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and Amarin Pharmaceuticals Ireland Limited*

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

**AMARIN PHARMA, INC. and AMARIN
PHARMACEUTICALS IRELAND LIMITED,**

Plaintiffs,

V.

**HIKMA PHARMACEUTICALS USA, INC.,
HIKMA PHARMACEUTICALS
INTERNATIONAL LIMITED**

Defendants.

Case No.: _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited (collectively, “Plaintiffs” or “Amarin”), by their attorneys, for their complaint against Hikma Pharmaceuticals USA, Inc. and Hikma Pharmaceuticals International Limited (hereinafter, “Defendants” or “Hikma”) allege as follows:

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Nature of the Action

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(a, b, e) for infringement of U.S. Patent No. 8,293,728 (“the ‘728 Patent”), U.S. Patent No. 8,318,715 (“the ‘715 Patent”), U.S. Patent No. 8,357,677 (“the ‘677 Patent”), U.S. Patent No. 8,367,652 (“the ‘652 Patent”), U.S. Patent No. 8,377,920 (“the ‘920 Patent”), U.S. Patent No. 8,415,335 (“the ‘335 Patent”), U.S. Patent No. 8,426,399 (“the ‘399 Patent”), U.S. Patent No. 8,440,650 (“the ‘650 Patent”), U.S. Patent No. 8,518,929 (“the ‘929 Patent”), U.S. Patent No. 8,524,698 (“the ‘698 Patent”), U.S. Patent No. 8,546,372 (“the ‘372 Patent”), and U.S. Patent No. 8,617,594 (“the ‘594 Patent”). This action relates to an Abbreviated New Drug Application (“ANDA”) No. 209457 filed by or for the benefit of Defendants with the United States Food and Drug Administration (“FDA”) for approval to market generic versions of Plaintiffs’ VASCEPA® pharmaceutical products that are sold in the United States, including within this judicial district.

The Parties

2. Plaintiff Amarin Pharma, Inc. is a company organized and existing under the laws of Delaware with its principal place of business at 440 Route 22, Suite 330, Bridgewater, NJ 08807.

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

4. Upon information and belief, Defendant Hikma Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 246 Industrial Way West. Eatontown, NJ 07724.

5. Upon information and belief, Defendant Hikma Pharmaceuticals International, Limited is a corporation organized and existing under the laws of the United Kingdom with its principal place of business at 1 New Burlington Place, London W1S 2HR.

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6. Upon information and belief, Hikma Pharmaceuticals USA, Inc. acts at the direction, and for the benefit, of Hikma Pharmaceuticals International, Limited, and is controlled and/or dominated by Hikma Pharmaceuticals International, Limited.

7. Upon information and belief, Defendants collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Defendants are agents of each other and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

8. Upon information and belief, Hikma Pharmaceuticals USA, Inc. acts as the U.S. agent for Hikma Pharmaceuticals International, Limited. for purposes of regulatory submissions to the U.S. Food and Drug Administration (“FDA”) in seeking approval for generic drugs.

9. Upon information and belief, Roxane Laboratories, Inc., prepared and submitted ANDA No. 209457. Subsequently, Roxane Laboratories, Inc. transferred ANDA No. 209457 to Hikma Pharmaceuticals International, Limited, previously named West-Ward Pharmaceuticals International, Limited.

10. Upon information and belief, Defendants are the current owners of ANDA No. 209457 and seek FDA approval of an amendment to ANDA No. 209457 concerning a 0.5 g dosage strength of icosapent ethyl.

11. Upon information and belief, Defendants intend to commercially manufacture, market, offer for sale, and sell the pharmaceutical product described in Defendants' ANDA ("the ANDA Products") throughout the United States, including this jurisdiction, in the event FDA approves Defendants' amended ANDA.

12. Upon information and belief, Defendants intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell the ANDA Products, in the event FDA approved Defendants' amended ANDA.

Jurisdiction and Venue

13. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the U.S. Code, for infringement of the '728 Patent, the '715 Patent, the

1 ‘677 Patent, the ‘652 Patent, the ‘920 Patent, the ‘335 Patent, the ‘399 Patent, the ‘650 Patent,
 2 the ‘929 Patent, the ‘698 Patent, the ‘372 Patent, and the ‘594 Patent.

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

5 15. On information and belief, and as stated in a letter dated June 1, 2020 sent by
 6 Defendants to Amarin (the “June Notice Letter”), Defendants prepared and filed patent
 7 certifications with the FDA in support of amended ANDA No. 209457 with the intention of
 8 seeking to market a generic version of the 0.5 gram strength of Amarin’s VASCEPA® product
 9 (“generic VASCEPA® 0.5 g product”), including within this judicial district. Amarin received
 10 the June Notice Letter on June 2, 2020.

