

1 Nicholas J. Santoro (Nev. Bar No. 532)
2 SANTORO WHITMIRE, LTD.
3 10100 W. Charleston Blvd., Suite 250
4 Las Vegas, Nevada 89135
5 Telephone: (702) 948-8771
6 Facsimile: (702) 948-8773
7 E-mail: nsantoro@santoronevada.com

8 Christopher N. Sipes (*pro hac vice* forthcoming)
9 Einar Stole (*pro hac vice* forthcoming)
10 Michael N. Kennedy (*pro hac vice* forthcoming)
11 Megan P. Keane (*pro hac vice* forthcoming)
12 COVINGTON & BURLING LLP
13 One CityCenter, 850 Tenth Street, NW
14 Washington, DC 20001
15 Telephone: (202) 662-6000
16 Facsimile: (202) 662-6291
17 E-mail: csipes@cov.com, estole@cov.com,
18 mkennedy@cov.com, mkeane@cov.com

19 *Attorneys for Plaintiffs Amarin Pharma, Inc. and*
20 *Amarin Pharmaceuticals Ireland Limited*

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

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

26 Plaintiffs,

27 v.

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

30 Defendants.

Case No.: 2:16-cv-2562

**COMPLAINT FOR PATENT
INFRINGEMENT**

31 Plaintiffs Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited (collectively,
32 "Plaintiffs" or "Amarin"), by their attorneys, for their complaint against Dr. Reddy's

1 Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "Defendants" or "DRL")
2 allege as follows:

3 **Nature of the Action**

4 1. This is a civil action for patent infringement arising under the patent laws of the
5 United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(a-c, e) for
6 infringement of U.S. Patent No. 8,293,728 ("the '728 Patent"), U.S. Patent No. 8,318,715 ("the
7 '715 Patent"), U.S. Patent No. 8,357,677 ("the '677 Patent"), U.S. Patent No. 8,367,652 ("the
8 '652 Patent"), U.S. Patent No. 8,377,920 ("the '920 Patent"), U.S. Patent No. 8,399,446 ("the
9 '446 Patent"), U.S. Patent No. 8,415,335 ("the '335 Patent"), U.S. Patent No. 8,426,399 ("the
10 '399 Patent"), U.S. Patent No. 8,431,560 ("the '560 Patent"), U.S. Patent No. 8,440,650 ("the
11 '650 Patent"), U.S. Patent No. 8,518,929 ("the '929 Patent"), U.S. Patent No. 8,524,698 ("the
12 '698 Patent"), U.S. Patent No. 8,546,372 ("the '372 Patent"), and U.S. Patent No. 8,617,594
13 ("the '594 Patent"). This action relates to an Abbreviated New Drug Application ("ANDA") No.
14 209499 filed by or for the benefit of Defendants with the United States Food and Drug
15 Administration ("FDA") for approval to market generic versions of Plaintiffs' VASCEPA®
16 pharmaceutical products that are sold in the United States, including within this judicial district.
17 This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331
18 and 1338(a).

19 **The Parties**

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

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

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

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

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

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

10 8. Upon information and belief, Dr. Reddy's Laboratories, Inc., with the assistance
11 and/or at the direction of Dr. Reddy's Laboratories, Ltd., develops, manufactures, distributes,
12 markets, offers to sell, and sells generic drug products for sale and use throughout the United
13 States, including within this 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 '446 Patent, the '335 Patent, the '399 Patent,
18 the '560 Patent, the '650 Patent, the '929 Patent, the '698 Patent, the '372 Patent, and the '594
19 Patent.

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

22 11. On information and belief and as stated in the ANDA Notice Letter, DRL
23 prepared and filed ANDA No. 209499, through Dr. Reddy's Laboratories, Inc., with the
24 intention of seeking to market a generic version of Amarin's VASCEPA® product, including
25 within this judicial district.

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

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

4 14. Upon information and belief, DRL receives Medicaid reimbursements for drugs
5 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, DRL plans to sell a generic VASCEPA® product
8 in Nevada, list a generic VASCEPA® product on Nevada’s prescription drug formulary, and
9 seek Medicaid reimbursements for sales of a generic VASCEPA® product in Nevada, either
10 directly or through one or more of their wholly owned subsidiaries and/or agents.

