of the patents listed in the Orange Book for NDA No.
20 202057. Hence, Defendants’ purpose in submitting ANDA No. 209499 and the paragraph IV
21 certifications is to market products described therein before expiration of the ‘728, ‘715, ‘677,
22 ‘652, ‘920, ‘335, ‘399, ‘650, ‘929, ‘698, ‘372, and ‘594 Patents.

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

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

26 35. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 34
27 above.

1 36. United States Patent No. 8,293,728, entitled “METHODS OF TREATING
2 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and
3 Trademark Office on October 23, 2012. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
4 owner of the ‘728 Patent. A true and complete copy of the ‘728 Patent is attached hereto as
5 Exhibit B.

6 37. Upon information and belief, Defendants submitted ANDA No. 209499 and the
7 second paragraph IV certification to the FDA seeking approval to engage in the commercial
8 manufacture, use, offer for sale, and sale of a generic version of the 500 mg strength of
9 VASCEPA® before the expiration of the ‘728 Patent.

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

12 39. Upon information and belief, if approved, the generic VASCEPA® 500 mg
13 product for which approval is sought in Defendants’ ANDA No. 209499 will be administered to
14 human 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 ‘728 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 generic VASCEPA® 500 mg product as an adjunct to diet
20 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
21 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
22 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs’
23 rights under the ‘728 Patent.

24 40. Defendants’ manufacture, use, offer for sale, or sale in the United States, or
25 importation into the United States, of the generic VASCEPA® 500 mg product for which
26 approval is sought in ANDA No. 209499 would actively induce and contribute to infringement
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1 of the '728 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
2 and/or (c).

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

7 42. Defendants gave written notice of their certification of invalidity and/or non-
8 infringement of the '728 Patent, alleging that claims of the '728 Patent are invalid and/or that
9 certain claims would not be infringed by Defendants' generic VASCEPA® 500 mg product, and
10 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
11 use, and sale of a product bioequivalent to the 500 mg strength of VASCEPA® prior to the
12 expiration of the '728 Patent.

13 43. Defendants have infringed the '728 Patent under 35 U.S.C. § 271(e)(2)(A) by
14 virtue of submitting ANDA No. 209499 and the second paragraph IV certification, and seeking
15 FDA approval of ANDA No. 209499 to market a generic version of the 500 mg strength of
16 VASCEPA® prior to the expiration of the '728 Patent. Moreover, if Defendants commercially
17 use, offer for sale, or sell their generic VASCEPA® 500 mg product, or induce or contribute to
18 such conduct, they would further infringe the '728 Patent under 35 U.S.C. § 271(a), (b), and/or
19 (c).

20 44. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
21 infringing or actively inducing or contributing to infringement of the '728 Patent. Plaintiffs do
22 not have an adequate remedy at law.

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

24 45. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 44
25 above.

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

4 47. Upon information and belief, Defendants submitted ANDA No. 209499 and the
5 second paragraph IV certification to the FDA seeking approval to engage in the commercial
6 manufacture, use, offer for sale, and sale of a generic version of the 500 mg strength of
7 VASCEPA® before the expiration of the '715 Patent.

8 48. Defendants' manufacture, use, offer for sale, or sale of such product would
9 infringe the claims of the '715 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

10 49. Upon information and belief, if approved, the generic VASCEPA® 500 mg
11 product for which approval is sought in Defendants' ANDA No. 209499 will be administered to
12 human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
13 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
14 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
15 '715 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
16 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
17 marketing, and distribution of their generic VASCEPA® 500 mg product as an adjunct to diet
18 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
19 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
20 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs'
21 rights under the '715 Patent.

22 50. Defendants' manufacture, use, offer for sale, or sale in the United States, or
23 importation into the United States, of the generic VASCEPA® 500 mg product for which
24 approval is sought in ANDA No. 209499 would actively induce and contribute to infringement
25 of the '715 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
26 and/or (c).

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

5 52. 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 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 ‘715 Patent.