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

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

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

19 19. Upon information and belief, Defendants plan to sell a generic VASCEPA® 0.5
 20 g product in Nevada, list a generic VASCEPA® 0.5 g product on Nevada’s prescription drug
 21 formulary, and seek Medicaid reimbursements for sales of a generic VASCEPA® 0.5 g product
 22 in Nevada, either directly or through one or more of their wholly owned subsidiaries and/or
 23 agents.

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

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

10 22. On the basis of at least the facts alleged in paragraphs 15–21, venue is proper in
 11 this judicial district as to Hikma Pharmaceutical International Limited pursuant to 28 U.S.C. §§
 12 1391 and 1400(b) because, *inter alia*, Hikma Pharmaceutical International Limited is a
 13 corporation organized and existing under the laws of the United Kingdom and is subject to
 14 personal jurisdiction in this judicial district.

15 23. Upon the basis of at least the facts alleged in paragraphs 15–21, venue is proper
 16 in this judicial district as to Hikma Pharmaceuticals USA Inc. pursuant to 28 U.S.C. §§ 1391 and
 17 1400(b) because, *inter alia*, Hikma Pharmaceuticals USA Inc. is subject to personal jurisdiction in
 18 this judicial district and, on information and belief, has a regular, established place of business in
 19 this judicial district.

Regulatory Requirements for New and Generic Drugs

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

24 25. A person wishing to market a generic copy of a drug that previously has been
 25 approved by the FDA may follow a truncated approval process by filing an Abbreviated New
 26 Drug Application ("ANDA") for a generic version of that drug. In the ANDA, the applicant
 27

1 must demonstrate, among other things, bioequivalence of the generic copy with the pioneering
 2 drug. 21 U.S.C. § 355(j)(2)(A)(iv).

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

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

The Approved Drug Product

12 28. Amarin Pharmaceuticals Ireland Limited is the current holder of NDA No.
 13 202057 for 1 g and 0.5 g icosapent ethyl capsules. NDA No. 202057 was first approved by the
 14 FDA on July 26, 2012 for the 1 g strength of icosapent ethyl capsules. A supplement to NDA
 15 No. 202057 for the 0.5 g strength of icosapent ethyl capsules was approved on February 16,
 16 2017. Amarin Pharma, Inc. is Amarin Pharmaceuticals Ireland Limited's agent in the United
 17 States for purposes of communicating with the FDA regarding NDA No. 202057. Amarin
 18 Pharmaceuticals Ireland Limited and Amarin Pharma, Inc. market both strengths of the
 19 approved drug product under the tradename VASCEPA®.

20 29. VASCEPA® is currently indicated, *inter alia*, as an adjunct to diet to reduce
 21 triglyceride levels in adult patients with severe hypertriglyceridemia. VASCEPA® is also
 22 indicated as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial
 23 infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in
 24 adult patients with elevated triglyceride levels and established cardiovascular disease or diabetes
 25 mellitus and 2 or more additional risk factors for cardiovascular disease. A true, correct, and
 26 complete copy of the FDA-approved Prescribing Information for VASCEPA®, covering both
 27 the 1 g and 0.5 g strengths, is attached as Exhibit A.

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1 30. FDA has listed the ‘728, ‘715, ‘677, ‘652, ‘920, ‘335, ‘399, ‘650, ‘929, ‘698, ‘372,
 2 and ‘594 Patents in the Orange Book—formally known as Approved Drug Products With
 3 Therapeutic Equivalence Evaluations—in connection with NDA No. 202057, including for the
 4 0.5 g strength of VASCEPA®.

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

7 32. On March 30, 2020, the United States District Court for the District of Nevada
 8 entered a judgment that the following claims were invalid as obvious: Claims 1 and 16 of the
 9 ‘728 patent, Claim 14 of the ‘715 patent, Claims 1 and 8 of the ‘677 patent, Claim 1 of the ‘652
 10 patent, Claims 4 and 17 of the ‘560 patent, and Claims 1 and 5 of the ‘929 patent. Amarin took a
 11 timely appeal from that judgment, which is currently pending in the United States Court of
 12 Appeals for the Federal Circuit. In addition, Amarin asserts in this lawsuit patent claims that
 13 contain non-obvious limitations as compared to the claims invalidated by the March 30, 2020
 14 judgment. The issues raised by the additional patent claims Amarin asserts in this lawsuit are not
 15 identical to the claims that were previously invalidated.

ANDA No. 209457

17 33. Upon information and belief, on or before June 1, 2020, Defendants, through
 18 Hikma Pharmaceuticals USA, Inc., submitted to the FDA an amendment to ANDA No. 209457
 19 to obtain approval for 0.5 g icosapent ethyl capsules purportedly bioequivalent to VASCEPA®,
 20 along with a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic
 21 Act (“FDCA”), 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the “paragraph IV certification”).

