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

LUPIN ATLANTIS HOLDINGS S.A.,

Plaintiff,

v.

RANBAXY LABORATORIES LIMITED, RANBAXY PHARMACEUTICALS INC., RANBAXY, INC. and ETHYPHARM S.A.,

Defendants.

COMPLAINT

Plaintiff Lupin Atlantis Holdings S.A., by its attorneys, for its complaint against Ranbaxy Laboratories Limited, Ranbaxy Pharmaceuticals Inc., Ranbaxy, Inc. (collectively, "Ranbaxy") 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 Ranbaxy Laboratories Limited is a company organized and existing under the laws of India with a principal place of business at Plot 90, Sector 32, Gurgaon (Haryana) 122 001, India.

3. Upon information and belief, Ranbaxy Laboratories Limited 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 Commonwealth of Pennsylvania and in this judicial district, through various operating subsidiaries, including Ranbaxy Pharmaceuticals Inc. and Ranbaxy Inc.

4. Upon information and belief, Defendant Ranbaxy Pharmaceuticals Inc. is a corporation organized and existing under the laws of Delaware, and is a wholly-owned subsidiary and alter ego of Ranbaxy Laboratories Limited. Ranbaxy Pharmaceuticals Inc. has a principal place of business at 600 College Road East, Princeton, New Jersey 08540.

5. 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.

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

7. Upon information and belief, Ranbaxy Pharmaceuticals Inc. is a United States agent for Ranbaxy Laboratories Limited for, among others, making regulatory submissions to the United States Food and Drug Administration ("FDA").

8. Upon information and belief, Defendant Ranbaxy Inc. is a corporation organized and existing under the laws of Delaware, and is a wholly-owned subsidiary and alter ego of Ranbaxy Laboratories Limited. Ranbaxy Inc. has a principal place of business at 600 College Road East, Princeton, New Jersey 08540.

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

10. Upon information and belief, consistent with their practice with respect to other generic products, Ranbaxy Laboratories Limited, Ranbaxy Pharmaceuticals Inc.

and Ranbaxy Inc. collaborated in the research and development of Ranbaxy's Abbreviated New Drug Application ("ANDA") No. 201748 for capsules that contain 43 mg and 130 mg of fenofibrate as the active ingredient ("the Ranbaxy 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 Ranbaxy ANDA Product throughout the United States, including in the Commonwealth of Pennsylvania and in this judicial district, in the event the FDA approves the Ranbaxy ANDA.

JURISDICTION AND VENUE

11. 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 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).

12. Upon information and belief, Ranbaxy Laboratories Limited is subject to personal jurisdiction in this judicial district because, *inter alia*, Ranbaxy Laboratories Limited alone, and through its wholly-owned subsidiaries and alter egos Ranbaxy Pharmaceuticals Inc. and Ranbaxy 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, Ranbaxy Laboratories Limited, itself and through its wholly-owned subsidiaries Ranbaxy Pharmaceuticals Inc. and Ranbaxy Inc., markets and sells branded and generic drugs throughout the United States, and in particular within this judicial district, and therefore Ranbaxy Laboratories Limited has engaged in systematic and continuous business within this judicial district. In addition, and upon information and belief, Ranbaxy Laboratories Limited controls and dominates Ranbaxy Pharmaceuticals Inc. and Ranbaxy Inc., and thus the activities of the latter two entities in this judicial district are attributable to Ranbaxy Laboratories Limited.

13. Upon information and belief, Ranbaxy Pharmaceuticals Inc. is subject to personal jurisdiction in this judicial district because, *inter alia*, Ranbaxy Pharmaceuticals

Inc., alone and through its parent Ranbaxy Laboratories Limited and related company Ranbaxy 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, Ranbaxy Pharmaceuticals Inc., alone and through its parent Ranbaxy Laboratories Limited and related company Ranbaxy Inc., markets and sells branded and generic drugs throughout the United States, and in particular within this judicial district, and therefore Ranbaxy Pharmaceuticals Inc. has engaged in systematic and continuous business within this judicial district.

