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and Laboratoires Fournier S.A.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ABBOTT LABORATORIES and)
LABORATOIRES FOURNIER S.A.,)
)
Plaintiffs,)
)
v.)
)
RANBAXY LABORATORIES LTD.,)
RANBAXY PHARMACEUTICALS,)
INC., and RANBAXY INC.,)
)
Defendants.)
_____)

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Abbott Laboratories ("Abbott") and Laboratoires Fournier S.A. ("Fournier") for their Complaint against Ranbaxy Laboratories Ltd., Ranbaxy Pharmaceuticals, Inc. and Ranbaxy Inc. (collectively, "Ranbaxy") allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 6,277,405 ("the '405 patent"), 7,037,529 ("the '529 patent"), and 7,041,319 ("the '319 patent"). The '405,

'529, and '319 patents are collectively referred to herein as the "Patents-in-Suit." This action arises out of Defendants' filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell generic copies of Plaintiffs' highly successful TRICOR® 48 mg and 145 mg products prior to the expiration of Plaintiffs' patents.

THE PARTIES

2. Plaintiff Abbott Laboratories is a corporation organized under the laws of the State of Illinois, having its headquarters and principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

3. Plaintiff Laboratoires Fournier S.A. is a French corporation having its principal place of business at 28 Boulevard Clemenceau, 21000 Dijon, France.

4. On information and belief, Defendant Ranbaxy Laboratories Ltd. is a corporation organized and existing under the laws of India, with places of business at Plot No. 90, Sector 32, Gurgaon 122 001 (Haryana), India and 600 College Road East, Suite 2100, Princeton, NJ 08540. On information and belief, Ranbaxy Laboratories Ltd. is in the business of, among other things, developing, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market through various operating subsidiaries, including Ranbaxy Inc.

5. On information and belief, Defendant Ranbaxy Pharmaceuticals, Inc. is a Florida corporation, with places of business at 9431 Florida Mining Boulevard East, Jacksonville, FL 32257 and 600 College Road East, Suite 2100, Princeton, NJ 08540. On information and belief, Ranbaxy Pharmaceuticals, Inc. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S.

market. Ranbaxy Pharmaceuticals, Inc. is a wholly owned subsidiary of Ranbaxy Laboratories Ltd.

6. On information and belief, Defendant Ranbaxy Inc. is a Delaware corporation, with a principal place of business at 600 College Road East, Suite 2100, Princeton, NJ 08540. On information and belief, Ranbaxy Inc. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. Ranbaxy Inc. is a wholly owned subsidiary of Ranbaxy Laboratories Ltd.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. On information and belief, this Court has personal jurisdiction over Ranbaxy Laboratories Ltd. because Ranbaxy Laboratories Ltd. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Ranbaxy Laboratories Ltd. has had persistent and continuous contacts with this judicial district, including developing or manufacturing pharmaceutical products that are sold in this judicial district.

9. On information and belief, this Court has personal jurisdiction over Ranbaxy Pharmaceuticals, Inc. because Ranbaxy Pharmaceuticals, Inc. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Ranbaxy Pharmaceuticals, Inc. has had persistent and continuous contacts with this judicial district, including developing, manufacturing, or selling pharmaceutical products that are sold in this judicial district.

10. On information and belief, this Court has personal jurisdiction over Ranbaxy Inc. because Ranbaxy Inc. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Ranbaxy Inc. has had persistent and continuous contacts with this judicial district, including developing, manufacturing, or selling pharmaceutical products that are sold in this judicial district.

11. On information and belief, Ranbaxy Pharmaceuticals, Inc. and Ranbaxy Inc. encouraged, directed, participated in, contributed to, aided, or induced the submission to the United States Food and Drug Administration ("FDA") of the ANDA at issue in this case.

12. By letter dated April 22, 2010 and an enclosed Offer of Confidential Access pursuant to 21 U.S.C. § 555(j)(5)(C)(i)(III), Ranbaxy Laboratories Ltd. named as its agent Joseph Todisco, Vice President – Business Development, Ranbaxy Inc., Suite 2100, 600 College Road East, Princeton, NJ 08540.

13. On information and belief, Ranbaxy Laboratories Ltd., Ranbaxy Pharmaceuticals, Inc. and Ranbaxy Inc. operate as an integrated, unitary business. For example, Ranbaxy Laboratories Ltd. includes within its annual report the activities of Ranbaxy Pharmaceuticals, Inc. and Ranbaxy Inc., including revenue earned.

14. On information and belief, Ranbaxy Inc. is registered to do business in New Jersey.

15. Ranbaxy Laboratories Ltd., Ranbaxy Pharmaceuticals, Inc. and Ranbaxy Inc. admitted in previous litigation that they are subject to personal jurisdiction in this Court. See Ranbaxy's Answer to Complaint/Counterclaims ¶¶ 4-5, *Wyeth Cardinal Health, Inc. v. Ranbaxy Labs. Ltd.*, No. 05-2252-GEB (D.N.J.) (June 30, 2005).