22 34. Upon information and belief, the indication set forth in the proposed labeling
 23 submitted in amended ANDA No. 209457, covering generic versions of the 0.5 g strength of
 24 VASCEPA®, is to reduce triglyceride levels in adult patients with severe hypertriglyceridemia,
 25 *i.e.*, the same indication as that set forth in the approved labeling for VASCEPA®.

26 35. Upon information and belief, the purpose of amended ANDA No. 209457 and
 27 Hikma’s paragraph IV certification is to obtain approval under section 505(j) of the FDCA to
 28 engage in the commercial manufacture and sale of generic versions of the 0.5 g strength of

VASCEPA® before the expiration of the patents listed in the Orange Book for NDA No. 202057. Hence, Defendants' purpose in submitting amended ANDA No. 209457 and the paragraph IV certification is to market products described therein before expiration of the '728, '715, '677, '652, '920, '335, '399, , '650, '929, '698, '372, and '594 Patents.

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

Count I: Patent Infringement of the '728 Patent

37. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 36 above.

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

39. Upon information and belief, Defendants submitted amended ANDA No. 209457 and the paragraph IV certification to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of the 0.5 g strength of VASCEPA® before the expiration of the '728 Patent.

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

41. Upon information and belief, if approved, the generic VASCEPA® 0.5 g product for which approval is sought in Defendants' amended ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '728 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales, marketing, and distribution of their generic VASCEPA® 0.5 g product as an adjunct to diet to

1 reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
 2 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
 3 the generic VASCEPA® 0.5 g product with knowledge that it is in contravention of Plaintiffs'
 4 rights under the '728 Patent.

5 42. Defendants' manufacture, use, offer for sale, or sale in the United States, or
 6 importation into the United States, of the generic VASCEPA® 0.5 g product for which
 7 approval is sought in amended ANDA No. 209457 would actively induce infringement of the
 8 '728 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

9 43. Upon information and belief, as part of the amended ANDA filing, Defendants
 10 purportedly provided written certification to the FDA that the claims of the '728 Patent are
 11 invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
 12 VASCEPA® 0.5 g product.

13 44. Defendants gave written notice of their certification of invalidity and/or non-
 14 infringement of the '728 Patent, alleging that claims of the '728 Patent are invalid and/or that
 15 certain claims would not be infringed by Defendants' generic VASCEPA® 0.5 g product, and
 16 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
 17 use, and sale of a product bioequivalent to the 0.5 g strength of VASCEPA® prior to the
 18 expiration of the '728 Patent.

19 45. Defendants have infringed the '728 Patent under 35 U.S.C. § 271(e)(2)(A) by
 20 virtue of submitting amended ANDA No. 209457 and the paragraph IV certification, and
 21 seeking FDA approval of amended ANDA No. 209457 to market a generic version of the 0.5 g
 22 strength of VASCEPA® prior to the expiration of the '728 Patent. Moreover, if Defendants
 23 commercially use, offer for sale, or sell their generic VASCEPA® 0.5 g product, or induce such
 24 conduct, they would further infringe the '728 Patent under 35 U.S.C. § 271(a) and/or (b).

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

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

2 47. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 46
3 above.

4 48. 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 49. Upon information and belief, Defendants submitted amended ANDA No.
10 209457 and the paragraph IV certification to the FDA seeking approval to engage in the
11 commercial manufacture, use, offer for sale, and sale of a generic version of the 0.5 g strength of
12 VASCEPA® before the expiration of the ‘715 Patent.

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

15 51. Upon information and belief, if approved, the generic VASCEPA® 0.5 g product
16 for which approval is sought in Defendants’ amended ANDA No. 209457 will be administered
17 to 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 ‘715 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® 0.5 g product as an adjunct to diet to
23 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® 0.5 g product with knowledge that it is in contravention of Plaintiffs’
26 rights under the ‘715 Patent.

27 52. Defendants’ manufacture, use, offer for sale, or sale in the United States, or
28 importation into the United States, of the generic VASCEPA® 0.5 g product for which

1 approval is sought in amended ANDA No. 209457 would actively induce infringement of the
 2 ‘715 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

3 53. Upon information and belief, as part of the amended ANDA filing, Defendants
 4 purportedly provided written certification to the FDA that the claims of the ‘715 Patent are
 5 invalid and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic
 6 VASCEPA® 0.5 g product.

7 54. 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 VASCEPA® 0.5 g 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 0.5 g strength of VASCEPA® prior to the
 12 expiration of the ‘715 Patent.

13 55. Defendants have infringed the ‘715 Patent under 35 U.S.C. § 271(e)(2)(A) by
 14 virtue of submitting amended ANDA No. 209457 and the paragraph IV certification, and
 15 seeking FDA approval of amended ANDA No. 209457 to market a generic VASCEPA® 0.5 g
 16 product prior to the expiration of the ‘715 Patent. Moreover, if Defendants commercially use,
 17 offer for sale, or sell their generic VASCEPA® 0.5 g product, or induce such conduct, they
 18 would further infringe the ‘715 Patent under 35 U.S.C. § 271(a) and/or (b).

