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

ELAN PHARMA INTERNATIONAL LTD.)
and FOURNIER LABORATORIES)
IRELAND LTD.,)
)
Plaintiffs,)
) Civil Action No. _____
v.)
)
RANBAXY LABORATORIES LTD.,)
RANBAXY PHARMACEUTICALS, INC.)
and RANBAXY INC.,)
)
Defendants.)

COMPLAINT FOR PATENT INFRINGEMENT

Elan Pharma International Ltd. (“Elan”) and Fournier Laboratories Ireland, Ltd. (“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. 7,276,249 (“the ’249 patent”) and 7,320,802 (“the ’802 patent”). This action arises out of Defendants’ filing of an Abbreviated New Drug Application (“ANDA”) seeking approval to sell generic copies of the highly-successful TRICOR® 48 mg and 145 mg products prior to the expiration of Plaintiffs’ patents, and is based on the patent laws of the United States, 35 U.S.C. § 100 *et seq.*

THE PARTIES

2. Plaintiff Elan Pharma International Ltd. is an Irish corporation having a principal place of business at Monksland, Athlone, Co. Westmeath, Ireland.

3. Plaintiff Fournier Laboratories Ireland Ltd. is an Irish corporation having a principal place of business at Anngrove, Carrigtwohill, Co. Cork, Ireland.

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* June 30, 2005 Answer to Complaint and Counterclaims ¶¶ 4-5, *Wyeth Cardinal Health, Inc. v. Ranbaxy Laboratories Ltd.*, Case No. 05-2252-GEB (D.N.J.).

16. Three related lawsuits are currently pending in this Court. On November 3, 2008, Elan and Fournier filed suit in this Court against Biovail Laboratories International SRL and Biovail Corporation (collectively “Biovail”) seeking a judgment that each of the ’249 and ’802 patents, in addition to two other patents, is infringed by Biovail’s filing of its ANDA No. 90-715. *See Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Biovail Laboratories International SRL and Biovail Corp.*, Case No. 08-5412 (D.N.J.). On March 6, 2009, Elan and Fournier filed suit in this Court against Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively “Lupin”) seeking a judgment that each of the ’249 and ’802 patents is infringed by Lupin’s filing of its ANDA No. 90-856. *See Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, Case No. 09-1008 (D.N.J.). On October 29, 2009, Elan and Fournier filed suit in this Court against Impax Laboratories, Inc. (“Impax”) seeking a judgment that each of the ’249 and ’802 patents, in addition to one other patent, is infringed by Impax’s filing of its ANDA No. 91-548. *See Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Impax Laboratories, Inc.*, Case No. 09-5541 (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. On October 2, 2007, the ’249 patent, entitled “Nanoparticulate Fibrate Formulations,” was duly and legally issued to Elan and Fournier as assignees. A true and correct copy of the ’249 patent is attached as Exhibit A.

19. On January 22, 2008, the '802 patent, entitled "Methods of Treatment Using Nanoparticulate Fenofibrate Compositions," was duly and legally issued to Elan and Fournier as assignees. A true and correct copy of the '802 patent is attached as Exhibit B.

20. On November 5, 2004, the FDA approved New Drug Application No. 21-656 for TRICOR® tablets, which contain fenofibrate, under § 505(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a), as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia and to reduce elevated LDL-C, Total-C, Triglycerides and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia, or mixed dyslipidemia.

21. The '249 and '802 patents are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for TRICOR® tablets.

22. 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.

23. By letter dated April 22, 2010, Ranbaxy advised Elan and Fournier that it had submitted ANDA No. 200884 seeking approval to manufacture, use, or sell Ranbaxy's Tablets, 48 mg and 145 mg, prior to the expiration of the '249 and '802 patents.

24. The April 22, 2010 letter also advised Elan and Fournier that Ranbaxy's ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Ranbaxy's

opinion, the '249 and '802 patents are invalid and/or will not be infringed by the commercial manufacture, use, or sale of Ranbaxy's Tablets, 48 mg and 145 mg.

COUNT I

25. Plaintiffs incorporate each of the preceding paragraphs 1-24 as if fully set forth herein.

26. By filing ANDA No. 200884 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Ranbaxy's Tablets, 48 mg and 145 mg, prior to the expiration of the '249 patent, Defendants have committed an act of infringement, and/or induced infringement, of the '249 patent under 35 U.S.C. § 271(e)(2).

27. The commercial manufacture, use, offer to sell, sale, or importation of Ranbaxy's Tablets, 48 mg and 145 mg, would infringe one or more of the claims of the '249 patent under 35 U.S.C. § 271.

28. On information and belief, Ranbaxy was aware of the existence of the '249 patent and was aware that the filing of its ANDA and certification with respect to the '249 patent constituted infringement of that patent. This is an exceptional case.

COUNT II

29. Plaintiffs incorporate each of the preceding paragraphs 1-28 as if fully set forth herein.

30. By filing ANDA No. 200884 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Ranbaxy's Tablets, 48 mg and 145 mg, prior to the expiration of the '802 patent, Defendants have committed an act of infringement, and/or induced infringement, of the '802 patent under 35 U.S.C. § 271(e)(2).

31. The commercial manufacture, use, offer to sell, sale, or importation of Ranbaxy's Tablets, 48 mg and 145 mg, would infringe one or more of the claims of the '802 patent under 35 U.S.C. § 271.

32. On information and belief, Ranbaxy was aware of the existence of the '802 patent and was aware that the filing of its ANDA and certification with respect to the '802 patent constituted infringement of that patent. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Ranbaxy has infringed the '249 and '802 patents, each of which is valid and enforceable;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Ranbaxy's ANDA No. 200884 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), be a date which is not earlier than the expiration date of the '249 and '802 patents;

C. An injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Ranbaxy and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from infringement of the '249 and '802 patents for the full terms thereof;

D. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

E. Costs and expenses in this action; and

F. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

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*Attorneys for Plaintiff
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Dated: June 4, 2010

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