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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

'677 Patent, the '652 Patent, the '920 Patent, the '335 Patent, the '399 Patent, the '650 Patent, the '929 Patent, the '698 Patent, the '372 Patent, and the '594 Patent.

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

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

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

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

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

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

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

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

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

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

Regulatory Requirements for New and Generic Drugs

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

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

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

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

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

The Approved Drug Product

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

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

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

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

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

ANDA No. 209457

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

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

35. Upon information and belief, the purpose of amended ANDA No. 209457 and Hikma's paragraph IV certification is to obtain approval under section 505(j) of the FDCA to 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

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 '728 Patent.

42. 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 '728 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

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

44. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '728 Patent, alleging that claims of the '728 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 '728 Patent.

45. Defendants have infringed the '728 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 version of the 0.5 g strength of VASCEPA® prior to the expiration of the '728 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 '728 Patent under 35 U.S.C. § 271(a) and/or (b).

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

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Count II: Patent Infringement of the '715 Patent

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

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

49. 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 '715 Patent.

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

51. 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 '715 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 '715 Patent.

52. 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 '715 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

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

54. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '715 Patent, alleging that claims of the '715 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 '715 Patent.

55. Defendants have infringed the '715 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 '715 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 '715 Patent under 35 U.S.C. § 271(a) and/or (b).

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

Count III: Patent Infringement of the '677 Patent

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

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

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

59. 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 '677 Patent.

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

61. 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 '677 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 '677 Patent.

62. 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 '677 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

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

64. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '677 Patent, alleging that claims of the '677 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 '677 Patent.

65. Defendants have infringed the '677 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 '677 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 '677 Patent under 35 U.S.C. § 271(a) and/or (b).

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

Count IV: Patent Infringement of the '652 Patent

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

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

69. 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 '652 Patent.

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

71. 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 '652 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 '652 Patent.

72. 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 '652 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

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

74. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '652 Patent, alleging that claims of the '652 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 '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

'920 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 '920 Patent.

82. 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 '920 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

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

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

85. Defendants have infringed the '920 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 '920 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 '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.

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

99. 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 '399 Patent.

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

101. 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 '399 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 '399 Patent.

102. 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 '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 I.

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109. 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 '650 Patent.

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

111. 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 '650 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 '650 Patent.

112. 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 '650 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

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

114. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '650 Patent, alleging that claims of the '650 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 '650 Patent.

115. Defendants have infringed the '650 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 '650 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 '650 Patent under 35 U.S.C. § 271(a) and/or (b).

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

Count IX: Patent Infringement of the '929 Patent

117. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 116 above.

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

119. 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 '929 Patent.

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

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121. 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 '929 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 '929 Patent.

122. 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 '929 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

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

124. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '929 Patent, alleging that claims of the '929 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 '929 Patent.

125. Defendants have infringed the '929 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 '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,

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 '698 Patent.

132. 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 '698 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

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

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

135. Defendants have infringed the '698 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 '698 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 '698 Patent under 35 U.S.C. § 271(a) and/or (b).

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

Count XI: Patent Infringement of the '372 Patent

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

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

139. 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 '372 Patent.

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

141. 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 '372 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 '372 Patent.

142. 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 '372 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

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

144. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '372 Patent, alleging that claims of the '372 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 '372 Patent.

145. Defendants have infringed the '372 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 '372 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 '372 Patent under 35 U.S.C. § 271(a) and/or (b).

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

Count XII: Patent Infringement of the '594 Patent

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

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

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

149. 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 '594 Patent.

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

151. 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 '594 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 '594 Patent.

152. 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 '594 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b).

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

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

155. Defendants have infringed the '594 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 '594 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 '594 Patent under 35 U.S.C. § 271(a) and/or (b).

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

Prayer for Relief

WHEREFORE, Plaintiffs seek the following relief:

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

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

C. A permanent injunction restraining and enjoining Defendants and their officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or 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,

/s/ Adam Hosmer-Henner

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INDEX OF EXHIBITS

Exhibit	Description	Pages
A	VASCEPA® Prescribing Information	14
B	The '728 Patent	22
C	The '715 Patent	23
D	The '677 Patent	22
E	The '652 Patent	23
F	The '920 Patent	23
G	The '335 Patent	24
H	The '399 Patent	22
I	The '650 Patent	22
J	The '929 Patent	23
K	The '698 Patent	24
L	The '372 Patent	22
M	The '594 Patent	30