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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PADDOCK LABORATORIES, INC., **Plaintiff,** **v.** **ETHYPHARM S.A.,** **Defendant.**	Civil Action No. _____ **COMPLAINT**

Plaintiff Paddock Laboratories, Inc. ("Paddock"), by its undersigned attorneys, for its Complaint against Defendant Ethypharm S.A. ("Ethypharm" or "Defendant"), a corporation organized and existing under the laws of the Republic of France with a United States affiliate Ethypharm Corporation, a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at 821 Alexander Road, Princeton, New Jersey 08540, alleges as follows:

NATURE OF THE ACTION

1. This is an action seeking a declaratory judgment of noninfringement of United States Patent No. 7,101,574 ("the '574 patent"; Exhibit A hereto) pursuant to the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*; the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(5)(C)(i); and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202; 21 U.S.C. § 355(j)(5)(C)(i)(II); and 35 U.S.C. § 271(e)(5).

3. This Court has personal jurisdiction over the Defendant based on, *inter alia*, its significant business activities in this judicial district such as soliciting business in and deriving substantial revenue from this judicial district, including through its United States affiliate Ethypharm Corporation, a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at 821 Alexander Road, Princeton, New Jersey 08540.

4. This Court has personal jurisdiction over the Defendant based on exclusive field-of-use licensing agreements of the '574 patent that impose obligations to enforce the '574 patent, and/or other activities that relate to the enforcement or defense of the '574 patent, with parties residing or regularly doing business in this judicial district.

5. Accordingly, this Court may assert personal jurisdiction and personal jurisdiction exists over Defendant.

6. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b), and 21 U.S.C. § 355(j)(5)(C)(i)(II) in that, *inter alia*, a substantial part of the events or omissions giving rise to the claims asserted occurred in this judicial district, including exclusive field-of-use licensing of the '574 patent with certain obligations to enforce the '574 patent, and/or other activities that relate to the enforcement or defense of the '574 patent, with parties residing or regularly doing business in this judicial district.

THE PARTIES

7. Plaintiff Paddock is a corporation organized and existing under the laws of the State of Minnesota, with its headquarters and principal place of business at 3940 Quebec Avenue North, Minneapolis, Minnesota 55427.

8. Upon information and belief, Defendant Ethypharm is a corporation organized and existing under the laws of the Republic of France, with a principal place of business at 194 Bureaux de la Colline, 922 13 Saint Cloud, France.

FACTUAL BACKGROUND

9. The '574 patent, entitled "Pharmaceutical composition containing fenofibrate and the preparation method" issued on September 5, 2006 to Laboratoires des Produits Ethiques Ethypharm. Upon information and belief, Ethypharm is currently the owner of the '574 patent.

10. Upon information and belief, on or about May 7, 2001, Ethypharm granted an exclusive field-of-use license to Reliant Pharmaceuticals LLC, a corporation with a principal place of business at 110 Allen Road, Liberty Corner, New Jersey 07938 ("the Ethypharm-Reliant license").

11. Upon information and belief, the Ethypharm-Reliant license agreement imposes obligations to enforce the '574 patent.

12. Upon information and belief, the Ethypharm-Reliant license is governed by the laws of the State of New Jersey.

13. Upon information and belief, pursuant to the Ethypharm-Reliant license, Reliant sought and obtained United States Food and Drug Administration ("FDA")-approval for, and marketed, sold and distributed ANTARA® (micronized fenofibrate) capsules, 43 mg and 130 mg ("the ANTARA® Product").

14. Upon information and belief, FDA approved ANTARA® under New Drug Application ("NDA") No. 21-695 on November 30, 2004 ("the ANTARA® NDA").

15. Upon information and belief, Ethypharm is the party directly responsible for the development, manufacture and entry of the ANTARA® Product into the fenofibrate market throughout the United States, including the State of New Jersey.

16. Upon information and belief, on or about August 2006, Reliant sold its rights under the '574 patent and to the ANTARA® Product to Oscient Pharmaceuticals Corporation ("Oscient"), a corporation registered to do business in the State of New Jersey, and with commercial sales and marketing operations at 23 Orchard Road, Skillman, New Jersey 08558 ("the Ethypharm-Oscient license").

17. Upon information and belief, Oscient assumed Reliant's duties and obligations under the Ethypharm-Reliant license, including but not limited to the obligation to launch and promote, and otherwise commercialize, the ANTARA® Product throughout the United States, including the State of New Jersey.

18. Upon information and belief, the Ethypharm-Oscient license agreement imposes obligations to enforce the '574 patent.

19. Upon information and belief, the Ethypharm-Oscient license is governed by the laws of the State of New Jersey.

20. Upon information and belief, Ethypharm, by virtue of the Ethypharm-Reliant license, caused FDA to list the '574 patent in FDA's publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the *Orange Book*") in connection with ANTARA® as a patent that could reasonably be asserted against anyone marketing or seeking to market unlicensed fenofibrate capsules.

21. Upon information and belief, Ethypharm, by virtue of the Ethypharm-Oscient license, continues to maintain the listing of the '574 patent in the *Orange Book* in connection with ANTARA®.

22. By listing and maintaining the listing of the '574 patent in the *Orange Book* in connection with ANTARA®, Ethypharm created and maintains a legal uncertainty that it would file a patent infringement action against Abbreviated New Drug Application ("ANDA") applicants seeking FDA-approval to market generic fenofibrate capsules.

23. Upon information and belief, Ethypharm has demonstrated an intent to prevent generic competition for ANTARA® by attempting to enforce the '574 patent against another ANDA applicant seeking FDA-approval to market generic fenofibrate capsules based on the ANTARA® NDA. *Oscient Pharmaceuticals Corp., Guardian II Acquisition Corp. and Ethypharm S.A. v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, No. 09-0083 (D. Md. filed Jan. 14, 2009) ("the Lupin action").

