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

ABBOTT LABORATORIES and LABORATOIRES FOURNIER S.A., Plaintiffs, v. IMPAX LABORATORIES, INC., Defendant.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Abbott Laboratories ("Abbott") and Laboratoires Fournier S.A. ("Fournier") for their Complaint against Impax Laboratories, Inc. ("Impax") 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 Defendant's 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, Impax is a Delaware corporation having its principal place of business at 30831 Huntwood Avenue, Hayward, California, 94544, and having a its primary commercial center at 3735 Castor Avenue, Philadelphia, PA 19124. On information and belief, Impax is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products.

JURISDICTION AND VENUE

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

6. On information and belief, this Court has personal jurisdiction over Impax because Impax 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, Impax has had persistent and continuous contacts with this judicial district, including developing

and/or manufacturing pharmaceutical products that are sold in this judicial district.

7. Impax previously consented to personal jurisdiction in this district in prior patent cases. *E.g.*, Answer, Affirmative Defenses, and Counterclaims, *Warner Chilcott Laboratories et al. v. Impax Laboratories, Inc.*, Case No. 09-1233 (D.N.J. Apr. 3, 2009) (refusing to contest personal jurisdiction in that case and admitting that it had not contested personal jurisdiction in another case in this judicial district).

8. Three related lawsuits are currently pending in this Court. On February 29, 2008, Abbott and Fournier filed suit in the United States District Court for the Northern District of Illinois against Teva Pharmaceuticals USA, Inc. ("Teva") seeking a judgment that each of the Patents-in-Suit is infringed by Teva's filing of its ANDA No. 90-069. *See Abbott Laboratories and Laboratoires Fournier S.A. v. Teva Pharmaceuticals USA, Inc.*, Case No. 08-CV-1243 (N.D. Ill.). On November 12, 2008, the Illinois court transferred the lawsuit to this Court. On December 3, 2008, this Court acknowledged the transfer. *See Abbott Laboratories and Laboratoires Fournier S.A. v. Teva Pharmaceuticals USA, Inc.*, Case No. 08-CV-5869 (D.N.J.). On November 3, 2008, Abbott and Fournier filed suit in the United States District Court for the Northern District of Illinois against Biovail Laboratories International SRL and Biovail Corporation (collectively "Biovail") seeking a judgment that each of the Patents-in-Suit is infringed by Biovail's filing of its ANDA No. 90-715. *See Abbott Laboratories and Laboratoires Fournier S.A. v. Biovail Laboratories International SRL and Biovail Corp.*, Case No. 08-CV-6274 (N.D. Ill.). On December 10, 2008, the Illinois court transferred the lawsuit to this Court. On January 5, 2009, this Court acknowledged the transfer. *See Abbott Laboratories and Laboratoires Fournier S.A. v. Biovail Laboratories International SRL and Biovail Corp.*, Case No. 09-CV-0005 (D.N.J.). On March 6, 2009, Abbott and Fournier filed suit in this Court

against Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively "Lupin") seeking a judgment that each of the Patents-in-Suit is infringed by Lupin's filing of its ANDA No. 90-856. *See Abbott Laboratories and Laboratoires Fournier, S.A. v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, Case No. 09-CV-1007 (D.N.J.).

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

BACKGROUND

10. 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).

11. 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."

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

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

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

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

16. 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).

17. 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).

18. On information and belief, Impax submitted ANDA No. 91-548 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 ("Impax's Tablets, 48 mg and 145 mg") as generic versions of the TRICOR® 48 mg and 145 mg tablets. Upon information and belief, Impax will market and/or distribute Impax's Tablets, 48 mg and 145 mg if ANDA No. 91-548 is approved by the FDA.

19. By letter dated September 14, 2009, Impax advised Abbott and Fournier that it had submitted ANDA No. 91-548 seeking approval to manufacture, use, or sell fenofibrate tablets in 145 mg doses prior to the expiration of the Patents-in-Suit.

20. By letter dated September 30, 2009, Impax advised Abbott and Fournier that it had submitted an amendment to its ANDA No. 91-548 seeking approval to manufacture, use, or sell fenofibrate tablets in 48 mg doses prior to the expiration of the Patents-in-Suit.

21. The September 14, 2009 and September 30, 2009 letters also advised Abbott and Fournier that Impax's ANDA included a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in Impax's opinion, the Patents-in-Suit are invalid and/or will not be infringed by the commercial manufacture, use, or sale of Impax's Tablets, 48 mg and 145 mg.

COUNT I

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

23. 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. Impax's submission of an ANDA for approval to sell Impax'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, Impax's Tablets, 48 mg and145 mg infringe one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271.

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

25. Plaintiffs have no adequate remedy at law to redress Impax's infringement.

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

27. Plaintiffs will be irreparably harmed if Defendant 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 Impax's filing of its ANDA No. 91-548;

(b) an order that the effective date of the approval of ANDA No. 91-548 be subsequent to the expiration date of each of the Patents-in-Suit;

(c) an injunction prohibiting Impax 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 Impax;

(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, with the exception of the related lawsuits identified in Paragraph 8 of this Complaint involving different defendants but the same Patents-in-Suit.

Respectfully submitted,

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