11 53. Defendants have infringed the ‘715 Patent under 35 U.S.C. § 271(e)(2)(A) by
12 virtue of submitting ANDA No. 209499 and the second paragraph IV certification, and seeking
13 FDA approval of ANDA No. 209499 to market a generic VASCEPA® 500 mg product prior to
14 the expiration of the ‘715 Patent. Moreover, if Defendants commercially use, offer for sale, or
15 sell their generic VASCEPA® 500 mg product, or induce or contribute to such conduct, they
16 would further infringe the ‘715 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

17 54. 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 55. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 54
22 above.

23 56. 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.

1 57. Upon information and belief, Defendants submitted ANDA No. 209499 and the
2 second paragraph IV certification to the FDA seeking approval to engage in the commercial
3 manufacture, use, offer for sale, and sale of a generic VASCEPA® 500 mg product before the
4 expiration of the ‘677 Patent.

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

7 59. Upon information and belief, if approved, the generic VASCEPA® 500 mg
8 product for which approval is sought in Defendants’ ANDA No. 209499 will be administered to
9 human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
10 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
11 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
12 ‘677 Patent. Upon information and belief, this infringement will occur at Defendants’ behest,
13 with their intent, knowledge, and encouragement as a result of, for example, Defendants’ sales,
14 marketing, and distribution of their generic VASCEPA® 500 mg product as an adjunct to diet
15 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
16 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
17 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs’
18 rights under the ‘677 Patent.

19 60. Defendants’ manufacture, use, offer for sale, or sale in the United States, or
20 importation into the United States, of the generic VASCEPA® 500 mg product for which
21 approval is sought in ANDA No. 209499 would actively induce and contribute to infringement
22 of the ‘677 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
23 and/or (c).

24 61. Upon information and belief, as part of the ANDA filing, Defendants
25 purportedly provided written certification to the FDA that the claims of the ‘677 Patent are
26 invalid and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic
27 VASCEPA® 500 mg product.

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1 62. Defendants gave written notice of their certification of invalidity and/or non-
2 infringement of the ‘677 Patent, alleging that claims of the ‘677 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 ‘677 Patent.

7 63. Defendants have infringed the ‘677 Patent under 35 U.S.C. § 271(e)(2)(A) by
8 virtue of submitting ANDA No. 209499 and the second paragraph IV certification, and seeking
9 FDA approval of ANDA No. 209499 to market a generic VASCEPA® 500 mg product prior to
10 the expiration of the ‘677 Patent. Moreover, if Defendants commercially use, offer for sale, or
11 sell their generic VASCEPA® 500 mg product, or induce or contribute to such conduct, they
12 would further infringe the ‘677 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

13 64. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
14 infringing or actively inducing or contributing to infringement of the ‘677 Patent. Plaintiffs do
15 not have an adequate remedy at law.

16 **Count IV: Patent Infringement of the ‘652 Patent**

17 65. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 64
18 above.

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

24 67. Upon information and belief, Defendants submitted ANDA No. 209499 and the
25 second paragraph IV certification to the FDA seeking approval to engage in the commercial
26 manufacture, use, offer for sale, and sale of a generic VASCEPA® 500 mg product before the
27 expiration of the ‘652 Patent.

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

3 69. Upon information and belief, if approved, the generic VASCEPA® 500 mg
4 product for which approval is sought in Defendants' ANDA No. 209499 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 '652 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 '652 Patent.

15 70. 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. 209499 would actively induce and contribute to infringement
18 of the '652 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
19 and/or (c).

20 71. Upon information and belief, as part of the ANDA filing, Defendants
21 purportedly provided written certification to the FDA that the claims of the '652 Patent are
22 invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
23 VASCEPA® 500 mg product.

24 72. Defendants gave written notice of their certification of invalidity and/or non-
25 infringement of the '652 Patent, alleging that claims of the '652 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,
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1 use, and sale of a product bioequivalent to the 500 mg strength of VASCEPA® prior to the
2 expiration of the ‘652 Patent.

