

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 Fournier Laboratories Ireland Ltd.

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

ABBOTT LABORATORIES and)
FOURNIER LABORATORIES)
IRELAND LTD.,)
)
Plaintiffs,)
)
v.)
)
ANCHEN PHARMACEUTICALS,)
INC.,)
)
Defendant.)
_____)

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Abbott Laboratories ("Abbott") and Fournier Laboratories Ireland Ltd. ("Fournier"), for their Complaint against defendant Anchen Pharmaceuticals, Inc. ("Anchen") allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent No. 7,259,186 (the "'186 patent"). This action arises out of Anchen's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell a generic copy of Plaintiffs' highly successful TRILIPIX® 135 mg product prior to the expiration of the '186 patent.

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

4. Abbott Laboratories is a parent of Fournier Laboratories Ireland Ltd.

5. On information and belief, Anchen Pharmaceuticals, Inc. is a corporation organized under the laws of California having a principal place of business at 9601 Jeronimo Road, Irvine, California 92618.

6. On information and belief, Anchen is in the business of, among other things, developing, manufacturing and selling generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

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 Anchen because, *inter alia*, it has committed a tortious act of patent infringement leading to

foreseeable harm and injury to Abbott and Fournier; namely, the submission to the U.S. Food and Drug Administration ("FDA") of the ANDA at issue in this case.

9. On information and belief, this Court has personal jurisdiction over Anchen because, *inter alia*, 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, Anchen has had persistent, continuous and systematic contacts with this judicial district, including, *inter alia*, directly or through an agent, deriving substantial revenue from the development, manufacture or sale of generic drug products that are sold in New Jersey.

10. Anchen has previously consented to personal jurisdiction in patent litigation in this judicial district. *See* Defs.' Answer, Affirmative Defenses, Countercls. at 5, *AstraZeneca Pharm. LP v. Anchen Pharm., Inc.* (D.N.J. June 3, 2010) (No. 10-1835).

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

BACKGROUND

12. Abbott and Fournier jointly own all rights, title and interest in and to the '186 patent (attached hereto as Exhibit A), titled "Salts of Fenofibric Acid and Pharmaceutical Formulations Thereof."

13. The '186 patent, which currently expires on January 7, 2025, claims novel salts of and formulations of fenofibric acid.

14. These novel salts and formulations of fenofibric acid are useful as lipid and cholesterol lowering agents for treatment of adults with increased triglyceride levels.

15. Abbott has approval from the FDA to market choline fenofibrate delayed-release capsules under the name TRILIPIX®.

16. TRILIPIX® (choline 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).

17. The FDA's "Orange Book" also lists patents associated with approved drugs. The '186 patent is listed in the "Orange Book" in association with TRILIPIX® (choline fenofibrate).

18. On information and belief, Anchen submitted ANDA No. 201573 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 choline fenofibrate delayed-release capsules in a 135 mg dosage ("Anchen's DR Capsules, 135 mg") as a generic version of the TRILIPIX® 135 mg delayed-release capsules.

19. Upon information and belief, Anchen will market and/or distribute Anchen's DR Capsules, 135 mg if ANDA No. 201573 is approved by the FDA.

20. By letter dated May 28, 2010, Anchen advised Abbott and Fournier that it had submitted ANDA No. 201573 seeking approval to manufacture, use, or sell Anchen's DR Capsules, 135 mg prior to the expiration of the '186 patent.

21. The May 28, 2010 letter also advised Abbott and Fournier that ANDA No. 201573 included a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in Anchen's opinion, the '186 patent is invalid and/or claims 3-15 will not be infringed by the commercial manufacture, use, or sale of Anchen's DR Capsules, 135 mg.

22. Anchen's May 28, 2010 letter did not contest infringement of claims 1 and 2 of the '186 patent by the commercial manufacture, use, or sale of Anchen's DR Capsules, 135 mg.

COUNT I

Patent Infringement

23. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 22 hereof, as if fully set forth herein.

24. 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.

25. Anchen's submission of ANDA No. 201573 for approval to sell Anchen's DR Capsules, 135 mg prior to the expiration of the '186 patent constitutes an act of infringement of one or more claims of the '186 patent under 35 U.S.C. § 271(e)(2). In addition, Anchen's DR Capsules, 135 mg infringe one or more claims of the '186 patent under 35 U.S.C. § 271.

26. On information and belief, Anchen acted without a reasonable basis or a good-faith belief that it would not be liable for infringing the '186 patent.

27. Plaintiffs have no adequate remedy at law to redress the infringement by Anchen.

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

29. Plaintiffs will be irreparably harmed if Anchen is not enjoined from infringing the '186 patent.

PRAYER

WHEREFORE, Plaintiffs respectfully request relief and judgment as follows:

- (a) a judgment that the '186 patent is valid and enforceable, and infringed under 35 U.S.C. § 271(e)(2) by Anchen's filing of its ANDA No. 201573;
- (b) an order that the effective date of the approval of ANDA No. 201573 be subsequent to the expiration date of the '186 patent;
- (c) an injunction prohibiting Anchen from commercially manufacturing, selling or offering for sale, using, or importing the choline fenofibrate compositions claimed in the '186 patent or otherwise infringing one or more claims of the '186 patent;
- (d) damages and/or other monetary relief pursuant to 35 U.S.C. § 284 in the event of any commercial manufacture, use or sale by Anchen of choline fenofibrate compositions falling within the scope of one or more claims of the '186 patent;
- (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.

Plaintiffs, by their undersigned counsel, further certify that there are currently five actions pending in this Court alleging infringement of the '186 patent: *Abbott Labs. v. Impax Labs., Inc.*, No. 10-1322 (D.N.J. Mar. 12, 2010); *Abbott Labs. v. Lupin Ltd.*, No. 10-1578 (D.N.J. Mar. 26, 2010); *Abbott Labs. v. Mylan Pharm.*, No. 10-2073 (D.N.J. Apr. 23, 2010); *Abbott Labs. v. Watson Labs., Inc.-Fla.*, No. 10-2139 (D.N.J. Apr. 27, 2010); and *Abbott Labs. v. Actavis Elizabeth LLC*, No. 10-2352 (D.N.J. May 7, 2010).

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 Fournier Laboratories Ireland, Ltd.*

Of Counsel:

Michael F. Buchanan

Chad J. Peterman

Jesse A. Devine

Edward R. Tempesta

PATTERSON BELKNAP

WEBB & TYLER LLP

1133 Avenue of the Americas

New York, New York 10036

Tel.: (212) 336-2000

Fax: (212) 336-2222

Dated: June 14, 2010