19 56. 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.

Count III: Patent Infringement of the ‘677 Patent

22 57. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 56
 23 above.

24 58. United States Patent No. 8,357,677, entitled “METHODS OF TREATING
 25 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and
 26 Trademark Office on January 22, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the
 27
 28

1 owner of the '677 Patent. A true and complete copy of the '677 Patent is attached hereto as
2 Exhibit D.

3 59. Upon information and belief, Defendants submitted amended ANDA No.
4 209457 and the paragraph IV certification to the FDA seeking approval to engage in the
5 commercial manufacture, use, offer for sale, and sale of a generic VASCEPA® 0.5 g product
6 before the expiration of the '677 Patent.

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

9 61. Upon information and belief, if approved, the generic VASCEPA® 0.5 g product
10 for which approval is sought in Defendants' amended ANDA No. 209457 will be administered
11 to 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 '677 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® 0.5 g product as an adjunct to diet to
17 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® 0.5 g product with knowledge that it is in contravention of Plaintiffs'
20 rights under the '677 Patent.

21 62. Defendants' manufacture, use, offer for sale, or sale in the United States, or
22 importation into the United States, of the generic VASCEPA® 0.5 g product for which
23 approval is sought in amended ANDA No. 209457 would actively induce infringement of the
24 '677 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

25 63. Upon information and belief, as part of the amended ANDA filing, Defendants
26 purportedly provided written certification to the FDA that the claims of the '677 Patent are
27 invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
28 VASCEPA® 0.5 g product.

1 64. 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® 0.5 g 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 0.5 g strength of VASCEPA® prior to the
 6 expiration of the ‘677 Patent.

7 65. Defendants have infringed the ‘677 Patent under 35 U.S.C. § 271(e)(2)(A) by
 8 virtue of submitting amended ANDA No. 209457 and the paragraph IV certification, and
 9 seeking FDA approval of amended ANDA No. 209457 to market a generic VASCEPA® 0.5 g
 10 product prior to the expiration of the ‘677 Patent. Moreover, if Defendants commercially use,
 11 offer for sale, or sell their generic VASCEPA® 0.5 g product, or induce such conduct, they
 12 would further infringe the ‘677 Patent under 35 U.S.C. § 271(a) and/or (b).

13 66. 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.

Count IV: Patent Infringement of the ‘652 Patent

17 67. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 66
 18 above.

19 68. 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 69. Upon information and belief, Defendants submitted amended ANDA No.
 25 209457 and the paragraph IV certification to the FDA seeking approval to engage in the
 26 commercial manufacture, use, offer for sale, and sale of a generic VASCEPA® 0.5 g product
 27 before the expiration of the ‘652 Patent.

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1 70. 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) and/or (b).

3 71. Upon information and belief, if approved, the generic VASCEPA® 0.5 g product
4 for which approval is sought in Defendants' amended ANDA No. 209457 will be administered
5 to 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® 0.5 g product as an adjunct to diet to
11 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® 0.5 g product with knowledge that it is in contravention of Plaintiffs'
14 rights under the '652 Patent.

15 72. Defendants' manufacture, use, offer for sale, or sale in the United States, or
16 importation into the United States, of the generic VASCEPA® 0.5 g product for which
17 approval is sought in amended ANDA No. 209457 would actively induce infringement of the
18 '652 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

19 73. Upon information and belief, as part of the amended ANDA filing, Defendants
20 purportedly provided written certification to the FDA that the claims of the '652 Patent are
21 invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
22 VASCEPA® 0.5 g product.

23 74. Defendants gave written notice of their certification of invalidity and/or non-
24 infringement of the '652 Patent, alleging that claims of the '652 Patent are invalid and/or that
25 certain claims would not be infringed by Defendants' generic VASCEPA® 0.5 g product, and
26 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
27 use, and sale of a product bioequivalent to the 0.5 g strength of VASCEPA® prior to the
28 expiration of the '652 Patent.

75. Defendants have infringed the ‘652 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting amended ANDA No. 209457 and the paragraph IV certification, and seeking FDA approval of amended ANDA No. 209457 to market a generic VASCEPA® 0.5 g product prior to the expiration of the ‘652 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic VASCEPA® 0.5 g product, or induce such conduct, they would further infringe the ‘652 Patent under 35 U.S.C. § 271(a) and/or (b).

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

Count V: Patent Infringement of the '920 Patent

77. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 76 above.

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

79. Upon information and belief, Defendants submitted amended ANDA No. 209457 and the paragraph IV certification to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic VASCEPA® 0.5 g product before the expiration of the '920 Patent.

