UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO.

ABBOTT LABORATORIES; and,
FOURNIER LABORATORIES IRELAND LTD.,

Plaintiffs,

vs.

WATSON LABORATORIES, INC.-FLORIDA;
WATSON PHARMA, INC.; and, WATSON
PHARMACEUTICALS, INC.,

Defendants.
_____/

COMPLAINT FOR PATENT INFRINGEMENT

Abbott Laboratories ("Abbott") and Fournier Laboratories Ireland Ltd. ("Fournier") for their Complaint against Watson Laboratories, Inc.-Florida ("Watson Laboratories"), Watson Pharma, Inc. ("Watson Pharma") and Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") (collectively, "Watson") allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 7,259,186 (the "'186 patent"). This action arises out of Watson'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, County Cork, Ireland.

4. On information and belief, Watson Pharmaceuticals is a Nevada corporation having places of business at 311 Bonnie Circle, Corona, California 92880 and 360 Mount Kemble Avenue, Morristown, New Jersey 07962.

5. On information and belief, Watson Pharmaceuticals is in the business of, among other things, developing, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market through various directly or indirectly owned operating subsidiaries, including Watson Laboratories and Watson Pharma.

6. On information and belief, Watson Laboratories is a Florida corporation having places of business at 4955 Orange Drive, Davie, Florida 33314 and 360 Mount Kemble Avenue, Morristown, New Jersey 07962.

7. On information and belief, Watson Laboratories was formerly known as Andrx Pharmaceuticals, Inc. Watson Laboratories is a wholly owned subsidiary of Andrx Corp., a Delaware corporation that is a wholly owned subsidiary of Watson Pharmaceuticals.

8. On information and belief, Watson Laboratories is in the business of, among other things, developing and manufacturing generic copies of branded pharmaceutical products for the U.S. market.

9. On information and belief, Watson Pharma is a Delaware corporation having its principal place of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07962.

10. On information and belief, Watson Pharma is a wholly owned subsidiary of Watson Pharmaceuticals.

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11. On information and belief, Watson Pharma is in the business of, among other things, distributing and selling generic copies of branded pharmaceutical products for the U.S. market.

JURISDICTION AND VENUE

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

13. This Court has personal jurisdiction over Watson Laboratories by virtue of its incorporation in Florida.

14. On information and belief, this Court has personal jurisdiction over Watson Pharmaceuticals, Watson Laboratories and Watson Pharma because, *inter alia*, they have committed, aided, abetted, actively induced, contributed to or participated in the commission of 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.

15. On information and belief, this Court has personal jurisdiction over Watson Pharmaceuticals, Watson Laboratories and Watson Pharma because, *inter alia*, they have purposely availed themselves of the benefits and protections of Florida's laws such that they should reasonably anticipate being haled into court here. On information and belief, Watson Pharmaceuticals, Watson Laboratories and Watson Pharma have had persistent, continuous and systematic contacts with this judicial district by, *inter alia*, deriving substantial revenue, either directly or through an agent, from the development, manufacture and/or sale of pharmaceutical products that are sold in Florida.

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16. On information and belief, Watson Pharmaceuticals, Watson Laboratories and/or Watson Pharma share certain common employees, officers and directors.

17. On information and belief, Watson Pharmaceuticals organizes its operations by division, including at least the Generic, Brand and Distribution divisions, and reports its financial results in its Securities and Exchange Commission ("SEC") filings by reference to these divisions.

18. On information and belief, Watson's Generic Division, which develops, manufactures, markets and sells generic copies of branded pharmaceutical products for the U.S. market, relies on the respective coordinated contributions of at least Watson Pharmaceuticals, Watson Laboratories and Watson Pharma.

19. On information and belief, Watson Pharmaceuticals, Watson Laboratories and Watson Pharma are agents of each other and/or operate in concert as integrated parts of Watson's Generic Division.

20. On information and belief, Watson Pharmaceuticals has consolidated its activities and financial results, including revenue earned, with, *inter alia*, Watson Laboratories and Watson Pharma in its most recent SEC filings and Annual Report.

