

Thomas R. Curtin  
George C. Jones  
Kathleen N. Fennelly  
GRAHAM CURTIN  
A Professional Association  
4 Headquarters Plaza  
P.O. Box 1991  
Morristown, New Jersey, 07962-1991  
Tel: (973) 292-1700  
Fax: (973) 292-1767

*Attorneys for Plaintiffs Abbott Laboratories  
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.

MYLAN PHARMACEUTICALS INC.,  
and MYLAN INC.,

Defendants.  
\_\_\_\_\_

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR PATENT INFRINGEMENT**

Abbott Laboratories (“Abbott”) and Laboratoires Fournier S.A. (“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. 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 Mylan Inc. is a Pennsylvania corporation with its primary place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. On information and belief, Mylan Inc. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products through various operating subsidiaries, including Mylan Pharmaceuticals.

5. On information and belief, Defendant Mylan Pharmaceuticals is a West Virginia corporation with an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. On information and belief, Mylan Pharmaceuticals is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products. 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 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, Mylan Inc. has had persistent and continuous contacts with this judicial district, including developing and/or manufacturing pharmaceutical products that are sold in this judicial district.

8. On information and belief, this Court has personal jurisdiction over Mylan Pharmaceuticals because Mylan Pharmaceuticals 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, Mylan Pharmaceuticals has had persistent and continuous contacts with this judicial district, including developing and/or manufacturing pharmaceutical products that are sold in this judicial district with the authorization, participation or assistance of Mylan Inc.

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, New Jersey 08628.

12. On information and belief, Mylan Inc. maintains facilities in this judicial district at One Woodbridge Center, 9<sup>th</sup> Floor, Suite 920, Woodbridge, New Jersey 07095.

13. Both Mylan Inc. and Mylan Pharmaceuticals have consented to personal jurisdiction in this district in numerous prior patent cases. *See, e.g.*, Defs.’ Answer and Countercls. to Pls.’ Compl. for Patent Infringement ¶ 9, *Novartis AG v. Mylan Pharm. Inc.* (D.N.J. Jan. 8, 2010) (No. 09-3604); Answer and Countercl. at 4, *Warner Chilcott Labs. Ireland Ltd. v. Mylan Pharm. Inc.*, (D.N.J. May 26, 2009) (No. 09-2073); Answer, Defenses and Countercls. of Defs. Mylan Inc. and Mylan Pharma. Inc. at 4, *Hoffman-La Roche Inc. v. Mylan Inc.* (D.N.J. May 20, 2009) (No. 09-1692).

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

#### BACKGROUND

15. 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).

16. 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.”

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

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

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

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

21. 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).

22. 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).

23. 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 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. Upon 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.

24. By letter dated July 14, 2011, Mylan advised Abbott and Fournier that it had submitted ANDA No. 20-2856 seeking approval manufacture, use, or sell Mylan's Tablets, 48 mg and 145 mg, prior to the expiration of the Patents-in-Suit.

#### COUNT I

25. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 24 hereof, as if fully set forth herein.

26. 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. Mylan's submission of an ANDA for approval to sell Mylan'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, Mylan'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.

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

28. Plaintiffs have no adequate remedy at law to redress Mylan's infringement.

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

30. Plaintiffs will be irreparably harmed if Mylan 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 Mylan's filing of ANDA No. 20-2856;

(b) an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 20-2856 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 Mylan

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 Mylan;

(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.

Respectfully submitted,

s/ Thomas R. Curtin

Thomas R. Curtin

George C. Jones

Kathleen N. Fennelly

GRAHAM CURTIN

A Professional Association

4 Headquarters Plaza

P.O. Box 1991

Morristown, New Jersey 07962-1991

Tel: (973) 292-1700

Fax: (973) 292-1767

*Attorneys for Plaintiff Abbott Laboratories  
and Laboratoires Fournier S.A.*

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

Fax: (212) 336-2222

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