IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

LUPIN ATLANTIS HOLDINGS S.A. and ETHYPHARM S.A., *Plaintiffs,* v. PADDOCK LABORATORIES, INC. and CEROVENE, INC., *Defendants.*	File No. _____ **COMPLAINT**

COMPLAINT

Plaintiffs Lupin Atlantis Holdings S.A. and Ethypharm S.A., by their attorneys, for their complaint against Paddock Laboratories, Inc. and Cerovene, Inc. 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. Plaintiff 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.

3. Upon information and belief, Defendant Paddock Laboratories, Inc. ("Paddock") is a company organized and existing under the laws of Minnesota,

with a principal place of business at 3940 Quebec Avenue North, Minneapolis, Minnesota 55427.

4. Upon information and belief, Paddock is in the business of, among other activities, manufacturing and selling copies of branded pharmaceutical products which are used and sold throughout the United States, including in the State of New York and in this judicial district.

5. Upon information and belief, Defendant Cerovene, Inc. ("Cerovene") is a company organized and existing under the laws of Delaware, with a principal place of business at 612 Corporate Way, Suite 10, Valley Cottage, New York 10989.

6. Upon information and belief, Cerovene is in the business of, among other things, developing and manufacturing dosage forms and delivery systems for pharmaceutical products which are used and sold throughout the United States, including in the State of New York and in this judicial district.

7. Upon information and belief, consistent with its practice with respect to other generic products, Paddock holds Abbreviated New Drug Application ("ANDA") No. 91-362 for capsules that contain 43 mg and 130 mg of fenofibrate as the active ingredient ("the Paddock ANDA Product"), is seeking approval of that application by the U.S. Food and Drug Administration ("FDA"), and intends to manufacture, market, offer for sale, and sell the Paddock ANDA Product throughout the United States, including in the State of New York and in this judicial district, in the event the FDA approves Paddock ANDA No. 91-362.

8. Upon information and belief, Cerovene has and will continue to aid, abet, induce, contribute to, and otherwise participate in the infringement of U.S. Patent No. 7,101,574 by, *inter alia*, supplying the pharmaceutical dosage form technology used in development of the Paddock ANDA Product, and has otherwise aided and abetted Paddock in the preparation and submission of Paddock's ANDA No. 91-362 in its preparations to commercialize the Paddock ANDA Product upon FDA approval of Paddock's ANDA No. 91-362.

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 No. 7,101,574 ("the '574 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, this Court has personal jurisdiction over Paddock because it has its principal place of business in Minnesota, is a resident and citizen thereof, and has purposefully availed itself of the benefits and protections of this State's laws such that it should reasonably anticipate being haled into court in this judicial district. On information and belief, Paddock markets and sells generic drugs throughout the United States, and in particular within this judicial district, and therefore, Paddock has engaged in systematic and continuous business within this judicial district.

11. Upon information and belief, Paddock markets Paddock's generic drug products to persons residing within this judicial district, for example, via its website.

12. Upon information and belief, Paddock offers Paddock's generic drug products for sale to persons residing within this judicial district on third-party websites that these persons can use to purchase Paddock products for shipment to and within this judicial district.

13. Upon information and belief, persons residing within this judicial district purchase generic drug products, including Paddock products, from Paddock in this judicial district.

14. Upon information and belief, Paddock receives revenue from the sales and marketing of generic drug products, including Paddock products, within this judicial district.

15. Upon information and belief, Paddock intends to market and sell the Paddock ANDA Product, if approved, to residents of this judicial district.

16. Upon information and belief, Cerovene is subject to personal jurisdiction in this judicial district because Cerovene has purposefully availed itself of the benefits and protections of this State's laws such that it should reasonably anticipate being haled into court in this judicial district. On information and belief, Cerovene develops and manufactures dosage forms and delivery systems for pharmaceutical products, which are used and sold through the United States, including in the State of Minnesota, and has conducted business

transactions with a Minnesota company regarding such pharmaceutical dosage forms and delivery systems.

17. Upon information and belief, Cerovene markets its products and services to persons residing within this judicial district, for example, via its website.

