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, allege 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 actual case or controversy 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, upon approval of Epanova™ by the United States Food and Drug Administration ("FDA"), 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 9, 2013, Omthera announced that it had submitted a New Drug Application to the FDA seeking regulatory approval for the marketing and sale of Epanova™ as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

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

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

19. On or about September 18, 2013, AstraZeneca announced via a press release that the FDA had accepted the New Drug Application for Epanova™ for review. AstraZeneca's press release states that "The NDA submission for Epanova was filed by Omthera Pharmaceuticals, now a wholly-owned subsidiary of AstraZeneca, as a 505(b)(1) application in July 2013." The press release also refers to pharmacokinetic and clinical studies conducted by Defendants to evaluate the safety and efficacy of Epanova™ that were submitted to the FDA in support of regulatory approval. A copy of the press release is attached to this Complaint as Exhibit B.

20. AstraZeneca's press release states that the Prescription Drug User Fee Act ("PDUFA") goal date for the FDA to approve the marketing and sale of Epanova™ is May 5, 2014.

21. On information and belief, upon approval by the FDA, Omthera and AstraZeneca, working in concert, intend to and will engage in the commercial manufacture, sale, offer for sale, and/or importation of Epanova™, including in this judicial district.

COUNT I

(Declaratory Judgment of Infringement of the '662 Patent

under 35 U.S.C. § 271(b) and (c))

22. Paragraphs 1 to 21 are incorporated herein as set forth above.

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

24. Defendants have actual knowledge of the '662 patent no later than the date of filing this Complaint.

25. The use of Epanova™ by patients and/or doctors directly infringes at least claim 1 of the ’662 patent.

26. 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™.

27. 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

28. Defendants’ acts described in paragraphs 26 and 27 will be done with knowledge of the ’662 patent and with the intent to encourage infringement.

29. 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).

30. On information and belief, Defendants know or should know Epanova™ will be 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.

31. 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.

32. Defendants’ acts described in paragraphs 29 through 31 will be done with knowledge of the ’662 patent and with the intent to encourage infringement.

33. On information and belief, Defendants intend to, and will, actively induce and contribute to the infringement of the '662 patent when Epanova™ is approved by the FDA, and plan and intend to, and will, do so immediately and imminently upon approval.

34. 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).

35. 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.

36. 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:

a) That a declaration be issued 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);

b) If Defendants engage in the commercial manufacture, offer to sell, sale or importation of Epanova™ prior to the expiration of the '662 patent, as extended by any

applicable period of exclusivity, an injunction be entered under at least 35 U.S.C. § 283 enjoining such conduct;

c) If Defendants engage in the commercial manufacture, offer to sell, sale or importation of Epanova™ prior to the expiration of the ’662 patent, a judgment against Defendants for money damages under 35 U.S.C. § 287 sustained as a result of Defendants’ infringement of the ’662 patent and an accounting of any infringing sales not presented at trial and an award of any additional damages for any such infringing sales;

d) That this is an exceptional case under 35 U.S.C. § 285, and that Plaintiff be awarded its reasonable attorneys’ fees and costs;

e) 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: March 4, 2014

FISH & RICHARDSON P.C.

By: */s/ Susan M. Coletti*

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