3 73. Defendants have infringed the ‘652 Patent under 35 U.S.C. § 271(e)(2)(A) by
4 virtue of submitting ANDA No. 209499 and the second paragraph IV certification, and seeking
5 FDA approval of ANDA No. 209499 to market a generic VASCEPA® 500 mg product prior to
6 the expiration of the ‘652 Patent. Moreover, if Defendants commercially use, offer for sale, or
7 sell their generic VASCEPA® 500 mg product, or induce or contribute to such conduct, they
8 would further infringe the ‘652 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

9 74. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
10 infringing or actively inducing or contributing to infringement of the ‘652 Patent. Plaintiffs do
11 not have an adequate remedy at law.

12 **Count V: Patent Infringement of the ‘920 Patent**

13 75. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 74
14 above.

15 76. United States Patent No. 8,377,920, entitled “METHODS OF TREATING
16 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and
17 Trademark Office on February 19, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is
18 the owner of the ‘920 Patent. A true and complete copy of the ‘920 Patent is attached hereto as
19 Exhibit F.

20 77. Upon information and belief, Defendants submitted ANDA No. 209499 and the
21 second paragraph IV certification to the FDA seeking approval to engage in the commercial
22 manufacture, use, offer for sale, and sale of a generic VASCEPA® 500 mg product before the
23 expiration of the ‘920 Patent.

24 78. Defendants’ manufacture, use, offer for sale, or sale of such product would
25 infringe the claims of the ‘920 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

26 79. Upon information and belief, if approved, the generic VASCEPA® 500 mg
27 product for which approval is sought in Defendants’ ANDA No. 209499 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 '920 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 '920 Patent.

11 80. 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. 209499 would actively induce and contribute to infringement
14 of the '920 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
15 and/or (c).

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

20 82. Defendants gave written notice of their certification of invalidity and/or non-
21 infringement of the '920 Patent, alleging that claims of the '920 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 '920 Patent.

26 83. Defendants have infringed the '920 Patent under 35 U.S.C. § 271(e)(2)(A) by
27 virtue of submitting ANDA No. 209499 and the second paragraph IV certification, and seeking
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1 FDA approval of ANDA No. 209499 to market a generic VASCEPA® 500 mg product prior to
2 the expiration of the '920 Patent. Moreover, if Defendants commercially use, offer for sale, or
3 sell their generic VASCEPA® 500 mg product, or induce or contribute to such conduct, they
4 would further infringe the '920 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

5 84. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
6 infringing or actively inducing or contributing to infringement of the '920 Patent. Plaintiffs do
7 not have an adequate remedy at law.

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

9 85. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 84
10 above.

11 86. United States Patent No. 8,415,335, entitled "METHODS OF TREATING
12 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and
13 Trademark Office on April 9, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
14 owner of the '335 Patent. A true and complete copy of the '335 Patent is attached hereto as
15 Exhibit G.

16 87. Upon information and belief, Defendants submitted ANDA No. 209499 and the
17 second paragraph IV certification to the FDA seeking approval to engage in the commercial
18 manufacture, use, offer for sale, and sale of a generic VASCEPA® 500 mg product before the
19 expiration of the '335 Patent.

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

22 89. Upon information and belief, if approved, the generic VASCEPA® 500 mg
23 product for which approval is sought in Defendants' ANDA No. 209499 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 '335 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 '335 Patent.

7 90. 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. 209499 would actively induce and contribute to infringement
10 of the '335 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
11 and/or (c).

12 91. Upon information and belief, as part of the ANDA filing, Defendants
13 purportedly provided written certification to the FDA that the claims of the '335 Patent are
14 invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
15 VASCEPA® 500 mg product.

16 92. Defendants gave written notice of their certification of invalidity and/or non-
17 infringement of the '335 Patent, alleging that claims of the '335 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 '335 Patent.

