IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

LUPIN ATLANTIS HOLDINGS S.A.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. _____
	:	
APOTEX INC., APOTEX CORP., and ETHYPHARM S.A.,	:	
	:	
Defendants.	:	

COMPLAINT

Plaintiff Lupin Atlantis Holdings S.A., by its attorneys, for its complaint against Apotex Inc., Apotex Corp. (collectively, "Apotex") 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 Apotex Inc. is a company organized and existing under the laws of Canada with a principal place of business at 150 Signet Drive, North York, Toronto, Ontario, Canada, M9L 1T9. Apotex Inc. is owned by Apotex Pharmaceutical Holdings Inc., which also owns Apotex Corp.

3. Upon information and belief, Apotex Inc. is, alone and/or through Apotex Corp., 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 this judicial district.

4. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware, and is owned by Apotex Pharmaceutical Holdings Inc., which also owns Apotex Inc. Apotex Corp. has a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

5. Upon information and belief, Apotex Corp. is in the business of, among other activities, offering for sale, selling and/or importing copies of branded pharmaceutical products manufactured by, among others, Apotex Inc., throughout the United States, including in this judicial district.

6. 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.

7. Upon information and belief, Apotex Inc. and Apotex Corp. collaborated in the research and development of Apotex's Abbreviated New Drug Application ("ANDA") No. 202252 for capsules that contain 43 mg and 130 mg of fenofibrate as the active ingredient ("the Apotex 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 Apotex ANDA Product throughout the United States, including in this judicial district, in the event the FDA approves the Apotex ANDA.

JURISDICTION AND VENUE

8. 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).

9. Upon information and belief, Apotex Inc. is subject to personal jurisdiction in this judicial district because it has purposely 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, Apotex Inc., alone and/or through Apotex Corp., markets and sells generic drugs throughout the United States, and in particular within this judicial district, and therefore Apotex Inc. has engaged in systematic and continuous business within this judicial district. In addition, and upon information and belief, Apotex Inc. controls and dominates Apotex Corp., and thus the activities of the latter entity in this judicial district are attributable to Apotex Inc.

10. Upon information and belief, Apotex Corp. is subject to personal jurisdiction in this judicial district because, *inter alia*, Apotex Corp., alone and/or with Apotex Inc., has purposely 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. Apotex Corp. is a Delaware corporation. In addition, and upon information and belief, Apotex Corp., alone and/or with Apotex Inc., markets and sells generic drugs throughout the United States, and in particular within this judicial district, and therefore Apotex Corp. has engaged in systematic and continuous business within this judicial district.

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

12. Upon information and belief, Apotex Corp. and Apotex Inc. offer Apotex's generic drug products for sale to persons residing within this judicial district on third-party

websites that these persons can use to purchase Apotex 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 Apotex products, from Apotex Inc. (itself or through Apotex Corp.) in this judicial district.

14. Upon information and belief, persons residing within this judicial district purchase generic drug products, including Apotex products, from Apotex Corp. in this judicial district.

15. Upon information and belief, Apotex Inc. (itself or through Apotex Corp.) receives revenue from the sales and marketing of generic drug products, including Apotex products, within this judicial district.

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

17. Upon information and belief, Apotex Inc., alone and/or through Apotex Corp., intends to market and sell the Apotex ANDA Product, if approved, to residents of this judicial district.

18. Upon information and belief, Apotex Inc. and Apotex Corp. admitted in Civil Action No. 1:08-cv-00021-LPS (D. Del.), in which an action against each of them was brought arising under, *inter alia*, the Patent Laws of the United States (35 U.S.C. § 1 *et seq.*), and the Hatch-Waxman Act (21 U.S.C. § 301 *et seq.*), that this district has personal jurisdiction over them and that venue in this judicial district was proper.

19. 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 this judicial district.

20. Apotex Inc., Apotex Corp., and Ethypharm are subject to personal jurisdiction in this judicial district.

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

BACKGROUND

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

23. On information and belief, Apotex Corp. submitted ANDA No. 202252 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.

24. 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.