18. Upon information and belief, Cerovene receives revenue from the sales of its products and services within this judicial district.

19. Paddock and Cerovene are subject to personal jurisdiction in this judicial district.

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

BACKGROUND

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

22. On information and belief, Paddock submitted ANDA No. 91-362 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.

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

24. Upon information and belief, Cerovene is the assignee of U.S. Patent Application No. 12/466,261 ("the '261 Application"), published on November 18, 2010 as U.S. Patent Publication No. 2010/0291201 A1, which is entitled "Coated Pharmaceutical Capsule Dosage Form." A true and correct copy of the '261 application publication is attached hereto as Exhibit A.

25. The '261 application is directed to "pharmaceutical compositions in unit dose form comprising: (a) a hard or soft capsule containing a fill consisting of one or more inert ingredients . . . in a pharmaceutically acceptable vehicle, and (b) one or more coatings on the capsule, wherein at least one coating comprises at least one [active pharmaceutical ingredient]." *See* Exhibit A, Paragraph [0018]. The '261 application further states that "[i]n some preferred embodiments, the [active pharmaceutical ingredient] comprises a fibrate, such as fenofibrate." *See* Exhibit A, Paragraph [0025].

26. Example 1 of the '261 application provides a formulation containing 130 mg of micronized fenofibrate, and states that "when tested against the product marketed under the brand name ANTARA® capsules, the above formulation's in vitro dissolution matches very well." *See* Exhibit A, Paragraph [0076]. Example 1 describes the formulation as consisting of a capsule filled with inert ingredients having a "drug suspension" containing the micronized fenofibrate layered onto the outer surface of the filled capsules. *See* Exhibit A, Paragraphs [0061]-[0076].

27. Upon information and belief, the Paddock ANDA Product that is the subject of Paddock's ANDA No. 91-362 contains 43 mg and 130 mg of

micronized fenofibrate as the active ingredient, and the Paddock ANDA seeks approval for the treatment of hypercholesterolemia and hypertriglyceridemia.

28. Upon information and belief, Paddock sent a letter dated May 16, 2009, addressed to Ethypharm and the former ANTARA® NDA holder ("Paddock's First Notice Letter"), which purported to comply with the provisions of 21 U.S.C. § 355(j)(2)(B). This letter purportedly advised Ethypharm and the former NDA holder that Paddock's ANDA contained a Paragraph IV certification with respect to the '574 patent, and that no valid, enforceable claim of the '574 patent would be infringed by the manufacture, importation, use, sale, or offer for sale of the Paddock ANDA Product. A true and correct redacted copy of Paddock's First Notice Letter is attached hereto as Exhibit B.

29. Paddock's First Notice Letter made the following statements: "Paddock's proposed product comprises a fenofibrate composition coated on the outside of a capsule"; "Paddock's proposed formulation consists of a capsule coated with fenofibrate"; and, "Paddock coats the entire capsule of its proposed product with micronized fenofibrate." *See* Exhibit B at 4, 21, and 26.

30. In a prior litigation which was dismissed, namely *Paddock Laboratories, Inc. v. Ethypharm S.A., et al.*, Civil Action No. 3:09-cv-03779-GEB (D.N.J.), Paddock sought declaratory judgment that the Paddock ANDA Product purportedly described in Paddock's First Notice Letter did not infringe the claims of the '574 patent. In this prior litigation, Paddock filed an opposition brief which stated that "Paddock has informed the FDA that it will amend its ANDA to simply

place each of its ***presently coated capsules*** into a little larger-sized, rapidly dissolving capsule." A true and correct copy of Paddock's Memorandum in Support of the Opposition by Paddock Laboratories, Inc. to Ethypharm S.A.'s Motion to Dismiss the Amended Complaint, Civil Action No. 3:09-cv-03779-GEB (D.N.J.), is attached here to as Exhibit C. *See* Exhibit C at 17.