22 93. Defendants have infringed the '335 Patent under 35 U.S.C. § 271(e)(2)(A) by
23 virtue of submitting ANDA No. 209499 and the second paragraph IV certification, and seeking
24 FDA approval of ANDA No. 209499 to market a generic VASCEPA® 500 mg product prior to
25 the expiration of the '335 Patent. Moreover, if Defendants commercially use, offer for sale, or
26 sell their generic VASCEPA® 500 mg product, or induce or contribute to such conduct, they
27 would further infringe the '335 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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1 94. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
2 infringing or actively inducing or contributing to infringement of the '335 Patent. Plaintiffs do
3 not have an adequate remedy at law.

4 **Count VII: Patent Infringement of the '399 Patent**

5 95. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 94
6 above.

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

12 97. Upon information and belief, Defendants submitted ANDA No. 209499 and the
13 second paragraph IV certification to the FDA seeking approval to engage in the commercial
14 manufacture, use, offer for sale, and sale of a generic VASCEPA® 500 mg product before the
15 expiration of the '399 Patent.

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

18 99. Upon information and belief, if approved, the generic VASCEPA® 500 mg
19 product for which approval is sought in Defendants' ANDA No. 209499 will be administered to
20 human 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 '399 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 generic VASCEPA® 500 mg product as an adjunct to diet
26 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
27 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 ‘399 Patent.

3 100. 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. 209499 would actively induce and contribute to infringement
6 of the ‘399 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
7 and/or (c).

8 101. Upon information and belief, as part of the ANDA filing, Defendants
9 purportedly provided written certification to the FDA that the claims of the ‘399 Patent are
10 invalid and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic
11 VASCEPA® 500 mg product.

12 102. Defendants gave written notice of their certification of invalidity and/or non-
13 infringement of the ‘399 Patent, alleging that claims of the ‘399 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 ‘399 Patent.

18 103. Defendants have infringed the ‘399 Patent under 35 U.S.C. § 271(e)(2)(A) by
19 virtue of submitting ANDA No. 209499 and the second paragraph IV certification, and seeking
20 FDA approval of ANDA No. 209499 to market a generic VASCEPA® 500 mg product prior to
21 the expiration of the ‘399 Patent. Moreover, if Defendants commercially use, offer for sale, or
22 sell their generic VASCEPA® 500 mg product, or induce or contribute to such conduct, they
23 would further infringe the ‘399 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

24 104. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
25 infringing or actively inducing or contributing to infringement of the ‘399 Patent. Plaintiffs do
26 not have an adequate remedy at law.

Count VIII: Patent Infringement of the '650 Patent

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2 105. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
3 104 above.

4 106. United States Patent No. 8,440,650, entitled “METHODS OF TREATING
5 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and
6 Trademark Office on May 14, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
7 owner of the ‘650 Patent. A true and complete copy of the ‘650 Patent is attached hereto as
8 Exhibit I.

9 107. Upon information and belief, Defendants submitted ANDA No. 209499 and the
10 second paragraph IV certification to the FDA seeking approval to engage in the commercial
11 manufacture, use, offer for sale, and sale of a generic VASCEPA® 500 mg product before the
12 expiration of the ‘650 Patent.

13 108. Defendants’ manufacture, use, offer for sale, or sale of such product would
14 infringe the claims of the ‘650 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

15 109. Upon information and belief, if approved, the generic VASCEPA® 500 mg
16 product for which approval is sought in Defendants’ ANDA No. 209499 will be administered to
17 human 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 ‘650 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 generic VASCEPA® 500 mg product as an adjunct to diet
23 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
24 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
25 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs’
26 rights under the ‘650 Patent.

1 110. Defendants' manufacture, use, offer for sale, or sale in the United States, or
2 importation into the United States, of the generic VASCEPA® 500 mg product for which
3 approval is sought in ANDA No. 209499 would actively induce and contribute to infringement
4 of the '650 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
5 and/or (c).

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

10 112. Defendants gave written notice of their certification of invalidity and/or non-
11 infringement of the '650 Patent, alleging that claims of the '650 Patent are invalid and/or that
12 certain claims would not be infringed by Defendants' generic VASCEPA® 500 mg product, and
13 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
14 use, and sale of a product bioequivalent to the 500 mg strength of VASCEPA® prior to the
15 expiration of the '650 Patent.

