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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.	)	
TEVA PHARMACEUTICALS USA, INC.	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Elan Pharma International Ltd. ("Elan") and Fournier Laboratories Ireland, Ltd. ("Fournier") for their Complaint against Teva Pharmaceuticals USA, Inc. ("Teva") allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 5,145,684 ("the '684 patent"), 7,276,249 ("the '249 patent"), and 7,320,802 ("the '802 patent"). This action arises out of Teva's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell generic copies of the highly-successful TRICOR® 48 mg product 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 Teva Pharmaceuticals USA, Inc. is a Delaware corporation having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. On information and belief, Teva is in the business of, among other things, developing, manufacturing, and selling generic copies of branded pharmaceutical products for the U.S. market.

JURISDICTION AND VENUE

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

6. On information and belief, this Court has personal jurisdiction over Teva because it 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, Teva has had persistent and continuous contacts with this judicial district, including developing or manufacturing pharmaceutical products that are sold in this judicial district.

7. On information and belief, Teva maintains a place of business at 10 Gloria Lane, Fairfield, New Jersey 07004.

8. On information and belief, Teva is registered to do business in New Jersey.

9. Teva admitted in previous patent litigation that it is subject to personal jurisdiction in this Court. *See* Mem. Supp. Mot. to Transfer at 9, *Abbott Laboratories and Laboratoires Fournier S.A. v. Teva Pharmaceuticals USA, Inc.*, Case No. 08-1243 (N.D. Ill.) (Mar. 31, 2008).

10. This case is related to a previous lawsuit in this Court involving the same parties: *Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Teva Pharmaceuticals USA, Inc.*, Case No. 08-1085 (D.N.J.). That action, arising out of Teva's filing of ANDA No. 90-069 seeking approval to sell generic copies of the TRICOR® 145 mg product prior to the expiration of the '684, '249, and '802 patents, was dismissed by stipulation of the parties on December 1, 2009. Case No. 08-1085, D.I. 76.

11. This case is also related to four lawsuits 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 '684, '249, and '802 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 '684, '249, and '802 patents 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.). On June 4, 2010, Elan and Fournier filed suit in this Court against Ranbaxy Laboratories, Ltd., Ranbaxy Pharmaceuticals, Inc. and Ranbaxy Inc. (collectively "Ranbaxy") seeking a judgment that each of the '249 and '802 patents is infringed by Ranbaxy's filing of its ANDA No. 200884. *See Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Ranbaxy Laboratories Ltd., Ranbaxy Pharmaceuticals, Inc. and Ranbaxy Inc.*, Case No. 10-2872 (D.N.J.).

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

BACKGROUND

13. On September 8, 1992, the '684 patent, entitled "Surface Modified Drug Nanoparticles," was duly and legally issued. A true and correct copy of the '684 patent is attached as Exhibit A. Elan is the current assignee of the '684 patent.

14. 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 B.

15. 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 C.

16. 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.

17. The '684, '249, and '802 patents are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for TRICOR® tablets.

18. On information and belief, Teva submitted ANDA No. 200182 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 the 48 mg dosage strength ("Teva's Tablets, 48 mg"), as a generic version of the TRICOR® 48 mg tablet. On information and belief, Teva will market and/or distribute Teva's Tablets, 48 mg, if ANDA No. 200182 is approved by the FDA.

19. By letter dated May 25, 2010, Teva advised Elan and Fournier that it had submitted ANDA No. 200182, seeking approval to manufacture, use, or sell Teva's Tablets, 48 mg, prior to the expiration of the '684, '249, and '802 patents.

20. The May 25, 2010 letter also advised Elan and Fournier that Teva's ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Teva's opinion,

the '684, '249, and '802 patents are invalid and/or will not be infringed by the commercial manufacture, use, or sale of Teva's Tablets, 48 mg.

COUNT I

21. Plaintiffs incorporate each of the preceding paragraphs 1-20 as if fully set forth herein.

22. By filing ANDA No. 200182 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Teva's Tablets, 48 mg, prior to the expiration of the '684 patent, Teva has committed an act of infringement of the '684 patent under 35 U.S.C. § 271(e)(2).

23. The commercial manufacture, use, offer to sell, sale, or importation of Teva's Tablets, 48 mg, would infringe one or more of the claims of the '684 patent under 35 U.S.C. § 271.

24. On information and belief, Teva was aware of the existence of the '684 patent and was aware that the filing of its ANDA and certification with respect to the '684 patent constituted infringement of that patent. This is an exceptional case.

COUNT II

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

26. By filing ANDA No. 200182 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Teva's Tablets, 48 mg, prior to the expiration of the '249 patent, Teva has committed an act of 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 Teva's Tablets, 48 mg, would infringe one or more of the claims of the '249 patent under 35 U.S.C. § 271.

28. On information and belief, Teva 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 III

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

30. By filing ANDA No. 200182 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Teva's Tablets, 48 mg, prior to the expiration of the '802 patent, Teva has committed an act of 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 Teva's Tablets, 48 mg, would infringe one or more of the claims of the '802 patent under 35 U.S.C. § 271.

32. On information and belief, Teva 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 Teva has infringed the '684, '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 Teva's ANDA No. 200182 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 '684, '249, and '802 patents;

C. An injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Teva and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from infringement of the '684, '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,

Dated: July 9, 2010

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