IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LUPIN ATLANTIS HOLDINGS S.A.,

Plaintiff,

v.

MYLAN INC., MYLAN PHARMACEUTICALS, INC., and ETHYPHARM S.A.,

Defendants.

COMPLAINT

Plaintiff Lupin Atlantis Holdings S.A., by its attorneys, for its complaint against Mylan Inc. and Mylan Pharmaceuticals, Inc. (collectively, "Mylan") and Ethypharm S.A., allege as follows:

THE PARTIES

1. Plaintiff Lupin Atlantis Holdings S.A. ("Lupin Atlantis") is a corporation organized and existing under the laws of Switzerland, with a principal place of business at Bachstrasse 56, 8200 Schaffhausen SH, Switzerland.

2. Upon information and belief, Defendant Mylan Inc. is a company organized and existing under the laws of the Commonwealth of Pennsylvania with a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

3. Upon information and belief, Mylan Inc. is in the business of, among other activities, manufacturing and selling copies of branded pharmaceutical products that are

used and sold throughout the United States, including in the Commonwealth of Pennsylvania and in this judicial district.

4. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505 and is a wholly-owned subsidiary of Mylan Inc.

5. Upon information and belief, Mylan Pharmaceuticals, Inc. is in the business of, among other activities, offering for sale, selling and/or importing copies of branded pharmaceutical products throughout the United States, including in the Commonwealth of Pennsylvania and in this judicial district.

6. Upon information and belief, Mylan Pharmaceuticals, Inc. makes regulatory submissions to the United States Food and Drug Administration ("FDA"), including submissions on behalf of Mylan Inc.

7. Upon information and belief, Defendant Ethypharm S.A. ("Ethypharm") is a corporation organized and existing under the laws of France, with its principal offices at 194 Bureaux de la Colline, 922 13 St. Cloud, France.

8. Upon information and belief, Mylan Pharmaceuticals, Inc. and Mylan Inc. collaborated in the research and development of Mylan's Abbreviated New Drug Application ("ANDA") No. 202579 for capsules that contain 43 mg and 130 mg of fenofibrate as the active ingredient ("the Mylan ANDA Product"), continue to collaborate in seeking approval of that application by the FDA, and intend to collaborate in the commercial manufacture, marketing, offer for sale and sale of the Mylan ANDA Product throughout the United States, including in the Commonwealth of Pennsylvania and in this judicial district, in the event the FDA approves the Mylan ANDA.

JURISDICTION AND VENUE

9. This is a civil action arising under the patent laws of the United States, Title 35, United States Code, for infringement of U.S. Patent 7,101,574 ("the '574 patent") and U.S. Patent No. 7,863,331 ("the '331 patent"). This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

10. Upon information and belief, Mylan Inc. is subject to personal jurisdiction in this judicial district because it has purposely availed itself of the benefits and protections of this Commonwealth's laws such that it should reasonably anticipate being haled into court in this judicial district. Mylan Inc. is a Pennsylvania company. Upon information and belief, Mylan Inc. markets and sells generic drugs throughout the United States, and in particular within this judicial district, and therefore Mylan Inc. has engaged in systematic and continuous business within this judicial district. In addition, and upon information and belief, Mylan Inc. controls and dominates Mylan Pharmaceuticals, Inc., and thus the activities of the former entity in this judicial district are attributable to Mylan Inc.

11. Upon information and belief, Mylan Pharmaceuticals, Inc. is subject to personal jurisdiction in this judicial district because, *inter alia*, Mylan Pharmaceuticals, Inc., alone and through its parent Mylan Inc., has purposely availed itself of the benefits and protections of this Commonwealth's laws such that it should reasonably anticipate being haled into court in this judicial district. On information and belief, Mylan Pharmaceuticals, Inc., alone and through its parent Mylan Inc., markets and sells generic drugs throughout the United States, and in particular within this judicial district, and therefore Mylan Pharmaceuticals, Inc. has engaged in systematic and continuous business within this judicial district.

12. Upon information and belief, Mylan Pharmaceuticals, Inc. and Mylan Inc. market Mylan's generic drug products to persons residing within this judicial district, for example, via their website.