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

81. Upon information and belief, if approved, the generic VASCEPA® 0.5 g product for which approval is sought in Defendants' amended ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the

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 generic VASCEPA® 0.5 g product as an adjunct to diet to
 4 reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
 5 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
 6 the generic VASCEPA® 0.5 g product with knowledge that it is in contravention of Plaintiffs’
 7 rights under the ‘920 Patent.

8 82. Defendants’ manufacture, use, offer for sale, or sale in the United States, or
 9 importation into the United States, of the generic VASCEPA® 0.5 g product for which
 10 approval is sought in amended ANDA No. 209457 would actively induce infringement of the
 11 ‘920 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

12 83. Upon information and belief, as part of the amended ANDA filing, Defendants
 13 purportedly provided written certification to the FDA that the claims of the ‘920 Patent are
 14 invalid and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic
 15 VASCEPA® 0.5 g product.

16 84. 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 VASCEPA® 0.5 g 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 0.5 g strength of VASCEPA® prior to the
 21 expiration of the ‘920 Patent.

22 85. Defendants have infringed the ‘920 Patent under 35 U.S.C. § 271(e)(2)(A) by
 23 virtue of submitting amended ANDA No. 209457 and the paragraph IV certification, and
 24 seeking FDA approval of amended ANDA No. 209457 to market a generic VASCEPA® 0.5 g
 25 product prior to the expiration of the ‘920 Patent. Moreover, if Defendants commercially use,
 26 offer for sale, or sell their generic VASCEPA® 0.5 g product, or induce such conduct, they
 27 would further infringe the ‘920 Patent under 35 U.S.C. § 271(a) and/or (b).

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

Count VI: Patent Infringement of the '335 Patent

87. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 86 above.

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

89. Upon information and belief, Defendants submitted amended ANDA No. 209457 and the paragraph IV certification to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic VASCEPA® 0.5 g product before the expiration of the '335 Patent.

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

91. Upon information and belief, if approved, the generic VASCEPA® 0.5 g product for which approval is sought in Defendants' amended ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '335 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales, marketing, and distribution of their generic VASCEPA® 0.5 g product as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons, Defendants will actively induce, encourage, aid, and abet administration of

the generic VASCEPA® 0.5 g product with knowledge that it is in contravention of Plaintiffs' rights under the '335 Patent.

92. Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® 0.5 g product for which approval is sought in amended ANDA No. 209457 would actively induce infringement of the '335 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

93. Upon information and belief, as part of the amended ANDA filing, Defendants purportedly provided written certification to the FDA that the claims of the '335 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic VASCEPA® 0.5 g product.

94. Defendants gave written notice of their certification of invalidity and/or non-infringement of the ‘335 Patent, alleging that claims of the ‘335 Patent are invalid and/or that certain claims would not be infringed by Defendants’ generic VASCEPA® 0.5 g product, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to the 0.5 g strength of VASCEPA® prior to the expiration of the ‘335 Patent.

95. Defendants have infringed the ‘335 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting amended ANDA No. 209457 and the paragraph IV certification, and seeking FDA approval of amended ANDA No. 209457 to market a generic VASCEPA® 0.5 g product prior to the expiration of the ‘335 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic VASCEPA® 0.5 g product, or induce such conduct, they would further infringe the ‘335 Patent under 35 U.S.C. § 271(a) and/or (b).

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

Count VII: Patent Infringement of the ‘399 Patent

97. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 96 above.

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

6 99. Upon information and belief, Defendants submitted amended ANDA No.
 7 209457 and the paragraph IV certification to the FDA seeking approval to engage in the
 8 commercial manufacture, use, offer for sale, and sale of a generic VASCEPA® 0.5 g product
 9 before the expiration of the ‘399 Patent.

10 100. Defendants’ manufacture, use, offer for sale, or sale of such product would
 11 infringe the claims of the ‘399 Patent under 35 U.S.C. § 271(a) and/or (b).

12 101. Upon information and belief, if approved, the generic VASCEPA® 0.5 g product
 13 for which approval is sought in Defendants’ amended ANDA No. 209457 will be administered
 14 to 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 ‘399 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® 0.5 g product as an adjunct to diet to
 20 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® 0.5 g product with knowledge that it is in contravention of Plaintiffs’
 23 rights under the ‘399 Patent.

24 102. Defendants’ manufacture, use, offer for sale, or sale in the United States, or
 25 importation into the United States, of the generic VASCEPA® 0.5 g product for which
 26 approval is sought in amended ANDA No. 209457 would actively induce infringement of the
 27 ‘399 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

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103. Upon information and belief, as part of the amended ANDA filing, Defendants purportedly provided written certification to the FDA that the claims of the '399 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic VASCEPA® 0.5 g product.

