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

ABBOTT LABORATORIES and FOURNIER LABORATORIES IRELAND LTD.,	)	
Plaintiffs,	)	**Civil Action No. _____**
v.	)	
SANDOZ INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Abbott Laboratories ("Abbott") and Fournier Laboratories Ireland Ltd. ("Fournier"), for their Complaint against defendant Sandoz Inc. ("Sandoz") 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 Sandoz's 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. Abbott Laboratories is a parent of Fournier Laboratories Ireland Ltd.

5. On information and belief, Sandoz Inc. is a corporation organized under the laws of Colorado having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

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 Sandoz Inc. because Sandoz 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, Sandoz Inc. has had persistent and continuous contacts with this judicial district, including having a principal place of business in New Jersey, selling various products within New Jersey, and previously submitting to the jurisdiction of this Court.

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

BACKGROUND

9. 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."

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

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

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

13. 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).

14. 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).

15. On information and belief, Sandoz submitted ANDA No. 202401 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 ("Sandoz's DR Capsules, 45 mg and 135 mg") as generic versions of the TRILIPIX® 45 mg and 135 mg delayed-release capsules.

16. Upon information and belief, Sandoz will market and/or distribute Sandoz's DR Capsules, 45 mg and 135 mg if ANDA No. 202401 is approved by the FDA.

17. By letter dated January 31, 2011, Sandoz advised Abbott and Fournier that it had submitted ANDA No. 202401 seeking approval to manufacture, use, or sell Sandoz's DR Capsules, 45 mg and 135 mg prior to the expiration of the '186 patent.

18. The January 31, 2011 letter also advised Abbott and Fournier that ANDA No. 202401 included a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in Sandoz's opinion, the '186 patent is invalid and/or claims 3-15 will not be infringed by the commercial manufacture, use, or sale of Sandoz's DR Capsules, 45 mg and 135 mg.

19. Sandoz's January 31, 2011 letter did not contest infringement of claims 1 and 2 of the '186 patent by the commercial manufacture, use, or sale of Sandoz's DR Capsules, 45 mg and 135 mg.

COUNT I

Patent Infringement

20. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 19 hereof, as if fully set forth herein.

21. 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.

22. Sandoz's submission of ANDA No. 202401 for approval to sell Sandoz'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,

Sandoz's DR Capsules, 45 mg and 135 mg infringe one or more claims of the '186 patent under 35 U.S.C. § 271.

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

24. Plaintiffs have no adequate remedy at law to redress the infringement by Sandoz.

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

26. Plaintiffs will be irreparably harmed if Sandoz 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 Sandoz's filing of its ANDA No. 202401;

(b) an order that the effective date of the approval of ANDA No. 202401 be subsequent to the expiration date of the '186 patent;

(c) an injunction prohibiting Sandoz 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 Sandoz 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.

s/Kelly S. Crawford
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