13. Upon information and belief, Mylan Pharmaceuticals, Inc. and Mylan Inc. offer Mylan's generic drug products for sale to persons residing within this judicial district on third-party websites that these persons can use to purchase Mylan products for shipment to and within this judicial district.

14. Upon information and belief, persons residing within this judicial district purchase generic drug products, including Mylan products, from Mylan Inc. (itself or through its wholly-owned subsidiary Mylan Pharmaceuticals, Inc.) in this judicial district.

15. Upon information and belief, persons residing within this judicial district purchase generic drug products, including Mylan products, from Mylan Pharmaceuticals, Inc. in this judicial district.

16. Upon information and belief, Mylan Inc. (itself or through its wholly-owned subsidiary Mylan Pharmaceuticals, Inc.) receives revenue from the sales and marketing of generic drug products, including Mylan products, within this judicial district.

17. Upon information and belief, Mylan Pharmaceuticals, Inc. receives revenue from the sales and marketing of generic drug products, including Mylan products, within this judicial district.

18. Upon information and belief, Mylan Inc., or through its wholly-owned subsidiary Mylan Pharmaceuticals, Inc., intends to market and sell the Mylan ANDA Product, if approved, to residents of this judicial district.

19. Upon information and belief, Mylan Pharmaceuticals, Inc. and Mylan Laboratories Inc., the predecessor company to Mylan Inc., did not object to personal jurisdiction or venue in this judicial district in Civil Action No. 2:06-cv-1797-MSG (E.D.Pa.) and its multiple related proceedings.

20. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals, Inc. did not contest or otherwise object to personal jurisdiction or venue in this judicial district in Civil Action No. 2:11-cv-01939-GP (E.D.Pa.), which action concerns the same Mylan ANDA (No. 202579) and patent that are the subject of this Complaint.

21. Upon information and belief, Ethypharm is in the business of, among other activities, manufacturing pharmaceutical products for importation into and sale throughout the United States and promotes the importation and sale of such products, including in the Commonwealth of Pennsylvania and in this judicial district.

22. Mylan Pharmaceuticals, Inc., Mylan Inc., and Ethypharm are subject to personal jurisdiction in this judicial district.

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

BACKGROUND

24. Lupin Atlantis is the owner of the approved New Drug Application ("NDA") No. 21-695 for ANTARA® capsules.

25. On information and belief, Mylan Pharmaceuticals Inc. submitted ANDA No. 202579 to the FDA under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic copies of ANTARA® capsules.

26. The ANTARA® capsules contain 43 mg and 130 mg of fenofibrate as the active ingredient, and are currently approved for the treatment of hypercholesterolemia and hypertriglyceridemia.

27. Upon information and belief, the Mylan ANDA Product that is the subject of Mylan's ANDA No. 202579 are capsules containing 43 mg and 130 mg of fenofibrate as the active ingredient, for the treatment of hypercholesterolemia and hypertriglyceridemia.

28. On September 5, 2006, the U.S. Patent and Trademark Office ("USPTO") duly and legally issued the '574 patent titled "Pharmaceutical Composition Containing Fenofibrate and the Preparation Method." A true and correct copy of the '574 patent is attached hereto as Exhibit A.

29. On January 4, 2011, the USPTO duly and legally issued the '331 patent, titled "Pharmaceutical Composition Containing Fenofibrate and Method for the Preparation Thereof." A true and correct copy of the '331 patent is attached hereto as Exhibit B.

30. Ethypharm is the owner of the '574 patent, which discloses and claims, *inter alia*, a pharmaceutical composition containing fenofibrate and a method for preparing the composition.

31. Ethypharm also is the owner of the '331 patent, which discloses and claims, *inter alia*, methods of treatment using compositions containing fenofibrate.

32. Lupin Atlantis holds a license from Ethypharm under the '574 and '331 patents that contains provisions granting Lupin Atlantis the right to enforce the '574 and '331 patents in the case of an ANDA filing by a third party.

33. As owner of the '574 and '331 patents and licensor of the '574 and '331 patents to Lupin Atlantis, Defendant Ethypharm is jointly interested with, and contractually obligated to cooperate with, Lupin Atlantis in this cause of action, including without limitation joining this action if necessary. Although requested to file suit as Co-Plaintiff, Ethypharm has not, as of the date of the filing of this action, agreed to do so. For that reason, Ethypharm is named as a defendant.