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

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

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

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

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

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

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

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

19 **The Approved Drug Product**

20 23. Amarin Pharmaceuticals Ireland Limited is the current holder of NDA No.
21 202057, for 1g icosapent ethyl capsules, which was first approved by FDA on July 26, 2012.
22 Amarin Pharma, Inc. is Amarin Pharmaceuticals Ireland Limited’s agent in the United States for
23 purposes of communicating with FDA regarding NDA No. 202057. Amarin Pharmaceuticals
24 Ireland Limited and Amarin Pharma, Inc. market the approved drug product under the
25 tradename VASCEPA®.

1 24. VASCEPA® is indicated as an adjunct to diet to reduce triglyceride levels in adult
2 patients with severe hypertriglyceridemia. A true, correct, and complete copy of the Prescribing
3 Information for VASCEPA® approved in NDA No. 202057 is attached as Exhibit A.

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

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

9 **ANDA No. 209499**

10 27. Upon information and belief, on or before September 22, 2016, Defendants,
11 through Dr. Reddy’s Laboratories, Inc., submitted to FDA an ANDA (ANDA No. 209499)
12 with paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug,
13 and Cosmetic Act (“FDCA”), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for 1g icosapent ethyl capsules
14 purportedly bioequivalent to VASCEPA®. The purpose of the ANDA is to obtain approval
15 under section 505(j) of the FDCA to engage in the commercial manufacture and sale of a
16 generic VASCEPA® product.

17 28. Upon information and belief, the indication set forth in the proposed labeling
18 submitted in ANDA No. 209499 for the generic VASCEPA® product is to reduce triglyceride
19 levels in adult patients with severe hypertriglyceridemia, *i.e.*, the same indication as that set forth
20 in the approved labeling for VASCEPA®.

21 29. Upon information and belief, Defendants sent Amarin a letter dated September
22 22, 2016 (the “Notice Letter”). The Notice Letter represented that Defendants had submitted to
23 FDA an ANDA, No. 209499, with a paragraph IV certification for the ‘728, ‘715, ‘677, ‘652,
24 ‘920, ‘446, ‘335, ‘399, ‘560, ‘650, ‘929, ‘698, ‘372, and ‘594 Patents.

25 30. Upon information and belief, the purpose of the ANDA and paragraph IV
26 certifications is to obtain approval under section 505(j) of the FDCA to engage in the
27 commercial manufacture and sale of a generic version of VASCEPA® before the expiration of
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1 the patents listed in the Orange Book for NDA No. 202057. Hence, Defendants' purpose in
2 submitting ANDA No. 209499 is to market products described therein before expiration of the
3 '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 Patents.

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

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

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

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

14 34. Upon information and belief, Defendants submitted ANDA No. 209499 to FDA
15 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
16 generic version of VASCEPA® before the expiration of the '728 Patent.

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

19 36. Upon information and belief, if approved, the generic VASCEPA® product for
20 which approval is sought in Defendants' ANDA No. 209499 will be administered to human
21 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 '728 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 ANDA Product as an adjunct to diet to reduce triglyceride
27 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
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1 Defendants will actively induce, encourage, aid, and abet administration of the generic
2 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
3 '728 Patent.

4 37. Defendants' manufacture, use, offer for sale, or sale in the United States, or
5 importation into the United States, of the generic VASCEPA® product for which approval is
6 sought in ANDA No. 209499 would actively induce and contribute to infringement of the '728
7 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

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

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

18 40. Defendants have infringed the '728 Patent under 35 U.S.C. § 271(e)(2)(A) by
19 virtue of submitting ANDA No. 209499 with a paragraph IV certification and seeking FDA
20 approval of ANDA No. 209499 to market a generic version of VASCEPA® prior to the
21 expiration of the '728 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
22 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
23 further infringe the '728 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

Count II: Patent Infringement of the '715 Patent

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

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

9 44. Upon information and belief, Defendants submitted ANDA No. 209499 to FDA
10 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
11 generic version of VASCEPA® before the expiration of the '715 Patent.

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

14 46. Upon information and belief, if approved, the generic VASCEPA® product for
15 which approval is sought in Defendants' ANDA No. 209499 will be administered to human
16 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 '715 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 ANDA Product as an adjunct to diet to reduce triglyceride
22 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
23 Defendants will actively induce, encourage, aid, and abet administration of the generic
24 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
25 '715 Patent.

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

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

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

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

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

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

23 52. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 51
24 above.

25 53. United States Patent No. 8,357,677, entitled “METHODS OF TREATING
26 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and
27 Trademark Office on January 22, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
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1 owner of the '677 Patent. A true and complete copy of the '677 Patent is attached hereto as
2 Exhibit D.

3 54. Upon information and belief, Defendants submitted ANDA No. 209499 to FDA
4 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
5 generic version of VASCEPA® before the expiration of the '677 Patent.