104. Defendants gave written notice of their certification of invalidity and/or non-infringement of the ‘399 Patent, alleging that claims of the ‘399 Patent are invalid and/or that certain claims would not be infringed by Defendants’ generic VASCEPA® 0.5 g product, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to the 0.5 g strength of VASCEPA® prior to the expiration of the ‘399 Patent.

105. Defendants have infringed the ‘399 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting amended ANDA No. 209457 and the paragraph IV certification, and seeking FDA approval of amended ANDA No. 209457 to market a generic VASCEPA® 0.5 g product prior to the expiration of the ‘399 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic VASCEPA® 0.5 g product, or induce such conduct, they would further infringe the ‘399 Patent under 35 U.S.C. § 271(a) and/or (b).

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

Count VIII: Patent Infringement of the '650 Patent

107. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
106 above.

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

11

1 109. Upon information and belief, Defendants submitted amended ANDA No.
 2 209457 and the paragraph IV certification to the FDA seeking approval to engage in the
 3 commercial manufacture, use, offer for sale, and sale of a generic VASCEPA® 0.5 g product
 4 before the expiration of the ‘650 Patent.

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

7 111. Upon information and belief, if approved, the generic VASCEPA® 0.5 g product
 8 for which approval is sought in Defendants’ amended ANDA No. 209457 will be administered
 9 to 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 ‘650 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® 0.5 g product as an adjunct to diet to
 15 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® 0.5 g product with knowledge that it is in contravention of Plaintiffs’
 18 rights under the ‘650 Patent.

19 112. Defendants’ manufacture, use, offer for sale, or sale in the United States, or
 20 importation into the United States, of the generic VASCEPA® 0.5 g product for which
 21 approval is sought in amended ANDA No. 209457 would actively induce infringement of the
 22 ‘650 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

23 113. Upon information and belief, as part of the amended ANDA filing, Defendants
 24 purportedly provided written certification to the FDA that the claims of the ‘650 Patent are
 25 invalid and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic
 26 VASCEPA® 0.5 g product.

27 114. Defendants gave written notice of their certification of invalidity and/or non-
 28 infringement of the ‘650 Patent, alleging that claims of the ‘650 Patent are invalid and/or that

1 certain claims would not be infringed by Defendants' generic VASCEPA® 0.5 g 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 0.5 g strength of VASCEPA® prior to the
 4 expiration of the '650 Patent.

5 115. Defendants have infringed the '650 Patent under 35 U.S.C. § 271(e)(2)(A) by
 6 virtue of submitting amended ANDA No. 209457 and the paragraph IV certification, and
 7 seeking FDA approval of amended ANDA No. 209457 to market a generic VASCEPA® 0.5 g
 8 product prior to the expiration of the '650 Patent. Moreover, if Defendants commercially use,
 9 offer for sale, or sell their generic VASCEPA® 0.5 g product, or induce such conduct, they
 10 would further infringe the '650 Patent under 35 U.S.C. § 271(a) and/or (b).

11 116. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
 12 infringing or actively inducing or contributing to infringement of the '650 Patent. Plaintiffs do
 13 not have an adequate remedy at law.

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

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

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

22 119. Upon information and belief, Defendants submitted amended ANDA No.
 23 209457 and the paragraph IV certification to the FDA seeking approval to engage in the
 24 commercial manufacture, use, offer for sale, and sale of a generic VASCEPA® 0.5 g product
 25 before the expiration of the '929 Patent.

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

28 //

1 121. Upon information and belief, if approved, the generic VASCEPA® 0.5 g product
 2 for which approval is sought in Defendants' amended ANDA No. 209457 will be administered
 3 to 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 '929 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® 0.5 g product as an adjunct to diet to
 9 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® 0.5 g product with knowledge that it is in contravention of Plaintiffs'
 12 rights under the '929 Patent.

13 122. Defendants' manufacture, use, offer for sale, or sale in the United States, or
 14 importation into the United States, of the generic VASCEPA® 0.5 g product for which
 15 approval is sought in amended ANDA No. 209457 would actively induce infringement of the
 16 '929 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

17 123. Upon information and belief, as part of the amended ANDA filing, Defendants
 18 purportedly provided written certification to the FDA that the claims of the '929 Patent are
 19 invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
 20 VASCEPA® 0.5 g product.

21 124. Defendants gave written notice of their certification of invalidity and/or non-
 22 infringement of the '929 Patent, alleging that claims of the '929 Patent are invalid and/or that
 23 certain claims would not be infringed by Defendants' generic VASCEPA® 0.5 g product, and
 24 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
 25 use, and sale of a product bioequivalent to the 0.5 g strength of VASCEPA® prior to the
 26 expiration of the '929 Patent.