34. Upon information and belief, Mylan Inc. sent a letter dated February 25, 2011, to Lupin Atlantis, Laboratoires des Produits Ethiques Ethypharm, and Ethypharm S.A. which purported to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) (the "First Notice Letter"). The First Notice Letter purportedly advised Lupin Atlantis and Ethypharm that Mylan's ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to both the '574 and '331 patents, that no valid and enforceable claim of the '574 patent would be infringed by the manufacture, importation, use, sale or offer for sale of the Mylan ANDA Product containing either 43 mg or 130 mg of fenofibrate, and that no valid and enforceable claim of the '331 patent would be infringed by the manufacture, importation, use, sale or offer for sale of the Mylan ANDA Product containing 43 mg of fenofibrate.

35. Upon information and belief, Mylan Pharmaceuticals, Inc. submitted Mylan ANDA No. 202579 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of a generic copy of the ANTARA® product prior to the expiration of the '574 and '331 patents.

36. Upon information and belief, the Mylan ANDA contains a Paragraph IV Certification asserting that, in its opinion, the '574 and '331 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of the Mylan ANDA Product.

37. By filing ANDA No. 202579 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Mylan ANDA Product prior to the expiration of the '574 and '331 patents, Mylan has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, Mylan plans to commercially use, offer for sale,

and/or sell the Mylan ANDA Product, and/or to induce or contribute to such activity, and by such actions Mylan would infringe one or more claims of the '574 patent and the '331 patent under 35 U.S.C. § 271(a), (b) and/or (c).

38. Upon information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. participated in, contributed to, aided, and/or induced the submission of Mylan ANDA No. 202579 and its Paragraph IV Certification to the FDA. Additionally, upon information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. will market and/or distribute the Mylan ANDA Product in the United States, and within this judicial district, if Mylan ANDA No. 202579 is approved by the FDA. Mylan Pharmaceuticals Inc. and Mylan Inc. thus are jointly and severally liable for infringement of the '574 and '331 patents.

39. An action was filed in the Eastern District of Pennsylvania within 45 days of receipt by Lupin Atlantis and Ethypharm of the First Notice Letter, which purportedly advised Lupin Atlantis and Ethypharm of Mylan's Paragraph IV Certification with respect to the '574 and '331 patents. This action has been designated Civil Action No. 2:11-cv-01930-GP, and has been assigned to the Honorable Gene E.K. Pratter.

COUNT I FOR PATENT INFRINGEMENT

(Infringement of the '331 patent under 35 U.S.C. § 271(e)(2))

40. Lupin Atlantis incorporates paragraphs 1-39 of this Complaint as if fully set forth herein.

41. Upon information and belief, Mylan Inc. sent a letter dated April 5, 2011, to Lupin Atlantis, Laboratoires des Produits Ethiques Ethypharm, and Ethypharm S.A. which purported to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) (the "Second Notice Letter"). The Second Notice Letter purportedly advised Lupin Atlantis and Ethypharm that Mylan's ANDA contains a Paragraph IV Certification with respect to the '331 patent, and that no valid, enforceable claim of the '331 patent would be infringed by the manufacture, importation, use, sale or offer for sale of the Mylan ANDA Product containing 130 mg of fenofibrate.

42. Upon information and belief, the '331 patent is listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") relative to ANTARA®.

43. Upon information and belief, Mylan Pharmaceuticals Inc. submitted Mylan ANDA No. 202579 to the FDA for purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of a generic copy of the ANTARA® product prior to the expiration of the '331 patent.

44. Upon information and belief, the Mylan ANDA contains a Paragraph IV Certification asserting that, in its opinion, the '331 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of the Mylan ANDA Product containing 130 mg of fenofibrate.

45. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '331 patent, is "invalid or will not be infringed by the manufacture, use, offer for sale or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

46. Upon information and belief, at the time the Second Notice Letter was mailed (this letter purportedly serving as a notice of Paragraph IV Certification relative to the '331 patent), Mylan Inc. and/or Mylan Pharmaceuticals Inc. was aware of the statutory provisions and regulations referred to in paragraph 45, *supra*.