31. Paddock sent an undated letter, which was received by the domestic agent of Lupin Atlantis on December 21, 2010, addressed to Lupin Atlantis and Ethypharm, and which also purported to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) ("Paddock's Second Notice Letter"). This letter purported to advise Lupin Atlantis and Ethypharm that Paddock's ANDA contains a Paragraph IV certification with respect to the '574 patent, and that no valid, enforceable claim of the '574 patent would be infringed by the manufacture, importation, use, sale, or offer for sale of the Paddock ANDA Product.

32. Upon information and belief, the '574 patent was properly listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") relative to ANTARA® on the date Paddock filed ANDA No. 91-362.

33. Upon information and belief, Paddock submitted Paddock ANDA No. 91-362 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 '574 patent.

34. Upon information and belief, the Paddock ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") asserting that, in Paddock's opinion, the '574 patent is invalid or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of the Paddock ANDA Product.

35. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), an ANDA applicant is required to certify that the subject patent, here the '574 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 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 of supporting the allegation."

36. Upon information and belief, at the time Paddock's Second Notice Letter was mailed (the letter that purported to serve as a notice of Paragraph IV certification relative to the '574 patent, i.e., "Paddock's Notice of Certification"),

Paddock was aware of the statutory provisions and regulations referred to in paragraph 35, *supra*.

37. Paddock's Second Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding all bases for noninfringement, does not do so and provides only conclusory statements.

38. Paddock's Second Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding alleged unenforceability, does not allege unenforceability or allege inequitable conduct of the '574 patent.

39. Paddock'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.

THE PATENT-IN-SUIT

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

41. 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.

42. Lupin Atlantis holds a license from Ethypharm under the '574 patent, which contains provisions concerning the right to enforce the '574 patent in the case of an ANDA filing by a third party.

43. As owner of the '574 patent and licensor of the '574 patent to Lupin Atlantis, Plaintiff Ethypharm is jointly interested with, and contractually obligated to cooperate with, Lupin Atlantis in this cause of action.

COUNT FOR PATENT INFRINGEMENT

44. Lupin Atlantis and Ethypharm incorporate paragraphs 1-43 of this Complaint as if fully set forth herein.

45. By filing ANDA No. 91-362 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 Paddock ANDA Product prior to the expiration of the '574 patent, Paddock has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, Paddock plans to commercially use, offer for sale, and/or sell the Paddock ANDA Product, and/or to induce or contribute to such activity, and by such actions Paddock would infringe one or more claims of the '574 patent under 35 U.S.C. § 271(a), (b), and/or (c).

46. Upon information and belief, Paddock will market and/or distribute the Paddock ANDA Product in the United States, and within this judicial district, if Paddock's ANDA No. 91-362 is approved by the FDA.

47. To further investigate whether Paddock's ANDA Product infringed any of the '574 patent claims, in a letter dated January 18, 2011, Lupin Atlantis

requested access to certain documents and information, as well as access to Paddock's ANDA No. 91-362 and Drug Master File and physical samples of, *inter alia*, the final product that Paddock intends to market upon approval of Paddock ANDA No. 91-362 by the FDA. Lupin Atlantis requested the information to permit further evaluation and investigation relating to Paddock's ANDA and its ANDA Product.

48. In response, Paddock required that any technical expert that may be selected by Lupin Atlantis would need to be identified to and vetted by Paddock before any Paddock information could be provided to such technical expert.

49. Further, Paddock has refused to include any agreement to provide Lupin Atlantis with physical samples of, *inter alia*, the final Paddock ANDA Product in the Offer of Confidential Access.

50. Paddock has not provided access to any physical samples of the Paddock ANDA Product as requested by Lupin Atlantis.

51. Paddock's failure to agree to provide Lupin Atlantis with the requested samples under terms that would have allowed Lupin Atlantis a reasonable opportunity to evaluate Paddock's otherwise unsupported, conclusory statements in Paddock's Second Notice Letter precluded Lupin Atlantis from fully evaluating the issues in this case.

52. Lupin Atlantis brings this action, in part, to employ the judicial process and the aid of discovery to obtain under appropriate judicial safeguards

information to confirm that Paddock's ANDA Product infringes one or more claims of the '574 patent.