27 125. Defendants have infringed the '929 Patent under 35 U.S.C. § 271(e)(2)(A) by
 28 virtue of submitting amended ANDA No. 209457 and the paragraph IV certification, and

seeking FDA approval of amended ANDA No. 209457 to market a generic VASCEPA® 0.5 g product prior to the expiration of the ‘929 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic VASCEPA® 0.5 g product, or induce such conduct, they would further infringe the ‘929 Patent under 35 U.S.C. § 271(a) and/or (b).

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

Count X: Patent Infringement of the '698 Patent

127. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
126 above.

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

129. Upon information and belief, Defendants submitted amended ANDA No. 209457 and the paragraph IV certification to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic VASCEPA® 0.5 g product before the expiration of the ‘698 Patent.

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

131. Upon information and belief, if approved, the generic VASCEPA® 0.5 g product for which approval is sought in Defendants' amended ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '698 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,

1 marketing, and distribution of their generic VASCEPA® 0.5 g product as an adjunct to diet to
 2 reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at
 3 least these reasons, Defendants will actively induce, encourage, aid, and abet administration of
 4 the generic VASCEPA® 0.5 g product with knowledge that it is in contravention of Plaintiffs'
 5 rights under the '698 Patent.

6 132. Defendants' manufacture, use, offer for sale, or sale in the United States, or
 7 importation into the United States, of the generic VASCEPA® 0.5 g product for which
 8 approval is sought in amended ANDA No. 209457 would actively induce infringement of the
 9 '698 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

10 133. Upon information and belief, as part of the amended ANDA filing, Defendants
 11 purportedly provided written certification to the FDA that the claims of the '698 Patent are
 12 invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
 13 VASCEPA® 0.5 g product.

14 134. Defendants gave written notice of their certification of invalidity and/or non-
 15 infringement of the '698 Patent, alleging that claims of the '698 Patent are invalid and/or that
 16 certain claims would not be infringed by Defendants' generic VASCEPA® 0.5 g product, and
 17 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,
 18 use, and sale of a product bioequivalent to the 0.5 g strength of VASCEPA® prior to the
 19 expiration of the '698 Patent.

20 135. Defendants have infringed the '698 Patent under 35 U.S.C. § 271(e)(2)(A) by
 21 virtue of submitting amended ANDA No. 209457 and the paragraph IV certification, and
 22 seeking FDA approval of amended ANDA No. 209457 to market a generic VASCEPA® 0.5 g
 23 product prior to the expiration of the '698 Patent. Moreover, if Defendants commercially use,
 24 offer for sale, or sell their generic VASCEPA® 0.5 g product, or induce such conduct, they
 25 would further infringe the '698 Patent under 35 U.S.C. § 271(a) and/or (b).

26 136. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
 27 infringing or actively inducing or contributing to infringement of the '698 Patent. Plaintiffs do
 28 not have an adequate remedy at law.

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

2 137. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
 3 136 above.

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

9 139. Upon information and belief, Defendants submitted amended ANDA No.
 10 209457 and the paragraph IV certification to the FDA seeking approval to engage in the
 11 commercial manufacture, use, offer for sale, and sale of a generic VASCEPA® 0.5 g product
 12 before the expiration of the ‘372 Patent.

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

15 141. Upon information and belief, if approved, the generic VASCEPA® 0.5 g product
 16 for which approval is sought in Defendants’ amended ANDA No. 209457 will be administered
 17 to 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 ‘372 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® 0.5 g product as an adjunct to diet to
 23 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® 0.5 g product with knowledge that it is in contravention of Plaintiffs’
 26 rights under the ‘372 Patent.

27 142. Defendants’ manufacture, use, offer for sale, or sale in the United States, or
 28 importation into the United States, of the generic VASCEPA® 0.5 g product for which

1 approval is sought in amended ANDA No. 209457 would actively induce infringement of the
 2 '372 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

3 143. Upon information and belief, as part of the amended ANDA filing, Defendants
 4 purportedly provided written certification to the FDA that the claims of the '372 Patent are
 5 invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
 6 VASCEPA® 0.5 g product.

7 144. Defendants gave written notice of their certification of invalidity and/or non-
 8 infringement of the '372 Patent, alleging that claims of the '372 Patent are invalid and/or that
 9 certain claims would not be infringed by Defendants' generic VASCEPA® 0.5 g 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 0.5 g strength of VASCEPA® prior to the
 12 expiration of the '372 Patent.

13 145. Defendants have infringed the '372 Patent under 35 U.S.C. § 271(e)(2)(A) by
 14 virtue of submitting amended ANDA No. 209457 and the paragraph IV certification, and
 15 seeking FDA approval of amended ANDA No. 209457 to market a generic VASCEPA® 0.5 g
 16 product prior to the expiration of the '372 Patent. Moreover, if Defendants commercially use,
 17 offer for sale, or sell their generic VASCEPA® 0.5 g product, or induce such conduct, they
 18 would further infringe the '372 Patent under 35 U.S.C. § 271(a) and/or (b).