14. Upon information and belief, Ranbaxy Inc. is subject to personal jurisdiction in this judicial district because, *inter alia*, Ranbaxy Inc., alone and through its parent Ranbaxy Laboratories Limited and related company Ranbaxy Pharmaceuticals 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, Ranbaxy Inc., alone and through its parent Ranbaxy Laboratories Limited and related company Ranbaxy Pharmaceuticals Inc., markets and sells branded and generic drugs throughout the United States, and in particular within this judicial district, and therefore Ranbaxy Inc. has engaged in systematic and continuous business within this judicial district.

15. Upon information and belief, Ranbaxy Laboratories Limited, Ranbaxy Pharmaceuticals Inc. and Ranbaxy Inc. market Ranbaxy's branded and generic drug products to persons residing within this judicial district, for example, via its website.

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

17. Upon information and belief, persons residing within this judicial district purchase branded and generic drug products, including Ranbaxy products, from Ranbaxy Laboratories Limited (itself or through its wholly-owned subsidiaries Ranbaxy Pharmaceuticals Inc. and Ranbaxy Inc.) in this judicial district.

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

19. Upon information and belief, persons residing within this judicial district purchase branded and generic drug products, including Ranbaxy products, from Ranbaxy Inc. in this judicial district.

20. Upon information and belief, Ranbaxy Laboratories Limited (itself or through its wholly-owned subsidiaries Ranbaxy Pharmaceuticals Inc. and Ranbaxy Inc.) receives revenue from the sales and marketing of branded and generic drug products, including Ranbaxy products, within this judicial district.

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

22. Upon information and belief, Ranbaxy Inc. receives revenue from the sales and marketing of branded and generic drug products, including Ranbaxy products, within this judicial district.

23. Upon information and belief, Ranbaxy Laboratories Limited itself, or through its wholly-owned subsidiaries Ranbaxy Pharmaceuticals Inc. and Ranbaxy Inc., intends to market and sell the Ranbaxy ANDA Product, if approved, to residents of this judicial district.

24. Upon information and belief, Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Inc. admitted in Civil Action No. 2:06-cv-2768-MSG (E.D. Pa.), 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 venue in this judicial district was proper. Upon information and belief, Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Inc. did not contest personal jurisdiction in that action.

25. 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.

26. Ranbaxy Laboratories Limited, Ranbaxy Pharmaceuticals Inc., Ranbaxy, Inc. and Ethypharm are subject to personal jurisdiction in this judicial district.

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

BACKGROUND

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

29. On information and belief, Ranbaxy submitted ANDA No. 201748 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.

30. 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.

31. Upon information and belief, the Ranbaxy ANDA Product that is the subject of Ranbaxy ANDA No. 201748 are capsules containing 43 mg and 130 mg of fenofibrate as the active ingredient, and the Ranbaxy ANDA seeks approval for the treatment of hypercholesterolemia and hypertriglyceridemia.

THE PATENT-IN-SUIT

32. On January 4, 2011, the U.S. Patent and Trademark Office ("USPTO") 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 A.

33. Ethypharm is the owner of the '331 patent which discloses and claims, *inter alia*, a method for reducing food effect when treating hypertriglyceridemias and/or hypercholesterolemias.

34. Lupin Atlantis holds a license from Ethypharm under the '331 patent which contains provisions concerning the right to enforce the '331 patent in the case of an ANDA filing by a third party.

35. As owner of the '331 patent and licensor of the '331 patent 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 FOR PATENT INFRINGEMENT

36. Lupin Atlantis incorporates paragraphs 1-35 of this Complaint as if fully set forth herein.

37. Upon information and belief, Ranbaxy sent a letter dated March 1, 2011, to Lupin Atlantis and Ethypharm which purported to comply with the provisions of 21 U.S.C. § 355(j)(2)(B). This letter purportedly advised Lupin Pharmaceuticals, Inc. that Ranbaxy'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 Ranbaxy ANDA Product.