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

8 56. Upon information and belief, if approved, the generic VASCEPA® product for
9 which approval is sought in Defendants' ANDA No. 209499 will be administered to human
10 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 '677 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 ANDA Product as an adjunct to diet to reduce triglyceride
16 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
17 Defendants will actively induce, encourage, aid, and abet administration of the generic
18 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
19 '677 Patent.

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

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

1 59. 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 version of VASCEPA®, and
4 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
5 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the ‘677
6 Patent.

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

13 61. 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 62. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 61
18 above.

19 63. 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 64. Upon information and belief, Defendants submitted ANDA No. 209499 to FDA
25 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
26 generic version of VASCEPA® before the expiration of the ‘652 Patent.

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

2 66. Upon information and belief, if approved, the generic VASCEPA® product for
3 which approval is sought in Defendants' ANDA No. 209499 will be administered to human
4 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
5 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
6 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
7 '652 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
8 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
9 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
10 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
11 Defendants will actively induce, encourage, aid, and abet administration of the generic
12 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
13 '652 Patent.

14 67. Defendants' manufacture, use, offer for sale, or sale in the United States, or
15 importation into the United States, of the generic VASCEPA® product for which approval is
16 sought in ANDA No. 209499 would actively induce and contribute to infringement of the '652
17 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

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

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

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

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

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

11 72. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 71
12 above.

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

18 74. Upon information and belief, Defendants submitted ANDA No. 209499 to FDA
19 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
20 generic version of VASCEPA® before the expiration of the '920 Patent.

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

23 76. Upon information and belief, if approved, the generic VASCEPA® product for
24 which approval is sought in Defendants' ANDA No. 209499 will be administered to human
25 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
26 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
27 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
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1 '920 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
2 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
3 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
4 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
5 Defendants will actively induce, encourage, aid, and abet administration of the generic
6 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
7 '920 Patent.

8 77. Defendants' manufacture, use, offer for sale, or sale in the United States, or
9 importation into the United States, of the generic VASCEPA® product for which approval is
10 sought in ANDA No. 209499 would actively induce and contribute to infringement of the '920
11 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

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

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

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

1 81. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
2 infringing or actively inducing or contributing to infringement of the '920 Patent. Plaintiffs do
3 not have an adequate remedy at law.

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

5 82. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 81
6 above.

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

12 84. Upon information and belief, Defendants submitted ANDA No. 209499 to FDA
13 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
14 generic version of VASCEPA® before the expiration of the '446 Patent.

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

17 86. Upon information and belief, if approved, the generic VASCEPA® product for
18 which approval is sought in Defendants' ANDA No. 209499 will be administered to human
19 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 '446 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 ANDA Product as an adjunct to diet to reduce triglyceride
25 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
26 Defendants will actively induce, encourage, aid, and abet administration of the generic
27 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
28

1 '446 Patent.

2 87. Defendants' manufacture, use, offer for sale, or sale in the United States, or
3 importation into the United States, of the generic VASCEPA® product for which approval is
4 sought in ANDA No. 209499 would actively induce and contribute to infringement of the '446
5 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

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

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

16 90. Defendants have infringed the '446 Patent under 35 U.S.C. § 271(e)(2)(A) by
17 virtue of submitting ANDA No. 209499 with a paragraph IV certification and seeking FDA
18 approval of ANDA No. 209499 to market a generic version of VASCEPA® prior to the
19 expiration of the '446 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
20 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
21 further infringe the '446 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

25 **Count VII: Patent Infringement of the '335 Patent**

26 92. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 91
27 above.

1 93. 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 H.

6 94. Upon information and belief, Defendants submitted ANDA No. 209499 to FDA
7 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
8 generic version of VASCEPA® before the expiration of the ‘335 Patent.

9 95. 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 96. Upon information and belief, if approved, the generic VASCEPA® product for
12 which approval is sought in Defendants’ ANDA No. 209499 will be administered to human
13 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 ANDA Product as an adjunct to diet to reduce triglyceride
19 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
20 Defendants will actively induce, encourage, aid, and abet administration of the generic
21 VASCEPA® product with knowledge that it is in contravention of Plaintiffs’ rights under the
22 ‘335 Patent.

23 97. Defendants’ manufacture, use, offer for sale, or sale in the United States, or
24 importation into the United States, of the generic VASCEPA® product for which approval is
25 sought in ANDA No. 209499 would actively induce and contribute to infringement of the ‘335
26 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

27 98. Upon information and belief, as part of the ANDA filing, Defendants
28

1 purportedly provided written certification to FDA that the claims of the '335 Patent are invalid
2 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of
3 VASCEPA®.