19 146. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
 20 infringing or actively inducing or contributing to infringement of the '372 Patent. Plaintiffs do
 21 not have an adequate remedy at law.

Count XII: Patent Infringement of the '594 Patent

23 147. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to
 24 146 above.

25 148. United States Patent No. 8,617,594, entitled "STABLE PHARMACEUTICAL
 26 COMPOSITION AND METHODS OF USING SAME," was duly and legally issued by the
 27 United States Patent and Trademark Office on December 31, 2013. Plaintiff Amarin

1 Pharmaceuticals Ireland Limited is the owner of the '594 Patent. A true and complete copy of
2 the '594 Patent is attached hereto as Exhibit M.

3 149. Upon information and belief, Defendants submitted amended ANDA No.
4 209457 and the paragraph IV certification to the FDA seeking approval to engage in the
5 commercial manufacture, use, offer for sale, and sale of a generic VASCEPA® 0.5 g product
6 before the expiration of the '594 Patent.

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

9 151. Upon information and belief, if approved, the generic VASCEPA® 0.5 g product
10 for which approval is sought in Defendants' amended ANDA No. 209457 will be administered
11 to 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 '594 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® 0.5 g product as an adjunct to diet to
17 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® 0.5 g product with knowledge that it is in contravention of Plaintiffs'
20 rights under the '594 Patent.

21 152. Defendants' manufacture, use, offer for sale, or sale in the United States, or
22 importation into the United States, of the generic VASCEPA® 0.5 g product for which
23 approval is sought in amended ANDA No. 209457 would actively induce infringement of the
24 '594 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

25 153. Upon information and belief, as part of the amended ANDA filing, Defendants
26 purportedly provided written certification to the FDA that the claims of the '594 Patent are
27 invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic
28 VASCEPA® 0.5 g product.

1 154. Defendants gave written notice of their certification of invalidity and/or non-
 2 infringement of the ‘594 Patent, alleging that claims of the ‘594 Patent are invalid and/or that
 3 certain claims would not be infringed by Defendants’ generic VASCEPA® 0.5 g 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 0.5 g strength of VASCEPA® prior to the
 6 expiration of the ‘594 Patent.

7 155. Defendants have infringed the ‘594 Patent under 35 U.S.C. § 271(e)(2)(A) by
 8 virtue of submitting amended ANDA No. 209457 and the paragraph IV certification, and
 9 seeking FDA approval of amended ANDA No. 209457 to market a generic VASCEPA® 0.5 g
 10 product prior to the expiration of the ‘594 Patent. Moreover, if Defendants commercially use,
 11 offer for sale, or sell their generic VASCEPA® 0.5 g product, or induce such conduct, they
 12 would further infringe the ‘594 Patent under 35 U.S.C. § 271(a) and/or (b).

13 156. Plaintiffs will be irreparably harmed if Defendants are not enjoined from
 14 infringing or actively inducing or contributing to infringement of the ‘594 Patent. Plaintiffs do
 15 not have an adequate remedy at law.

Prayer for Relief

17 WHEREFORE, Plaintiffs seek the following relief:

18 A. A judgment that Defendants have infringed the ‘728, ‘715, ‘677, ‘652, ‘920, ‘335,
 19 ‘399, ‘650, ‘929, ‘698, ‘372, and ‘594 Patents under 35 U.S.C. § 271(e)(2)(A);

20 B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of
 21 any FDA approval of amended ANDA No. 209457 is not earlier than the expiration date of the
 22 ‘728, ‘715, ‘677, ‘652, ‘920, ‘335, ‘399, ‘650, ‘929, ‘698, ‘372, and ‘594 Patents, or any later
 23 expiration of exclusivity for the ‘728, ‘715, ‘677, ‘652, ‘920, ‘335, ‘399, ‘650, ‘929, ‘698, ‘372, and
 24 ‘594 Patents to which Plaintiffs are or become entitled;

25 C. A permanent injunction restraining and enjoining Defendants and their officers,
 26 agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active
 27 concert or participation with any of them, from making, using, selling, offering to sell, or
 28 importing any product that infringes the ‘728, ‘715, ‘677, ‘652, ‘920, ‘335, ‘399, ‘650, ‘929, ‘698,

‘372, and ‘594 Patents, including the product described in amended ANDA No. 209457;

D. A judgment declaring that making, using, selling, offering to sell, or importing the product described in amended ANDA No. 209457, or inducing or contributing to such conduct, would constitute infringement of the ‘728, ‘715, ‘677, ‘652, ‘920, ‘335, ‘399, ‘650, ‘929, ‘698, ‘372, and ‘594 Patents by Defendants pursuant to 35 U.S.C. § 271(a) and/or (b);

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

F. Costs and expenses in this action; and

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

DATED: July 13, 2020

Respectfully submitted,

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