21. On information and belief, Watson Pharma, acting as the agent of Watson Pharmaceuticals and/or Watson Laboratories, distributes and sells in Florida and elsewhere in the United States various generic pharmaceutical products that are manufactured by Watson Laboratories or for which Watson Laboratories is the named applicant on approved ANDAs. On information and belief, Watson Pharma and Watson Laboratories are parties to one or more contractual agreements regarding the distribution of such generic pharmaceutical products. On information and belief, such agreements are at less than arm's length.

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22. On information and belief, Watson Pharmaceuticals and/or Watson Laboratories earns revenue from the distribution in Florida by Watson Pharma of generic pharmaceutical products that are manufactured by Watson Laboratories or for which Watson Laboratories is the named applicant on approved ANDAs.

23. On information and belief, Watson Pharmaceuticals and Watson Pharma participated in, contributed to, aided, abetted and/or induced the submission to the U.S. Food and Drug Administration ("FDA") of ANDA No. 200564, the ANDA at issue in this litigation. For instance, by letter dated March 12, 2010, Watson Laboratories directed Abbott and Fournier to send any correspondence or requests for confidential access concerning ANDA No. 200564 to Mr. Michael G. Bryner at 2945 West Corporate Lakes Boulevard, Building, E Suite B, Weston, Florida 33331. Mr. Bryner is registered with the U.S. Patent and Trademark Office as an attorney employed by Watson Pharmaceuticals.

24. On information and belief, Watson Pharma is registered to do business in Florida and has appointed C T Corporation System, 1200 South Pine Island Road, Plantation , FL 33324, as its agent for receipt of service of process in Florida. On information and belief, Watson Pharma has sales personnel assigned to cover Florida for the purpose of marketing and selling Generic Division, including products developed or manufactured by Watson Laboratories.

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

BACKGROUND

26. 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."

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

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

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

30. 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).

31. 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).

32. On information and belief, Watson Laboratories, itself and with the authorization, contribution, participation, assistance or inducement of Watson Pharmaceuticals and Watson Pharma, submitted ANDA No. 200564 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 ("Watson'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, each of Watson Pharmaceuticals, Watson Laboratories and Watson Pharma, acting in concert as part of Watson's Generic Division, will market and/or distribute Watson's DR Capsules, 45 mg and 135 mg if ANDA No. 200564 is approved by the FDA.

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33. By letter dated March 12, 2010, Watson Laboratories advised Abbott and Fournier that it had submitted ANDA No. 200564 seeking approval to manufacture, use, or sell Watson's DR Capsules, 45 mg and 135 mg prior to the expiration of the '186 patent.

34. The March 12, 2010 letter also advised Abbott and Fournier that ANDA No. 200564 included a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in Watson's opinion, the '186 patent is invalid and/or claims 3-15 of the '186 patent will not be infringed by the commercial manufacture, use, or sale of Watson's DR Capsules, 45 mg and 135 mg.

35. The March 12, 2010 letter did not contest infringement of claims 1 and 2 of the '186 patent by the commercial manufacture, use, or sale of Watson's DR Capsules, 45 mg and 135 mg.

COUNT I

Patent Infringement

36. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 35 hereof, as if fully set forth herein.

37. 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.

38. Watson's submission of ANDA No. 200564 for approval to sell Watson'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, Watson's DR Capsules, 45 mg and 135 mg infringe one or more claims of the '186 patent under 35 U.S.C. § 271.

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

40. Plaintiffs have no adequate remedy at law to redress the infringement by Watson.

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

42. Plaintiffs will be irreparably harmed if Watson 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 Watson's filing of its ANDA No. 200564;

(b) an order that the effective date of the approval of ANDA No. 200564 be subsequent to the expiration date of the '186 patent;

(c) an injunction prohibiting Watson 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 Watson 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,

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(f) such other and further relief as the Court may deem just and proper.

Respectfully submitted,

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