John E. Flaherty
Jonathan M. H. Short
Elina Slavin
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
Tel: (973) 622-4444
Fax: (973) 624-7070
*Attorneys for Plaintiff EDT Pharma Holdings Ltd.*

Thomas R. Curtin
George C. Jones
Kathleen N. Fennelly
GRAHAM CURTIN, P.A.
4 Headquarters Plaza
P.O. Box 1991
Morristown, NJ 07962-1991
Tel: (973) 292-1700
Fax: (973) 292-1767
*Attorneys for Plaintiff Fournier Laboratories Ireland Ltd.*

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

| | | |
|---|---|---|
| EDT PHARMA HOLDINGS LTD. and FOURNIER LABORATORIES IRELAND LTD., | ) | |
| Plaintiffs, | ) | Civil Action No. _____ |
| v. | ) | |
| MYLAN PHARMACEUTICALS INC. and MYLAN INC. | ) | |
| Defendants. | ) | |

**COMPLAINT FOR PATENT INFRINGEMENT**

EDT Pharma Holdings Ltd. ("EDT") and Fournier Laboratories Ireland Ltd. ("Fournier") for their Complaint against Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") and Mylan Inc. (collectively, "Mylan") 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.

## THE PARTIES

2. Plaintiff EDT Pharma Holdings 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 Mylan Inc. is a Pennsylvania corporation having a principal place of business at 1500 Corporate Drive, Canonsburg, PA 15317. On information and belief, Mylan Inc. is in the business of, among other things, manufacturing, marketing, distributing, and selling generic copies of branded pharmaceutical products, including in the State of Jersey, through various operating subsidiaries, including Mylan Pharmaceuticals.

5. On information and belief, Defendant Mylan Pharmaceuticals is a West Virginia corporation having a principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505. On information and belief, Mylan Pharmaceuticals is in the business of, among other things, manufacturing, marketing, distributing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of New Jersey. Mylan Pharmaceuticals is a wholly owned subsidiary of Mylan Inc.

## JURISDICTION AND VENUE

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

7. On information and belief, this Court has personal jurisdiction over Mylan Inc. because Mylan Inc. has purposefully 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, Mylan Inc. has had persistent and continuous contacts with this judicial district, including developing, distributing, marketing, and/or selling pharmaceutical products in this judicial district. Moreover, on information and belief, Mylan Inc. has invoked the benefits and protections afforded by the State of New Jersey by bringing suit in this Court. *E.g.*, *Mylan Inc. v. SmithKline Beecham Corp.*, C.A. No. 10-4809.

8. On information and belief, this Court has personal jurisdiction over Mylan Pharmaceuticals because Mylan Pharmaceuticals has purposefully 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, Mylan Pharmaceuticals has had persistent and continuous contacts with this judicial district, including developing, distributing, marketing, and/or selling pharmaceutical products in this judicial district with the authorization, participation, or assistance of Mylan Inc. Moreover, on information and belief, Mylan Pharmaceuticals has invoked the benefits and protections afforded by the State of New Jersey by bringing suit in this Court. *E.g.*, *Mylan Inc. v. SmithKline Beecham Corp.*, C.A. No. 10-4809.

9. On information and belief, Mylan Inc. participated in, contributed to, aided, abetted, and/or induced the submissions to the U.S. Food and Drug Administration ("FDA") at issue in this case.

10. On information and belief, Mylan Inc. and Mylan Pharmaceuticals operate as an integrated, unitary business. For example, Mylan Inc. includes within its Annual Report the activities of Mylan Pharmaceuticals, including revenue earned.

11. On information and belief, Mylan Inc. and Mylan Pharmaceuticals are registered to do business in New Jersey and have appointed as their agent for receipt of service of process Corporation Service Company, 830 Bear Tavern Road, West Trenton, NJ 08628.

12. On information and belief, Mylan Inc. maintains facilities in this judicial district at One Woodbridge Center, 9th Floor, Suite 920, Woodbridge, NJ 07095.

13. Mylan Inc. and Mylan Pharmaceuticals previously consented to personal jurisdiction in this district in prior patent cases. *E.g.*, *Hoffmann-La Roche Inc. v. Mylan, Inc.*, C.A. No. 09-1692, Answer, Defenses and Counterclaims of Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. at 3 (D.N.J. May 20, 2009) (admitting that Mylan did not contest personal jurisdiction in three other patent cases filed in this judicial district: *Warner Chilcott Labs. Ireland Ltd. v. Impax Labs., Inc.*, C.A. No. 08-6304; *Novartis Pharms. Corp. v. Mylan Pharms. Inc.*, C.A. No. 08-5042; and *Sankyo Co., Ltd. v. Mylan Labs. Inc.*, C.A. No. 06-3462).

