

DECHERT LLP
A Pennsylvania Limited Liability Partnership
Princeton Pike Corporate Center
(Mail to) P.O. Box 5218
Princeton, NJ 08543-5218
(Deliver to) 997 Lenox Dr., Bldg. 3, Suite 210
Lawrenceville, NJ 08648
(609) 620-3200
ATTORNEYS FOR Plaintiff Elan Pharma
International Ltd.

DRINKER BIDDLE & REATH LLP
A Delaware Limited Liability Partnership
500 Campus Drive
Florham Park, NJ 07392-1047
(973) 360-1100
ATTORNEYS FOR Plaintiff Fournier Laboratories
Ireland Ltd.

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

ELAN PHARMA INTERNATIONAL LTD.,)
and FOURNIER LABORATORIES)
IRELAND LTD.,)

Plaintiffs,)

v.)

TEVA PHARMACEUTICALS USA, INC.,)

Defendant.)

C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Elan Pharma International Ltd. (“Elan”) and Fournier Laboratories Ireland Ltd. (“Fournier”) for their Complaint against Defendant 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 is based on the Patent Laws of the United States, 35 U.S.C § 100 *et seq.*

THE PARTIES

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

3. 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, Teva is a Delaware corporation having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454, and is engaged in the manufacture and sale of generic pharmaceutical products.

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. This Court has personal jurisdiction over Teva because Teva has had persistent and continuous contacts within this judicial district. On information and belief, Teva maintains places of business at least at 92 US Highway 46, Elmwood Park, New Jersey 07407, 10 Gloria Lane, Fairfield, New Jersey 07004 and 18-01 River Road, Fair Lawn, New Jersey 07410.

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

BACKGROUND

8. 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.

9. 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.

10. 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.

11. On November 5, 2004, the United States Food and Drug Administration ("FDA") approved new drug application ("NDA") 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.

12. 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.

13. On information and belief, Teva submitted to the FDA abbreviated new drug application ("ANDA") No. 90-069 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, 145 mg ("Teva's Fenofibrate Tablets, 145 mg"), as a generic version of the TRICOR® 145 mg tablet.

14. By letters dated January 16, 2008 and February 6, 2008 (the "Teva Letters"), Teva advised Elan and Fournier that it had submitted ANDA No. 90-069 seeking approval to manufacture, use, or sell Teva's Fenofibrate Tablets, 145 mg prior to the expiration of the '684, '249 and '802 patents.

15. The Teva Letters also advised Elan and Fournier that Teva's ANDA included a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in Teva's opinion, the manufacture, use or sale of Teva's Fenofibrate Tablets, 145 mg as described in its ANDA will not infringe any claim of the '684, '249 and '802 patents and that the claims of the '249 and '802 patents are invalid.

COUNT I

16. Plaintiffs incorporate each of the preceding paragraphs 1 to 15 as if fully set forth herein.

17. By filing ANDA No. 90-069 for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Teva's Fenofibrate Tablets, 145 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).

18. The commercial manufacture, use, offer to sell, sale or importation of Teva's Fenofibrate Tablets, 145 mg would infringe one or more claims of the '684 patent under 35 U.S.C. § 271.

19. 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

20. Plaintiffs incorporate each of the preceding paragraphs 1 to 15 as if fully set forth herein.

21. By filing ANDA No. 90-069 for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Teva's Fenofibrate Tablets, 145 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).

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

23. 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

24. Plaintiffs incorporate each of the preceding paragraphs 1 to 15 as if fully set forth herein.

25. By filing ANDA No. 90-069 for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Teva's Fenofibrate Tablets, 145 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).

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

27. 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.

28.

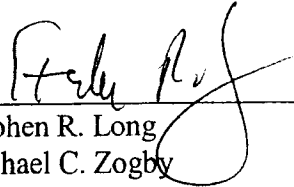
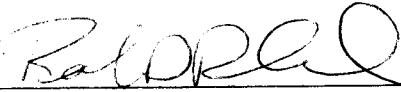
PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

- A. A judgment that Teva has infringed the '684, '249 and '802 patents;
- 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. 90-069 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. A permanent 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.

DECHERT LLP

DRINKER BIDDLE & REATH LLP



Robert D. Rhoad
Thomas P. Lihan
Princeton Pike Corporate Center
P. O. Box 5218
Princeton, N. J. 08543-5218
(609) 620-3200

Stephen R. Long
Michael C. Zogby
500 Campus Drive
Florham Park, NJ 07392-1047
(973) 360-1100

*Attorneys for Plaintiff
Elan Pharma International Ltd.*

*Attorneys for Plaintiff
Fournier Laboratories Ireland Ltd.*

Of Counsel:

Of Counsel:

Jack B. Blumenfeld
Maryellen Noreika
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200

Timothy C. Bickham
Roger W. Parkhurst
STEPTOE & JOHNSON LLP
1330 Connecticut Ave, NW
Washington, DC 20036
(202) 429-3000

February 29, 2008