16 113. Defendants have infringed the '650 Patent under 35 U.S.C. § 271(e)(2)(A) by
17 virtue of submitting ANDA No. 209499 and the second paragraph IV certification, and seeking
18 FDA approval of ANDA No. 209499 to market a generic VASCEPA® 500 mg product prior to
19 the expiration of the '650 Patent. Moreover, if Defendants commercially use, offer for sale, or
20 sell their generic VASCEPA® 500 mg product, or induce or contribute to such conduct, they
21 would further infringe the '650 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

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

26 115. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
27 114 above.

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

6 117. Upon information and belief, Defendants submitted ANDA No. 209499 and the
7 second paragraph IV certification to the FDA seeking approval to engage in the commercial
8 manufacture, use, offer for sale, and sale of a generic VASCEPA® 500 mg product before the
9 expiration of the ‘929 Patent.

10 118. 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).

12 119. Upon information and belief, if approved, the generic VASCEPA® 500 mg
13 product for which approval is sought in Defendants’ ANDA No. 209499 will be administered to
14 human 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 generic VASCEPA® 500 mg product as an adjunct to diet
20 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
21 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
22 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs’
23 rights under the ‘929 Patent.

24 120. Defendants’ manufacture, use, offer for sale, or sale in the United States, or
25 importation into the United States, of the generic VASCEPA® 500 mg product for which
26 approval is sought in ANDA No. 209499 would actively induce and contribute to infringement
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1 of the '929 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
2 and/or (c).

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

7 122. Defendants gave written notice of their certification of invalidity and/or non-
8 infringement of the '929 Patent, alleging that claims of the '929 Patent are invalid and/or that
9 certain claims would not be infringed by Defendants' generic VASCEPA® 500 mg product, and
10 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
11 use, and sale of a product bioequivalent to the 500 mg strength of VASCEPA® prior to the
12 expiration of the '929 Patent.

13 123. Defendants have infringed the '929 Patent under 35 U.S.C. § 271(e)(2)(A) by
14 virtue of submitting ANDA No. 209499 and the second paragraph IV certification, and seeking
15 FDA approval of ANDA No. 209499 to market a generic VASCEPA® 500 mg product prior to
16 the expiration of the '929 Patent. Moreover, if Defendants commercially use, offer for sale, or
17 sell their generic VASCEPA® 500 mg product, or induce or contribute to such conduct, they
18 would further infringe the '929 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

19 124. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
20 infringing or actively inducing or contributing to infringement of the '929 Patent. Plaintiffs do
21 not have an adequate remedy at law.

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

23 125. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
24 124 above.

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

3 127. Upon information and belief, Defendants submitted ANDA No. 209499 and the
4 second paragraph IV certification to the FDA seeking approval to engage in the commercial
5 manufacture, use, offer for sale, and sale of a generic VASCEPA® 500 mg product before the
6 expiration of the '698 Patent.

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

9 129. Upon information and belief, if approved, the generic VASCEPA® 500 mg
10 product for which approval is sought in Defendants' ANDA No. 209499 will be administered to
11 human 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 '698 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 generic VASCEPA® 500 mg product as an adjunct to diet
17 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
18 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
19 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs'
20 rights under the '698 Patent.

21 130. Defendants' manufacture, use, offer for sale, or sale in the United States, or
22 importation into the United States, of the generic VASCEPA® 500 mg product for which
23 approval is sought in ANDA No. 209499 would actively induce and contribute to infringement
24 of the '698 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
25 and/or (c).

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

3 132. Defendants gave written notice of their certification of invalidity and/or non-
4 infringement of the '698 Patent, alleging that claims of the '698 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 '698 Patent.

