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

ABBOTT LABORATORIES and)
FOURNIER LABORATORIES)
IRELAND LTD.,)
)
Plaintiffs,)
)
v.)
)
LUPIN LIMITED and LUPIN)
PHARMACEUTICALS, INC.,)
)
Defendants.)
_____)

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Abbott Laboratories ("Abbott") and Fournier Laboratories Ireland Ltd.
("Fournier"), for their Complaint against Lupin Limited ("Lupin Ltd.") and Lupin

Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") (together with Lupin Ltd., "Lupin") 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 Defendants' filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell generic copies of Plaintiffs' highly successful TRILIPIX® 45 mg and 135 mg products 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. On information and belief, Lupin Ltd. is an Indian corporation having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (W), Mumbai 400 051, India, and having a registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India. On information and belief, Lupin Ltd. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products through various operating subsidiaries, including Lupin Pharmaceuticals.

5. On information and belief, Lupin Pharmaceuticals is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202. On information and belief, Lupin Pharmaceuticals is in the business of, among other things,

manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. Lupin Pharmaceuticals is a wholly owned subsidiary of Lupin Ltd.

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 Lupin Ltd. because Lupin Ltd. 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, Lupin Ltd. 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 Lupin Pharmaceuticals because Lupin 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, Lupin Pharmaceuticals has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district.

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

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

11. On information and belief, Lupin Pharmaceuticals is registered to do business in New Jersey.

12. On information and belief, Lupin Pharmaceuticals has appointed National Registered Agents, Inc. of Princeton, New Jersey as its registered agent for the receipt of service of process.

13. Lupin Ltd. and Lupin Pharmaceuticals stipulated to personal jurisdiction in this district in a prior patent case. *See* Stipulation and Order ¶ 1, *Sepracor Inc. v. Sun Pharm. Indus. Ltd.*, (D.N.J. Dec. 17, 2008) (No. 07-4213). Lupin Ltd. and Lupin Pharmaceuticals also have consented to personal jurisdiction in this district in prior patent cases involving each of the plaintiffs here. *See* Lupin Ltd.'s and Lupin Pharmaceuticals, Inc.'s Answer, Defenses and Counterclaims at 4, *Abbott Labs. v. Lupin Ltd.*, (D.N.J. May 8, 2009) (No. 09-1007); Lupin Ltd. and Lupin Pharmaceuticals, Inc.'s Answer, Defenses and Counterclaims at 4, *Élan Pharma Int'l Ltd. v. Lupin Ltd.*, (D.N.J. May 8, 2009) (No. 09-1008).

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

BACKGROUND

15. 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."

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

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

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

19. 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).

20. 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).

21. On information and belief, Lupin Ltd., itself and/or through its subsidiary, agent and alter ego, Lupin Pharmaceuticals, submitted ANDA No. 200750 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 45 mg and 135 mg dosages ("Lupin's DR Capsules, 45 mg and 135 mg") as generic versions of the TRILIPIX® 45 mg and 135 mg delayed-release capsules. Upon information and belief, Lupin Pharmaceuticals will market and/or distribute Lupin's DR Capsules, 45 mg and 135 mg if ANDA No. 200750 is approved by the FDA.

22. By letter dated February 9, 2010, Lupin advised Abbott and Fournier that it had submitted ANDA No. 200750 seeking approval to manufacture, use, or sell Lupin's DR Capsules, 45 mg and 135 mg prior to the expiration of the '186 patent.

23. The February 9, 2010 letter also advised Abbott and Fournier that ANDA No. 200750 included a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in Lupin's opinion,

the '186 patent is invalid and/or claims 3-15 will not be infringed by the commercial manufacture, use, or sale of Lupin's DR Capsules, 45 mg and 135 mg.

24. Lupin's February 9, 2010 letter did not contest infringement of claims 1 and 2 of the '186 patent by the commercial manufacture, use, or sale of Lupin's DR Capsules, 45 mg and 135 mg.

COUNT I

Patent Infringement

25. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 18 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.

27. Lupin's submission of ANDA No. 200750 for approval to sell Lupin's DR Capsules, 45 mg and 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, Lupin's DR Capsules, 45 mg and 135 mg infringe one or more claims of the '186 patent under 35 U.S.C. § 271.

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

29. Plaintiffs have no adequate remedy at law to redress the infringement by Lupin.

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

31. Plaintiffs will be irreparably harmed if Lupin 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 Lupin's filing of its ANDA No. 200750;
- (b) an order that the effective date of the approval of ANDA No. 200750 be subsequent to the expiration date of the '186 patent;
- (c) an injunction prohibiting Lupin 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 Lupin 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.

Respectfully submitted,

s/ Thomas R. Curtin

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