24. Upon information and belief, Lupin Ltd. and/or Lupin Pharmaceuticals, Inc. (collectively "Lupin") are the first generic applicant seeking FDA-approval to market generic fenofibrate capsules based on the ANTARA® NDA. As a result, Lupin is entitled to a generic marketing exclusivity period during which FDA may not approve other generic fenofibrate capsule ANDAs based on the ANTARA® NDA. *See* 21 U.S.C § 355(j)(5)(B)(iv).

25. Upon information and belief, the Lupin action was brought within a statutory 45-day period, staying FDA from granting final approval to Lupin's ANDA for 30 months subject to certain conditions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

26. Paddock filed ANDA No. 91-362 ("Paddock's ANDA") seeking FDA-approval to market generic fenofibrate capsules, 43 mg and 130 mg, based on the ANTARA® NDA ("Paddock's Proposed Product"). As part of Paddock's ANDA, Paddock included a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. 314.94(a)(12)(i)(A)(4) that the '574 patent will not be infringed by Paddock's Proposed Product, and/or the '574 patent is invalid, and seeking FDA-approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Paddock's Proposed Product prior to the expiration of the '574 patent ("Paddock's Paragraph IV Certification").

27. Paddock provided notice of its Paragraph IV Certification to Ethypharm by letter dated May 15, 2009 pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ("Paddock's Notice Letter"). Paddock's Notice Letter was accompanied by an offer of confidential access to Paddock's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) for the purpose of determining whether an infringement action should be brought.

28. Upon information and belief, Ethypharm received Paddock's Notice Letter on or about May 26, 2009.

29. Paddock's Notice Letter initiated a 45-day statutory period during which Ethypharm had the opportunity to file an action for patent infringement.

30. Before the 45-day statutory period expired, Paddock provided a confidential copy of Paddock's ANDA to Ethypharm's counsel.

31. Ethypharm did not bring an action for patent infringement before the 45-day period expired.

COUNT FOR RELIEF
(Declaratory Judgment of Noninfringement of the '574 Patent)

32. Paddock reasserts and realleges each of the foregoing paragraphs as if fully set forth herein.

33. Where no action for patent infringement is filed within the 45-day statutory period, a civil action may be brought by a generic applicant to obtain patent certainty pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(II), 35 U.S.C. § 271(e)(5), and 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, which allows Paddock to obtain a declaratory judgment with respect to the '574 patent.

34. Notwithstanding the fact that Ethypharm has not yet brought an action for patent infringement, Ethypharm is not precluded from bringing an action for patent infringement at a later time.

35. Ethypharm's conduct has created an uncertainty of legal rights with respect to the '574 patent and Paddock's ANDA.

36. Ethypharm has caused an injury-in-fact by bringing the Lupin action, thereby restraining Paddock from commercially marketing Paddock's noninfringing generic fenofibrate capsule products.

37. Paddock seeks FDA-approval to market Paddock's Proposed Products. By preparing and filing its ANDA, Paddock has made, and will continue to make, substantial preparations to make, use, sell, offer to sell, and/or import its Proposed Product in the United States before the expiration of the '574 patent.

38. A case or controversy exists between Paddock and Ethypharm concerning the noninfringement of the '574 patent, which requires a declaration of rights by this Court.

39. The '574 patent generally concerns a fenofibrate composition in the form of granules wherein each granule comprises a neutral microgranule on which is a composition of fenofibrate, a surfactant, and a binding cellulose derivative, in various amounts and relationships including, *inter alia*: (i) greater than or equal to 60% fenofibrate; (ii) between 2 to 15% binding cellulose derivative; and (iii) a mass ratio between 5/1 and 15/1 of fenofibrate to binding cellulose derivative.

40. Paddock does not infringe any claim of the '574 patent, literally or under the doctrine of equivalents, for at least the following reasons: Paddock's Proposed Product (i) contains no neutral microgranules; (ii) lacks more than 60% fenofibrate by weight; (ii) does not contain between 2 to 15% of a binding cellulose derivative; and (iv) does not contain a mass ratio of fenofibrate to binding cellulose derivative of between 5/1 and 15/1.

41. A definite and concrete, real and substantial, justiciable controversy exists that affects the legal relations of Paddock and Ethypharm, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

42. Paddock is entitled to obtain patent certainty with respect to its ANDA and the '574 patent in view of the totality of the circumstances, including but not limited to Ethypharm's conduct and as alleged herein.

43. Paddock's injury-in-fact is redressible by a declaratory judgment that Paddock's Proposed Product does not or will not infringe the '574 patent.

44. A declaration of rights between the parties is both appropriate and necessary to establish that Paddock's Proposed Product does not infringe any claim of the '574 patent, and allow FDA-approval of Paddock's ANDA, which Ethypharm's actions would otherwise deny Paddock. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I).

45. Paddock is entitled to a declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of Paddock's generic fenofibrate capsules, 43 mg and 130 mg, does not or will not, if marketed, infringe any claim of the '574 patent either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in its favor and against Defendants and grant the following relief:

(a) A judgment declaring that the making, using, selling, offering for sale, and/or importation of Paddock's generic fenofibrate capsules, 43 mg and 130 mg, does not and will not infringe any claim in the '574 patent;

(b) A judgment awarding Paddock its costs and attorneys' fees in this action; and

(c) A judgment awarding Paddock such other and further relief as this Court may deem just and proper.

Respectfully submitted,

Dated: July 30, 2009

s/ Arnold B. Calmann
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