IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMARIN PHARMACEUTICALS IRELAND LIMITED, Plaintiff, v. OMTHERA PHARMACEUTICALS, INC. and ASTRAZENECA PHARMACEUTICALS LP, Defendants.	C.A. No. _____

COMPLAINT

Plaintiff Amarin Pharmaceuticals Ireland Limited ("Amarin" or "Plaintiff"), for its Complaint against Defendants Omthera Pharmaceuticals, Inc. ("Omthera") and AstraZeneca Pharmaceuticals LP ("AstraZeneca") (collectively, "Defendants") to the best of its knowledge, information and belief, and through its attorneys, alleges as follows:

NATURE OF THE ACTION

1. This is an action for declaratory judgment of infringement of United States Patent No. 8,663,662 ("the '662 patent") under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271.

THE PARTIES

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

3. On information and belief, Omthera Pharmaceuticals, Inc. is a company organized under the laws of the State of Delaware with its principal place of business at 707 State Road, Princeton, New Jersey 08540.

4. On information and belief, AstraZeneca Pharmaceuticals LP is a company organized under the laws of the State of Delaware with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19897.

5. On information and belief, AstraZeneca Pharmaceuticals LP is the parent company of Omthera Pharmaceuticals, Inc.

JURISDICTION AND VENUE

6. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq*. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338, based on an actual controversy between Plaintiff, on the one hand, and Defendants, on the other hand, for claims under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq*. Plaintiff is seeking relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. As detailed herein, there is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that the actual case or controversy between the parties requires a declaration of rights by this Court.

8. This Court has personal jurisdiction over Omthera because Omthera is incorporated under the laws of the State of Delaware, and has thus availed itself of the laws of this District.

9. This Court has personal jurisdiction over AstraZeneca because AstraZeneca is incorporated under the laws of the State of Delaware and resides in Delaware, having a principal place of business at 1800 Concord Pike, Wilmington, Delaware.

10. On information and belief, Defendants will market and sell Epanova™ throughout the United States, including in Delaware.

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and 1400.

12. On information and belief, Defendants are subject to personal jurisdiction in this judicial district, and thus reside in this judicial district under 28 U.S.C. § 1391(b)(1).

BACKGROUND

13. The ’662 patent, entitled “Stable Pharmaceutical Compositions and Methods of Using Same” issued to Mehar Manku, Ian Osterloh, Pierre Wicker, Rene Braeckman, and Paresh Soni on March 4, 2014. A copy of the ’662 patent is attached to this Complaint as Exhibit A.

14. Plaintiff is the owner by assignment of all right, title, and interest in the ’662 patent.

15. Plaintiff offers for sale and sells Vascepa® in the United States. Vascepa® is a prescription treatment indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. Vascepa® was approved by the FDA on July 26, 2012, and is the only approved product Plaintiff markets and sells in the United States.

16. On or about July 18, 2013, AstraZeneca announced that it had completed an acquisition of Omthera.

17. On information and belief, after AstraZeneca’s acquisition of Omthera, Omthera has operated as a subsidiary of AstraZeneca.

18. On March 4, 2014, Plaintiff filed an action in this Court against Defendants for infringement of the ‘662 Patent, C.A. No. 14-279-GMS (“the First Action”).

19. On April 24, 2014, Defendants filed a Motion to Dismiss the First Action.

20. On May 6, 2014, the FDA approved Epanova™ as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

21. In its May 6 announcement, which is attached to this Complaint as Exhibit B, AstraZeneca touted the FDA approval of Epanova™, and further touted that "Epanova is the first FDA approved prescription omega-3 in free fatty acid form. The dosage of Epanova is 2 grams (2 capsules) or 4 grams (4 capsules), making it the first prescription omega-3 to have a dosing option as few as two capsules once a day, with or without food." [Ex. B.]

22. On May 14, 2014, pursuant to a stipulation between the parties and pursuant to an Order of the Court, Plaintiffs filed an Amended Complaint reflecting, *inter alia*, information regarding the FDA approval of Epanova™.

23. On June 6, 2014, Defendants filed a second Motion to Dismiss the First Action.

24. In support of their second Motion to Dismiss, Defendants made two arguments. First, Defendants argued that as of March 4, 2014, the Court did not have subject matter jurisdiction because the FDA had not yet approved Epanova™ by that date and as of March 4, 2014, "Defendants could not predict when, or if, the FDA would approve the product." [C.A. No. 14-279-GMS, Doc. No. 17 at 5.] Second, Defendants argued that Count II of the Amended Complaint did not state a claim upon which relief could be granted because "AstraZeneca's Epanova™ product has not been made, used, offered for sale, sold or imported." [*Id*. at 7-9.]

25. On June 18, 2014, Plaintiff notified Defendants that it intended to file this case as a new action and dismiss the First Action in an effort to expedite the progress of this litigation on the merits.

26. On information and belief, Omthera and AstraZeneca, working in concert, are currently making substantial preparations to commercially launch Epanova™ in the United States, including in this judicial district.

27. Defendants have launched a website, http://www.epanovahcp.com, which is dedicated to the promotion of Epanova™. On the website, Defendants advertise Epanova™, display the FDA-approved label for Epanova™ and provide prescribing information for Epanova™.

28. Omthera notes on its website, excerpts of which are attached hereto as Exhibit C, that "We expect to build a U.S.-based sales and marketing infrastructure to support a launch of Epanova in patients with severe hypertriglyceridemia and anticipate to initially target specialists, cardiologists and primary care physicians who are the top prescribers of lipid regulating therapies." [Ex. C.]

29. Omthera also states on its website that it will seek additional indications for Epanova "[i]n addition to commercially launching Epanova in the severe hypertriglyceridemia indication." [Ex. C.]