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

10 100. Defendants have infringed the '335 Patent under 35 U.S.C. § 271(e)(2)(A) by
11 virtue of submitting ANDA No. 209499 with a paragraph IV certification and seeking FDA
12 approval of ANDA No. 209499 to market a generic version of VASCEPA® prior to the
13 expiration of the '335 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
14 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
15 further infringe the '335 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

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

20 102. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
21 101 above.

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

27 104. Upon information and belief, Defendants submitted ANDA No. 209499 to FDA
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1 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
2 generic version of VASCEPA® before the expiration of the '399 Patent.

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

5 106. Upon information and belief, if approved, the generic VASCEPA® product for
6 which approval is sought in Defendants' ANDA No. 209499 will be administered to human
7 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 '399 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 ANDA Product as an adjunct to diet to reduce triglyceride
13 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
14 Defendants will actively induce, encourage, aid, and abet administration of the generic
15 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
16 '399 Patent.

17 107. Defendants' manufacture, use, offer for sale, or sale in the United States, or
18 importation into the United States, of the generic VASCEPA® product for which approval is
19 sought in ANDA No. 209499 would actively induce and contribute to infringement of the '399
20 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

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

25 109. Defendants gave written notice of their certification of invalidity and/or non-
26 infringement of the '399 Patent, alleging that claims of the '399 Patent are invalid and/or that
27 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and
28

1 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
2 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the ‘399
3 Patent.

4 110. Defendants have infringed the ‘399 Patent under 35 U.S.C. § 271(e)(2)(A) by
5 virtue of submitting ANDA No. 209499 with a paragraph IV certification and seeking FDA
6 approval of ANDA No. 209499 to market a generic version of VASCEPA® prior to the
7 expiration of the ‘399 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
8 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
9 further infringe the ‘399 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

13 **Count IX: Patent Infringement of the ‘560 Patent**

14 112. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
15 111 above.

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

21 114. Upon information and belief, Defendants submitted ANDA No. 209499 to FDA
22 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
23 generic version of VASCEPA® before the expiration of the ‘560 Patent.

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

26 116. Upon information and belief, if approved, the generic VASCEPA® product for
27 which approval is sought in Defendants’ ANDA No. 209499 will be administered to human
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1 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 '560 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 ANDA Product as an adjunct to diet to reduce triglyceride
7 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
8 Defendants will actively induce, encourage, aid, and abet administration of the generic
9 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
10 '560 Patent.

11 117. Defendants' manufacture, use, offer for sale, or sale in the United States, or
12 importation into the United States, of the generic VASCEPA® product for which approval is
13 sought in ANDA No. 209499 would actively induce and contribute to infringement of the '560
14 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

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

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

25 120. Defendants have infringed the '560 Patent under 35 U.S.C. § 271(e)(2)(A) by
26 virtue of submitting ANDA No. 209499 with a paragraph IV certification and seeking FDA
27 approval of ANDA No. 209499 to market a generic version of VASCEPA® prior to the
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1 expiration of the '560 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
2 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
3 further infringe the '560 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

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

8 122. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
9 121 above.

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

15 124. Upon information and belief, Defendants submitted ANDA No. 209499 to FDA
16 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
17 generic version of VASCEPA® before the expiration of the '650 Patent.

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

20 126. Upon information and belief, if approved, the generic VASCEPA® product for
21 which approval is sought in Defendants' ANDA No. 209499 will be administered to human
22 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
23 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
24 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
25 '650 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
26 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
27 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
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1 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
2 Defendants will actively induce, encourage, aid, and abet administration of the generic
3 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
4 '650 Patent.

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

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

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

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

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

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Count XI: Patent Infringement of the '929 Patent

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2 132. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
3 131 above.

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

9 134. Upon information and belief, Defendants submitted ANDA No. 209499 to FDA
10 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
11 generic version of VASCEPA® before the expiration of the ‘929 Patent.

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

14 136. Upon information and belief, if approved, the generic VASCEPA® product for
15 which approval is sought in Defendants’ ANDA No. 209499 will be administered to human
16 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 ‘929 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 ANDA Product as an adjunct to diet to reduce triglyceride
22 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
23 Defendants will actively induce, encourage, aid, and abet administration of the generic
24 VASCEPA® product with knowledge that it is in contravention of Plaintiffs’ rights under the
25 ‘929 Patent.

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

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

7 139. 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 version of VASCEPA®, and
10 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
11 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the ‘929
12 Patent.