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

## BACKGROUND

15. On October 2, 2007, the ’249 patent, entitled “Nanoparticulate Fibrate Formulations,” was duly and legally issued to Elan Pharma International, Ltd. (“Elan”) and Fournier as assignees. Elan’s rights were subsequently transferred to EDT. A true and correct copy of the ’249 patent is attached as Exhibit A.

16. 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. Elan's rights were subsequently transferred to EDT. A true and correct copy of the '802 patent is attached as Exhibit B.

17. On November 5, 2004, the 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.

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

19. On information and belief, Mylan submitted ANDA No. 20-2856 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 and 145 mg dosages ("Mylan's Tablets, 48 mg and 145 mg"), as generic versions of the TRICOR® 48 mg and 145 mg tablets. On information and belief, Mylan will market and/or distribute Mylan's Tablets, 48 mg and 145 mg, if ANDA No. 20-2856 is approved by the FDA.

20. By letter dated July 14, 2011 (the "Mylan Letter"), Mylan advised Elan and Fournier that it had submitted ANDA No. 20-2856 to the FDA seeking approval to manufacture, use, or sell fenofibrate tablets in the 48 mg and 145 mg dosages prior to the expiration of the '249 and '802 patents.

21. The Mylan Letter also advised Elan and Fournier that Mylan's ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Mylan's opinion, the '249 and '802 patents are invalid and/or will not be infringed by the commercial manufacture, use, or sale of Mylan's Tablets, 48 mg and 145 mg.

**COUNT I**

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

23. Mylan's submission of ANDA No. 20-2856 to the FDA for fenofibrate tablets in the 48 mg and 145 mg dosages, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '249 patent under 35 U.S.C. § 271(e)(2)(A). Mylan's commercial manufacture, offer for sale, or sale of the proposed generic for fenofibrate tablets in the 45 mg and 148 mg dosages would infringe the '249 patent.

24. On information and belief, Mylan was aware of the existence of the '249 patent and was aware that the filing of ANDA No. 20-2856 and certification with respect to the '249 patent constituted infringement of that patent. This is an exceptional case.

**COUNT II**

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

26. Mylan's submission of ANDA No. 20-2856 to the FDA for fenofibrate tablets in the 48 mg and 145 mg dosages, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '802 patent under 35 U.S.C. § 271(e)(2)(A). Mylan's commercial manufacture, offer for sale, or sale of the proposed generic for fenofibrate tablets in the 45 mg and 148 mg dosages would infringe the '802 patent.

27. On information and belief, Mylan was aware of the existence of the '802 patent and was aware that the filing of ANDA No. 20-2856 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 Mylan has infringed the '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 Mylan's ANDA No. 20-2856 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 dates of the '249 and '802 patents, including any extensions;

C. An injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Mylan 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, including any extensions;

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,

McCARTER & ENGLISH LLP

*s/ John E. Flaherty*
John E. Flaherty
Jonathan M. H. Short
Elina Slavin
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
Tel: (973) 622-4444
Fax: (973) 624-7070

Of counsel:

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

*Attorneys for Plaintiff EDT Pharma Holdings Ltd.*

GRAHAM CURTIN, P.A.

*s/ Thomas R. Curtin*
Thomas R. Curtin
George C. Jones
Kathleen N. Fennelly
4 Headquarters Plaza
P.O. Box 1991
Morristown, NJ 07962-1991
Tel: (973) 292-1700
Fax: (973) 292-1767

Of counsel:

William F. Cavanaugh Jr.
Chad J. Peterman
Jesse A. Devine
Edward R. Tempesta
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036
Tel: (212) 336-2000

*Attorneys for Plaintiff Fournier Laboratories Ireland Ltd.*

Dated: August 26, 2011

**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. This action alleges infringement of U.S. Patent Nos. 7,276,249 and 7,320,802, which were also at issue in the following cases:

- *Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Biovail Laboratories International SRL and Bioval Corporation*, D.N.J., 08-cv-05412-GEB-MCA (closed);
- *Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Impax Laboratories, Inc.*, D.N.J., 09-cv-05541-GEB-MCA (closed);
- *Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, D.N.J., 09-cv-01008-GEB-MCA (closed);
- *Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Teva Pharmaceuticals USA, Inc.*, D.N.J., 10-cv-03495-GEB-MCA (closed); and
- *Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Ranbaxy Laboratories Ltd., Ranbaxy Pharmaceutical, Inc., and Ranbaxy Inc.*, D.N.J., 10-cv-02872-GEB-MCA (closed).

MCCARTER & ENGLISH LLP

*s/ John E. Flaherty*
John E. Flaherty
Jonathan M. H. Short
Elina Slavin
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
Tel: (973) 622-4444
Fax: (973) 624-7070

GRAHAM CURTIN, P.A.

*s/ Thomas R. Curtin*
Thomas R. Curtin
George C. Jones
Kathleen N. Fennelly
4 Headquarters Plaza
P.O. Box 1991
Morristown, NJ 07962-1991
Tel: (973) 292-1700
Fax: (973) 292-1767