53. This action is being filed within 45 days of receipt by Lupin Atlantis and Ethypharm of Paddock's Second Notice Letter, which purported to advise Lupin Atlantis and Ethypharm of Paddock's Paragraph IV certification with respect to the '574 patent.

54. Upon information and belief, Paddock had actual and constructive notice of the '574 patent prior to filing Paddock ANDA No. 91-362, and Paddock's infringement of the '574 patent has been, and continues to be, willful.

55. Upon information and belief, Cerovene is jointly and severally liable for any infringement of the '574 patent because Cerovene participated in, contributed to, aided, abetted, and/or induced the submission of Paddock's ANDA No. 91-362 by providing material information, including dosage form technology, to Paddock in connection with the preparation and submission of Paddock's ANDA No. 91-362, which information was relied upon and used by Paddock in the submission of ANDA No. 91-362. The information relied upon to support this allegation in part relates to the extreme similarities between the apparent fenofibrate coated capsule configuration of Paddock's product that is the subject of ANDA No. 91-362 and the fenofibrate coated capsule configuration that is the subject of Cerovene's published U.S. '261 application, which specifically relates to a capsule product that contains inert ingredients inside of the capsule and a coating on the outside of the capsule that may be fenofibrate. To Lupin Atlantis'

knowledge, Cerovene's published U.S. '261 application is the first and only other time that such a coated capsule product has ever been described. Moreover, Cerovene's '261 application makes specific bioequivalence-related comparisons to Lupin Atlantis' ANTARA® fenofibrate capsule product. Cerovene's published '261 application was filed a short time prior to filing by Paddock of its ANDA No. 91-362, which seeks approval to market a generic version of Lupin Atlantis' ANTARA® product. If ANDA No. 91-362 is approved by the FDA, the commercial sale and offer for sale within the United States of the Paddock ANDA Product, which is likely made using the dosage form technology supplied by Cerovene, will constitute infringement of the '574 patent.

56. In addition, upon information and belief, Cerovene has and will continue to supply material information regarding the dosage form of the Paddock ANDA Product to Paddock for use in the subsequent commercial sale and offer for sale within the United States under Paddock's ANDA No. 91-362, in violation of the '574 patent.

57. By supplying and continuing to supply material information to Paddock regarding the Paddock ANDA Product as stated above, and encouraging Paddock to obtain approval to engage in the commercial sale of Paddock's generic version of Lupin Atlantis' ANTARA® fenofibrate product, Cerovene will knowingly and intentionally contribute to, aid, abet, and/or induce the infringement of the '574 patent. Such acts constitute patent infringement under 35 U.S.C. §§ 271(a), 271(b), 271(c), and/or 271(e)(2).

58. Lupin Atlantis and Ethypharm are 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 Paddock ANDA No. 91-362 be a date that is not earlier than the expiration of the '574 patent, or any later expiration of exclusivity for the '574 patent to which it becomes entitled.

59. Lupin Atlantis and Ethypharm will be irreparably harmed if Paddock and Cerovene are not enjoined from infringing or actively inducing or contributing to infringement of the '574 patent, as Lupin Atlantis and Ethypharm have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Lupin Atlantis and Ethypharm respectfully request the following relief:

A. A judgment that Paddock has infringed one or more claims of the '574 patent under 35 U.S.C. § 271(e)(2);

B. A judgment that Cerovene has actively induced infringement of one or more claims of the '574 patent under 35 U.S.C. § 271(b);

C. An order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of Paddock's ANDA No. 91-362 be not earlier than the expiration date of the '574 patent or any later expiration of exclusivity for this patent to which it may become entitled;

D. A permanent injunction restraining and enjoining Paddock and its officers, agents, servants, employees, and those persons acting in privity or concert

with it, 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 Paddock ANDA Product, or any product that infringes the '574 patent;

E. Damages and treble damages from Paddock and Cerovene for any commercial activity constituting infringement of the '574 patent;

F. Costs and expenses in this action; and

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

Date: February 1, 2011

By: _____

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