16. Three related lawsuits are currently pending in this Court. On November 3, 2008, Abbott and Fournier filed suit in the United States District Court for the Northern District of Illinois against Biovail Laboratories International SRL and Biovail Corporation (collectively "Biovail") seeking a judgment that each of the Patents-in-Suit is infringed by Biovail's filing of its ANDA No. 90-715. *See Abbott Labs. v. Biovail Labs. Int'l SRL*, No. 08-CV-6274 (N.D. Ill.). On December 10, 2008, the Illinois court transferred the lawsuit to this Court. On January 5, 2009, this Court acknowledged the transfer. *See Abbott Labs. v. Biovail Labs. Int'l SRL*, No. 09-CV-0005 (D.N.J.). On March 6, 2009, Abbott and Fournier filed suit in this Court against Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively "Lupin") seeking a judgment that each of the Patents-in-Suit is infringed by Lupin's filing of its ANDA No. 90-856. *See Abbott Labs. v. Lupin Ltd.*, No. 09-CV-1007 (D.N.J.). On October 29, 2009, Abbott and Fournier filed suit in this Court against Impax Laboratories, Inc. ("Impax"), seeking a judgment that each of the Patents-in-Suit is infringed by Impax's filing of its ANDA No. 91-548. *See Abbott Labs. v. Impax Labs., Inc.*, No. 09-5517 (D.N.J.).

17. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

BACKGROUND

18. Fournier is the owner by assignment of: (a) the '405 patent (attached hereto as Exhibit A); (b) the '529 patent (attached hereto as Exhibit B); and (c) the '319 patent (attached hereto as Exhibit C).

19. The '405 and '529 patents are titled "Fenofibrate Pharmaceutical Composition Having High Bioavailability and Method for Preparing It." The '319 patent is titled "Fenofibrate Pharmaceutical Composition Having High Bioavailability."

20. Abbott is the exclusive licensee of the Patents-in-Suit.

21. The Patents-in-Suit, which currently expire on January 9, 2018, each claim novel fenofibrate compositions that exhibit a particular dissolution profile.

22. Fenofibrate is useful as a lipid and cholesterol lowering agent for treatment of adults with increased triglyceride levels.

23. Abbott has approval from the FDA to market fenofibrate tablets under the name TRICOR®.

24. TRICOR® (fenofibrate) is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations" also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's ANDA to obtain approval of the ANDA applicant's drug product under provisions of 21 U.S.C. § 355(j).

25. The FDA's "Orange Book" also lists patents associated with approved drugs. The Patents-In-Suit are listed in the "Orange Book" in association with TRICOR® (fenofibrate).

26. On information and belief, Ranbaxy submitted ANDA No. 200884 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21, U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of fenofibrate tablets in 48 mg and 145 mg dosages ("Ranbaxy's Tablets, 48 mg and 145 mg"), as generic versions of the TRICOR® 48 mg and 145 mg tablets. Upon information and belief, Ranbaxy will market and/or distribute Ranbaxy's Tablets, 48 mg and 145 mg, if ANDA No. 200884 is approved by the FDA.

27. By letter dated April 22, 2010, Ranbaxy advised Abbott and Fournier that it had submitted ANDA No. 200884 seeking approval manufacture, use, or sell Ranbaxy's Tablets, 48 mg and 145 mg, prior to the expiration of the Patents-in-Suit.

COUNT I

28. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 27 hereof, as if fully set forth herein.

29. 35 U.S.C. § 271(e)(2) provides that the submission of an application under 21 U.S.C. § 355(j) for a drug claimed in a patent or for a drug use claimed in a patent is an act of infringement if the applicant seeks FDA marketing approval effective prior to the expiration of the patent. Ranbaxy's submission of an ANDA for approval to sell Ranbaxy's Tablets, 48 mg and 145 mg prior to the expiration of the Patents-in-Suit constitutes an act of infringement of one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271(e)(2). In addition, Ranbaxy's Tablets, 48 mg and 145 mg infringe one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271.

30. On information and belief, Ranbaxy acted without a reasonable basis or a good faith belief that it would not be liable for infringing the Patents-in-Suit.

31. Plaintiffs have no adequate remedy at law to redress Ranbaxy's infringement.

32. Ranbaxy's conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

33. Plaintiffs will be irreparably harmed if Defendant is not enjoined from infringing the Patents-in-Suit.

PRAYER

WHEREFORE, Plaintiffs respectfully request relief and judgment as follows:

- (a) a judgment that each of the Patents-in-Suit is valid and enforceable, and each of the Patents-in-Suit is infringed under 35 U.S.C. § 271(e)(2) by Ranbaxy's filing of its ANDA No. 200884;
- (b) an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 200884 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) be subsequent to the expiration date of each of the Patents-in-Suit;
- (c) an injunction pursuant to 35 U.S.C. § 271(e)(4)(B) prohibiting Ranbaxy from commercially manufacturing, selling or offering for sale, using, or importing the fenofibrate compositions claimed in the Patents-in-Suit or otherwise infringing one or more claims of the Patents-in-Suit;
- (d) damages and/or other monetary relief pursuant to 35 U.S.C. § 284 in the event of any commercial manufacture, use or sale of fenofibrate compositions falling within the scope of one or more claims of the Patents-in-Suit by Ranbaxy;
- (e) an award of Plaintiffs' interest, costs, reasonable attorneys' fees and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and,
- (f) such other and further relief as the Court may deem just and proper.

CERTIFICATION PURSUANT TO L. CIV.R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L.Civ.R. 11.2 that the matters in controversy are not the subject of any other action pending in any other court or of any pending arbitration or administrative proceeding, with the exception of the related lawsuits identified in Paragraph 16 of this Complaint involving different defendants but the same Patents-in-Suit.

Respectfully submitted,

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Dated: June 4, 2010