38. Upon information and belief, the '331 patent is properly listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") relative to ANTARA®, and was so listed when Ranbaxy sent its letter of March 1, 2011, to Lupin Atlantis and Ethypharm.

39. Upon information and belief, Ranbaxy submitted Ranbaxy ANDA No. 201748 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.

40. Upon information and belief, the Ranbaxy 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 or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of the Ranbaxy ANDA Product.

41. 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."

42. Upon information and belief, at the time Ranbaxy's letter of March 1, 2011, was mailed (this letter purportedly serving as a notice of Paragraph IV certification relative to the '331 patent, *i.e.,* "Ranbaxy's Notice of Certification"), Ranbaxy was aware of the statutory provisions and regulations referred to in paragraph 41, *supra.*

43. Ranbaxy's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding all bases for noninfringement but does not do so. While providing some information on its noninfringement positions, Ranbaxy fails to provide a full explanation of such bases, stating in its Notice of Certification that it "*reserves the right to supplement its position, as needed,* or to present to a court, if litigation arises, any other defenses such as invalidity under 35 U.S.C. §§ 101, 102, 103, and 112 of the Patent Laws, invalidity for double patenting, or any of the other defenses available to it under 35 U.S.C. § 282, with respect to the particular patent mentioned, *whether or not such defense is described in detail herein below*" (emphasis added).

44. Ranbaxy's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding alleged invalidity, does not allege invalidity of any claims of the '331 patent. Instead, Ranbaxy states in its Notice of Certification that it "*reserves the right* to supplement its position, as needed, or *to present to a court, if litigation arises, any other defenses such as invalidity* under 35 U.S.C. §§ 101, 102, 103, and 112 of the Patent Laws, invalidity for double patenting, or any of the other defenses available to it under 35 U.S.C. § 282...." (emphasis added).

45. Ranbaxy's Notice of Certification, 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 '331 patent.

46. Ranbaxy'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.

47. By filing ANDA No. 201748 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 Ranbaxy ANDA Product prior to the expiration of the '331 patent, Ranbaxy has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, Ranbaxy plans to commercially use, offer for sale, and/or sell the Ranbaxy ANDA Product, and/or to induce or contribute to such activity, and by such actions Ranbaxy would infringe one or more claims of the '331 patent under 35 U.S.C. § 271(a), (b) and/or (c).

48. Upon information and belief, Ranbaxy Pharmaceuticals Inc. and Ranbaxy Inc. participated in, contributed to, aided, and/or induced the submission of Ranbaxy ANDA No. 201748 and its Paragraph IV certification to the FDA. Additionally, upon information and belief, Ranbaxy Pharmaceuticals Inc. and Ranbaxy Inc. will market and/or distribute the Ranbaxy ANDA Product in the United States, and within this judicial district, if Ranbaxy ANDA No. 201748 is approved by the FDA. Ranbaxy Pharmaceuticals Inc. and Ranbaxy Inc. thus are jointly and severally liable with Ranbaxy Laboratories Limited for infringement of the '331 patent.

49. This action is being filed within 45 days of receipt by Lupin Atlantis and Ethypharm of the Ranbaxy letter dated March 1, 2011, which purportedly advised Lupin Atlantis and Ethypharm of Ranbaxy's Paragraph IV certification with respect to the '331 patent

50. Upon information and belief, Ranbaxy had actual and constructive notice of the '331 patent prior to filing the amendments to Ranbaxy's ANDA No. 201748, and Ranbaxy's infringement of the '331 patent has been, and continues to be, willful.

51. 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 Ranbaxy ANDA No. 201748 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 becomes entitled.

52. Lupin Atlantis will be irreparably harmed if Ranbaxy 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 Ranbaxy 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 Ranbaxy's ANDA No. 201748 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 Ranbaxy Laboratories Limited, Ranbaxy Pharmaceuticals Inc. and Ranbaxy 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 Ranbaxy ANDA Product, or any product that infringes the '331 patent;

D. Damages and treble damages from Ranbaxy 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: March 31, 2011

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