25. Upon information and belief, the Apotex ANDA Product that is the subject of Apotex's ANDA No. 202252 are capsules containing 43 mg and 130 mg of fenofibrate as the active ingredient, for the treatment of hypercholesterolemia and hypertriglyceridemia.

THE PATENTS-IN-SUIT

26. On September 5, 2006, the U.S. Patent and Trademark Office ("PTO") 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.

27. On January 4, 2011, the PTO duly and legally issued U.S. Patent No. 7,863,331 (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.

28. 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.

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

30. 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.

31. 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.

COUNT I FOR PATENT INFRINGEMENT
(Infringement of the '574 patent under 35 U.S.C. § 271(e)(2))

32. Lupin Atlantis incorporates paragraphs 1-31 of this Complaint as if fully set forth herein.

33. Upon information and belief, Apotex sent a letter dated February 17, 2011, to Lupin Atlantis, Ethypharm, Lupine (Europe) Ltd, and Lupin Pharmaceuticals, Inc. which purported to comply with the provisions of 21 U.S.C. § 355(j)(2)(B). This letter purportedly advised Lupin Atlantis and Ethypharm that Apotex'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 Apotex ANDA Product.

34. Upon information and belief, the '574 patent was listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") relative to ANTARA®.

35. Upon information and belief, Apotex Corp. submitted Apotex ANDA No. 202252 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.

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

37. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) requires, inter alia, certification by the ANDA applicant 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, 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."

38. Upon information and belief, at the time Apotex Corp.'s letter of February 17, 2011, was mailed (this letter purportedly serving as a notice of Paragraph IV certification relative to the '574 patent, i.e., "Apotex's Notice of Certification"), Apotex Corp. and/or Apotex Inc. were aware of the statutory provisions and regulations referred to in paragraph 37, supra.

39. Apotex's Notice of Certification is required by statute and regulation to provide a full and detailed explanation regarding all bases for noninfringement of the '574 patent but does not do so. Instead, Apotex offers only conclusory statements.

40. Apotex's Notice of Certification is required by statute and regulation to provide a full and detailed explanation regarding all bases for invalidity of the '574 patent, but does not allege invalidity of any claims of the '574 patent. Instead, Apotex states in its Notice of Certification that it "*reserves the right to demonstrate additional factual and legal bases* concerning noninfringement, *invalidity*, or unenforceability should future information so warrant" (emphasis added).

41. Apotex's Notice of Certification 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 '574 patent. Instead, Apotex

states in its Notice of Certification that it "*reserves the right to demonstrate additional factual and legal bases* concerning noninfringement, invalidity, or *unenforceability* should future information so warrant" (emphasis added).

42. Apotex's Notice of Certification 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.

43. By filing ANDA No. 202252 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 Apotex ANDA Product prior to the expiration of the '574 patent, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, Apotex plans to commercially use, offer for sale, and/or sell the Apotex ANDA Product, and/or to induce or contribute to such activity, and by such actions Apotex would infringe one or more claims of the '574 patent under 35 U.S.C. § 271(a), (b) and/or (c).

44. Upon information and belief, Apotex Corp. and Apotex Inc. participated in, contributed to, aided, and/or induced the submission of Apotex ANDA No. 202252 and its Paragraph IV certification to the FDA. Additionally, upon information and belief, Apotex Corp. and Apotex Inc. will market and/or distribute the Apotex ANDA Product in the United States, and within this judicial district, if Apotex ANDA No. 202252 is approved by the FDA. Apotex Corp. and Apotex Inc. thus are jointly and severally liable for infringement of the '574 patent.

45. This action is being filed within 45 days of receipt by Lupin Atlantis and Ethypharm of the Apotex letter dated February 17, 2011, which purportedly advised Lupin Atlantis and Ethypharm of Apotex's Paragraph IV certification with respect to the '574 patent.

46. Upon information and belief, Apotex had actual and constructive notice of the '574 patent prior to filing Apotex ANDA No. 202252, and Apotex's infringement of the '574 patent has been, and continues to be, willful.

47. 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 Apotex ANDA No. 202252 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 they become entitled.

48. Lupin Atlantis will be irreparably harmed if Apotex is not enjoined from infringing or actively inducing or contributing to infringement of the '574 patent, as Lupin Atlantis has no adequate remedy at law.