COUNT I

(Declaratory Judgment of Infringement of the '662 Patent under 35 U.S.C. § 271(b) and (c))

30. Paragraphs 1 to 29 are incorporated herein as set forth above.

31. The commercial manufacture, sale, offer for sale, and/or importation of Epanova™ will induce the direct infringement of at least claim 1 of the '662 patent under 35 U.S.C. § 271(b).

32. Defendants have had actual knowledge of the '662 patent since at least March 4, 2014, the date that Plaintiff filed the First Action.

33. The use of Epanova™ by patients and/or doctors will directly infringe at least claim 1 of the '662 patent.

34. Defendants will encourage the direct infringement of at least claim 1 of the '662 patent by and through the commercial manufacture, sale, offer for sale, and/or importation of Epanova™.

35. On information and belief, Defendants know or should know that their commercial manufacture, sale, offer for sale, and/or importation of Epanova™ will actively induce direct infringement of at least claim 1 of the '662 patent.

36. At a minimum, the approved label for Epanova™ indicates that Epanova™ is "as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia." A copy of the approved label for Epanova™ is attached to this Complaint as Exhibit D.

37. The approved label for Epanova™ further encourages doctors that "the dosage of Epanova™ is 2 grams (2 capsules) or 4 grams (4 capsules) once daily. Individualize therapy according to patient response and tolerability."

38. The approved label for Epanova™ further encourages patients to "[t]ake Epanova™ exactly as your doctor tells you to take it."

39. The approved label for Epanova™ further cites clinical studies which indicate that treatment with Epanova™ in individuals with severe hypertriglyceridemia led to "increased LDL-C levels" that were 13 percent higher than a placebo group for the 2 gram dose, and 15 percent higher than a placebo group for the 4-gram dose.

40. Defendants' inducing acts, including those described in Paragraphs 36 through 39, are done with knowledge of the '662 patent, with the intent to encourage infringement, and with the knowledge that patients administering Epanova™ will directly infringe the '662 Patent.

41. Upon information and belief, patients will follow the label instructions provided by Omthera, and taking Epanova™ per the label instructions will result in the patients directly infringing the ’662 Patent.

42. The commercial manufacture, sale, offer for sale, and/or importation of Epanova™ will contribute to the direct infringement of at least claim 1 of the ’662 patent under 35 U.S.C § 271(c).

43. On information and belief, Defendants know or should know Epanova™ is especially made or especially adapted for use in an infringement of the ’662 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

44. Upon information and belief, there are no substantial noninfringing uses for Epanova™. At a minimum, the label for Epanova™ states that Epanova™ is indicated “as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.” There are no indications for other patient populations.

45. The approved label for Epanova™ further cites clinical studies which indicate that treatment with Epanova™ in individuals with severe hypertriglyceridemia led to “increased LDL-C levels” that were 13 percent higher than a placebo group for the 2 gram dose, and 15 percent higher than a placebo group for the 4-gram dose. On the approved label for Epanova™, there are no clinical studies cited for patients in which there was an increase of LDL-C levels of more than 20 percent against a placebo group.

46. On information and belief, Defendants know or should know that their offer for sale, sale and/or importation of Epanova™ will contribute to the direct infringement of the ’662 patent.

47. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, offer for sale, sale, and/or importation of Epanova™ by Defendants will induce and/or contribute to infringement of the '662 patent under 35 U.S.C. §§ 271(b) and (c).

48. The commercial manufacture, offer for sale, sale and/or importation of Epanova™ in violation of Plaintiff's patent rights will cause harm to Plaintiff for which damages are inadequate.

49. Unless Defendants are enjoined from actively inducing and contributing to the infringement of the '662 patent, sales of Epanova™ by Defendants will cause Plaintiff irreparable injury for which damages are an inadequate remedy.

PRAYER FOR RELIEF

Plaintiff respectfully prays for the following relief:

(1) That this Court issue a declaration under 28 U.S.C. § 2201 that if Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf engage in the commercial manufacture, offer for sale, sale and/or importation of Epanova™, it will constitute infringement of the '662 patent under 35 U.S.C. §§ 271(b) and (c);

(2) That this Court enter judgment that Defendants' manufacture, use, offer for sale and/or importation of Epanova™ infringes the '662 Patent under 35 U.S.C. §§ 271(b) and (c);

(3) That following the launch of Epanova™, this Court enter judgment against Defendants for money damages under 35 U.S.C. § 287 sustained as a result of Defendants' infringement of the '662 Patent and order an accounting of any infringing sales not presented at trial and an award of any additional damages for any such infringing acts;

(4) That this Count find that this is an exceptional case under 35 U.S.C. § 285, and that Plaintiff be awarded its reasonable attorneys' fees and costs;

(5) That this Court award such other and further relief as it may deem just and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff hereby requests a trial by jury on all issues so triable.

Dated: June 20, 2014

FISH & RICHARDSON P.C.

By: */s/ Robert M. Oakes*

Susan M. Coletti (#4690)
Robert M. Oakes (#5217)
222 Delaware Avenue, 17th Floor
P.O. Box 1114
Wilmington, DE 19899
Telephone: (302) 652-5070
Facsimile: (302) 652-0607
coletti@fr.com; oakes@fr.com

OF COUNSEL:

Jonathan E. Singer
John C. Adkisson
FISH & RICHARDSON P.C.
3200 RBC Plaza
60 South Sixth Street
Minneapolis, MN 55402
Telephone: (612) 335-5070
singer@fr.com; adkisson@fr.com

Attorneys for Plaintiff Amarin Pharmaceuticals Ireland Limited

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