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

19 141. 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 XII: Patent Infringement of the ‘698 Patent**

23 142. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
24 141 above.

25 143. 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 M.

3 144. Upon information and belief, Defendants submitted ANDA No. 209499 to FDA
4 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
5 generic version of VASCEPA® before the expiration of the '698 Patent.

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

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

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

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

1 149. Defendants gave written notice of their certification of invalidity and/or non-
2 infringement of the '698 Patent, alleging that claims of the '698 Patent are invalid and/or that
3 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and
4 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
5 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '698
6 Patent.

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

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

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

17 152. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
18 151 above.

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

24 154. Upon information and belief, Defendants submitted ANDA No. 209499 to FDA
25 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
26 generic version of VASCEPA® before the expiration of the '372 Patent.

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

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

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

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

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

1 160. Defendants have infringed the ‘372 Patent under 35 U.S.C. § 271(e)(2)(A) by
2 virtue of submitting ANDA No. 209499 with a paragraph IV certification and seeking FDA
3 approval of ANDA No. 209499 to market a generic version of VASCEPA® prior to the
4 expiration of the ‘372 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
5 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
6 further infringe the ‘372 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

10 **Count XIV: Patent Infringement of the ‘594 Patent**

11 162. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
12 161 above.

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

18 164. Upon information and belief, Defendants submitted ANDA No. 209499 to FDA
19 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a
20 generic version of VASCEPA® before the expiration of the ‘594 Patent.

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

23 166. Upon information and belief, if approved, the generic VASCEPA® product for
24 which approval is sought in Defendants’ ANDA No. 209499 will be administered to human
25 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe
26 hypertriglyceridemia. This administration by, for example, physicians would constitute direct
27 infringement, either literally or under the doctrine of equivalents, of one or more claims of the
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1 '594 Patent. Upon information and belief, this infringement will occur at Defendants' behest,
2 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,
3 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride
4 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,
5 Defendants will actively induce, encourage, aid, and abet administration of the generic
6 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the
7 '594 Patent.

8 167. Defendants' manufacture, use, offer for sale, or sale in the United States, or
9 importation into the United States, of the generic VASCEPA® product for which approval is
10 sought in ANDA No. 209499 would actively induce and contribute to infringement of the '594
11 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

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

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

22 170. Defendants have infringed the '594 Patent under 35 U.S.C. § 271(e)(2)(A) by
23 virtue of submitting ANDA No. 209499 with a paragraph IV certification and seeking FDA
24 approval of ANDA No. 209499 to market a generic version of VASCEPA® prior to the
25 expiration of the '594 Patent. Moreover, if Defendants commercially use, offer for sale, or sell
26 their generic version of VASCEPA®, or induce or contribute to such conduct, they would
27 further infringe the '594 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

1 171. 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, '446,
7 '335, '399, '560, '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. 209499 is not earlier than the expiration date of the '728, '715,
10 '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 Patents, or any later
11 expiration of exclusivity for the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698,
12 '372, and '594 Patents 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, '446, '335, '399, '560, '650,
17 '929, '698, '372, and '594 Patents, including the product described in ANDA No. 209499;

18 D. A judgment declaring that making, using, selling, offering to sell, or importing the
19 product described in ANDA No. 209499, or inducing or contributing to such conduct, would
20 constitute infringement of the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698,
21 '372, and '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
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1 G. Such further and other relief as this Court determines to be just and proper.

2
3 DATED: November 4, 2016

Respectfully submitted,

4
5 /s/ Nicholas J. Santoro

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

SANTORO WHITMIRE, LTD.

10100 W. Charleston Blvd., Suite 250

Las Vegas, Nevada 89135

Telephone: (702) 948-8771

Facsimile: (702) 948-8773

E-mail: nsantoro@santoronevada.com

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7
8
9
10 Christopher N. Sipes (*pro hac vice* forthcoming)

Einar Stole (*pro hac vice* forthcoming)

11 Michael N. Kennedy (*pro hac vice* forthcoming)

Megan P. Keane (*pro hac vice* forthcoming)

12 COVINGTON & BURLING LLP

13 One CityCenter, 850 Tenth Street, NW

Washington, DC 20001

14 Telephone: (202) 662-6000

15 Facsimile: (202) 662-6291

E-mail: csipes@cov.com, estole@cov.com,

16 mkennedy@cov.com, mkeane@cov.com

17 *Attorneys for Plaintiffs Amarin Pharma, Inc. and*

18 *Amarin Pharmaceuticals Ireland Limited*