COUNT II FOR PATENT INFRINGEMENT
(Infringement of the '331 patent under 35 U.S.C. § 271(e)(2))

49. Lupin Atlantis incorporates paragraphs 1-48 of this Complaint as if fully set forth herein.

50. Upon information and belief, Apotex sent a letter dated February 17, 2011, to Lupin Atlantis, Ethypharm, Lupine (Europe) Ltd, and Lupin Pharmaceuticals, Inc. which purported to comply with the provisions of 21 U.S.C. § 355(j)(2)(B). This letter purportedly advised Lupin Atlantis and Ethypharm that Apotex'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 Apotex ANDA Product.

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

52. Upon information and belief, Apotex Corp. submitted Apotex ANDA No. 202252 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.

53. Upon information and belief, the Apotex ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("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 Apotex ANDA Product.

54. 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."

55. Upon information and belief, at the time Apotex's letter of February 17, 2011, was mailed (this letter purportedly serving as a notice of Paragraph IV certification relative to the

'331 patent, i.e., "Apotex's Notice of Certification"), Apotex was aware of the statutory provisions and regulations referred to in paragraph 54, *supra*.

56. Apotex's Notice of Certification is required by statute and regulation to provide a full and detailed explanation regarding all bases for noninfringement of the '331 patent but does not do so. Instead, Apotex Corp. offers only conclusory statements.

57. Apotex's Notice of Certification 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, Apotex states in its Notice of Certification that it "*reserves the right to demonstrate additional factual and legal bases* concerning noninfringement, *invalidity*, or unenforceability should future information so warrant" (emphasis added).

58. Apotex's Notice of Certification 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, Apotex states in its Notice of Certification that it "*reserves the right to demonstrate additional factual and legal bases* concerning noninfringement, invalidity, or *unenforceability* should future information so warrant" (emphasis added).

59. Apotex's Notice of Certification 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.

60. By filing ANDA No. 202252 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 Apotex ANDA Product prior to the expiration of the '331 patent, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and

belief, Apotex plans to commercially use, offer for sale, and/or sell the Apotex ANDA Product, and/or to induce or contribute to such activity, and by such actions Apotex would infringe one or more claims of the '331 patent under 35 U.S.C. § 271(a), (b) and/or (c).

61. Upon information and belief, Apotex Corp. and Apotex Inc. participated in, contributed to, aided, and/or induced the submission of Apotex ANDA No. 202252 and its Paragraph IV certification to the FDA. Additionally, upon information and belief, Apotex Corp. and Apotex Inc. will market and/or distribute the Apotex ANDA Product in the United States, and within this judicial district, if Apotex ANDA No. 202252 is approved by the FDA. Apotex Corp. and Apotex Inc. thus are jointly and severally liable for infringement of the '331 patent.

62. This action is being filed within 45 days of receipt by Lupin Atlantis and Ethypharm of the Apotex letter dated February 17, 2011, which purportedly advised Lupin Atlantis and Ethypharm of Apotex's Paragraph IV certification with respect to the '331 patent.

63. Upon information and belief, Apotex had actual and constructive notice of the '331 patent prior to filing Apotex ANDA No. 202252, and Apotex's infringement of the '331 patent has been, and continues to be, willful.

64. 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 Apotex ANDA No. 202252 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 they become entitled.

65. Lupin Atlantis will be irreparably harmed if Apotex 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 Apotex has infringed one or more claims of the '574 patent under 35 U.S.C. § 271(e)(2);

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

C. An order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of Apotex's ANDA No. 202252 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. An order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of Apotex's ANDA No. 202252 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;

E. A permanent injunction restraining and enjoining Apotex Corp. and Apotex 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 Apotex ANDA Product, or any product that infringes the '574 patent;

F. A permanent injunction restraining and enjoining Apotex Corp. and Apotex 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 Apotex ANDA Product, or any product that infringes the '331 patent;

G. Damages and treble damages from Apotex from any commercial activity constituting infringement of the '574 patent;

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

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

J. Costs and expenses in this action; and

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

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