9 133. Defendants have infringed the '698 Patent under 35 U.S.C. § 271(e)(2)(A) by
10 virtue of submitting ANDA No. 209499 and the second paragraph IV certification, and seeking
11 FDA approval of ANDA No. 209499 to market a generic VASCEPA® 500 mg product prior to
12 the expiration of the '698 Patent. Moreover, if Defendants commercially use, offer for sale, or
13 sell their generic VASCEPA® 500 mg product, or induce or contribute to such conduct, they
14 would further infringe the '698 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

15 134. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
16 infringing or actively inducing or contributing to infringement of the '698 Patent. Plaintiffs do
17 not have an adequate remedy at law.

18 **Count XI: Patent Infringement of the '372 Patent**

19 135. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
20 134 above.

21 136. United States Patent No. 8,546,372, entitled "METHODS OF TREATING
22 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and
23 Trademark Office on October 1, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
24 owner of the '372 Patent. A true and complete copy of the '372 Patent is attached hereto as
25 Exhibit L.

26 137. Upon information and belief, Defendants submitted ANDA No. 209499 and the
27 second paragraph IV certification to the FDA seeking approval to engage in the commercial
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1 manufacture, use, offer for sale, and sale of a generic VASCEPA® 500 mg product before the
2 expiration of the '372 Patent.

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

5 139. Upon information and belief, if approved, the generic VASCEPA® 500 mg
6 product for which approval is sought in Defendants' ANDA No. 209499 will be administered to
7 human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
8 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
9 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
10 '372 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
11 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
12 marketing, and distribution of their generic VASCEPA® 500 mg product as an adjunct to diet
13 to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
14 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
15 the generic VASCEPA® 500 mg product with knowledge that it is in contravention of Plaintiffs'
16 rights under the '372 Patent.

17 140. Defendants' manufacture, use, offer for sale, or sale in the United States, or
18 importation into the United States, of the generic VASCEPA® 500 mg product for which
19 approval is sought in ANDA No. 209499 would actively induce and contribute to infringement
20 of the '372 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
21 and/or (c).

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

26 142. Defendants gave written notice of their certification of invalidity and/or non-
27 infringement of the '372 Patent, alleging that claims of the '372 Patent are invalid and/or that
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1 certain claims would not be infringed by Defendants' generic VASCEPA® 500 mg product, and
2 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
3 use, and sale of a product bioequivalent to the 500 mg strength of VASCEPA® prior to the
4 expiration of the '372 Patent.

5 143. Defendants have infringed the '372 Patent under 35 U.S.C. § 271(e)(2)(A) by
6 virtue of submitting ANDA No. 209499 and the second paragraph IV certification, and seeking
7 FDA approval of ANDA No. 209499 to market a generic VASCEPA® 500 mg product prior to
8 the expiration of the '372 Patent. Moreover, if Defendants commercially use, offer for sale, or
9 sell their generic VASCEPA® 500 mg product, or induce or contribute to such conduct, they
10 would further infringe the '372 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

11 144. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
12 infringing or actively inducing or contributing to infringement of the '372 Patent. Plaintiffs do
13 not have an adequate remedy at law.

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

15 145. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
16 144 above.

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

22 147. Upon information and belief, Defendants submitted ANDA No. 209499 and the
23 second paragraph IV certification to the FDA seeking approval to engage in the commercial
24 manufacture, use, offer for sale, and sale of a generic VASCEPA® 500 mg product before the
25 expiration of the '594 Patent.

26 148. Defendants' manufacture, use, offer for sale, or sale of such product would
27 infringe the claims of the '594 Patent under 35 U.S.C. § 271(a), (b), and/or (c).
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1 149. Upon information and belief, if approved, the generic VASCEPA® 500 mg
2 product for which approval is sought in Defendants' ANDA No. 209499 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 '594 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 '594 Patent.

13 150. 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. 209499 would actively induce and contribute to infringement
16 of the '594 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b)
17 and/or (c).

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

22 152. Defendants gave written notice of their certification of invalidity and/or non-
23 infringement of the '594 Patent, alleging that claims of the '594 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 '594 Patent.

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

3 F. Costs and expenses in this action; and

4 G. Such further and other relief as this Court determines to be just and proper.
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6 DATED: August 24, 2018

Respectfully submitted,

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8 /s/ Jason D. Smith

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