47. Mylan's Second Notice Letter is required by statute and regulation to provide a full and detailed explanation regarding all bases for noninfringement of the '331 patent but fails to do so. While providing some information on its noninfringement positions, Mylan fails to provide a full explanation of such bases, stating in its Second Notice Letter that it "*reserves the right to assert additional grounds*, reasons, and/or

authorities that any or all of the claims of these patents are invalid, unenforceable, and/or not *infringed*" by the Mylan ANDA Product (emphasis added).

48. Mylan's Second Notice Letter is required by statute and regulation to provide a full and detailed explanation regarding all bases for invalidity of the '331 patent, but does not allege invalidity of any claims of the '331 patent. Instead, Mylan states in its Second Notice Letter that it "*reserves the right to assert* additional grounds, reasons, and/or authorities that any or all of the claims of *these patents are invalid*, unenforceable, and/or not infringed" by the Mylan ANDA Product (emphasis added).

49. Mylan's Second Notice Letter is required by statute and regulation to provide a full and detailed explanation regarding alleged unenforceability of the patents-in-suit, but does not allege unenforceability or allege inequitable conduct of the '331 patent. Instead, Mylan states in its Second Notice Letter that it "*reserves the right to assert* additional grounds, reasons, and/or authorities that any or all of the claims of *these patents are* invalid, *unenforceable*, and/or not infringed" by the Mylan ANDA Product (emphasis added).

50. Mylan's Second Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

51. By filing ANDA No. 202579 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Mylan ANDA Product prior to the expiration of the '331 patent, Mylan has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, Mylan plans to commercially use, offer for sale, and/or sell the Mylan ANDA Product, and/or to induce or contribute to such activity, and by such actions Mylan would infringe one or more claims of the '331 patent under 35 U.S.C. § 271(a), (b) and/or (c).

52. Upon information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. participated in, contributed to, aided, and/or induced the submission of Mylan ANDA No. 202579 and its Paragraph IV Certification to the FDA. Additionally, upon information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. will market and/or distribute the Mylan ANDA Product containing 130 mg of fenofibrate in the United States, and within

this judicial district, if Mylan ANDA No. 202579 is approved by the FDA. Mylan Pharmaceuticals Inc. and Mylan Inc. thus are jointly and severally liable for infringement of the '331 patent.

53. This action is being filed within 45 days of receipt by Lupin Atlantis and Ethypharm of the Second Notice Letter, which purportedly advised Lupin Atlantis and Ethypharm of Mylan's Paragraph IV Certification with respect to the '331 patent concerning the Mylan ANDA product containing 130 mg of fenofibrate.

54. Upon information and belief, Mylan had actual and constructive notice of the '331 patent prior to filing Mylan's Paragraph IV Certification with respect to the '331 patent concerning the Mylan ANDA product containing 130 mg of fenofibrate, and Mylan's infringement of the '331 patent has been, and continues to be, willful.

55. Lupin Atlantis is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Mylan ANDA No. 202579 be a date that is not earlier than the expiration of the '331 patent, or any later expiration of exclusivity for the '331 patent to which it may become entitled.

56. Lupin Atlantis will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to infringement of the '331 patent, as Lupin Atlantis has no adequate remedy at law

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Lupin Atlantis respectfully requests the following relief:

A. A judgment that Mylan has infringed one or more claims of the '331 patent under 35 U.S.C. § 271(e)(2);

B. An order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of Mylan's ANDA No. 202579 be not earlier than the expiration date of the '331 patent or any later expiration of exclusivity for this patent to which it may become entitled;

C. A permanent injunction restraining and enjoining Mylan Pharmaceuticals Inc. and Mylan Inc. and each of their officers, agents, servants, employees and those persons acting in privity or concert with them, from engaging in the commercial

manufacture, use, offer for sale or sale within the United States or its territories, or importation into the United States or its territories, of the Mylan ANDA Product, or any product that infringes the '331 patent;

D. Damages and treble damages from Mylan from any commercial activity constituting infringement of the '331 patent;

E. That Defendant Ethypharm be realigned and named as a Plaintiff in this action;

F. Costs and expenses in this action; and

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

Respectfully submitted,

Date: May 12, 2011

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