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

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ABBOTT LABORATORIES and  
LABORATOIRES FOURNIER S.A.,

Plaintiffs,

v.

WOCKHARDT, LTD., and  
WOCKHARDT USA, LLC,

Defendants.

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) Civil Action No. 2:11-cv-7046 (DMC) (JAD)  
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**AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Abbott Laboratories (“Abbott”) and Laboratoires Fournier S.A. (“Fournier”), for their  
Amended Complaint against Wockhardt, Ltd. and Wockhardt USA, LLC (collectively,  
“Wockhardt”), 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 Defendants' 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 the Patents-in-Suit.

#### 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, Defendant Wockhardt, Ltd. is an Indian company having a principal place of business at Wockhardt Towers, Bandra-Kurla Complex, Bandra (East), Mumbai 400051, Maharashtra, India. On information and belief, Wockhardt Ltd. is in the business of, among other things, manufacturing, marketing, distributing, and selling generic copies of branded pharmaceutical products, including in the State of New Jersey, through various operating subsidiaries, including Wockhardt USA, LLC.

5. On information and belief, Defendant Wockhardt USA, LLC is a Delaware company having a principal place of business at 20 Waterview Boulevard, 3rd Floor, Parsippany, NJ 07054. On information and belief, Wockhardt USA, LLC is in the business of, among other things, manufacturing, marketing, distributing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of New Jersey. Wockhardt USA, LLC is a wholly owned subsidiary of Wockhardt, 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 Wockhardt, Ltd. because Wockhardt, Ltd. has purposefully 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, Wockhardt, Ltd. has had persistent and continuous contacts with this judicial district, including developing, distributing, marketing, and/or selling pharmaceutical products in this judicial district.

8. On information and belief, this Court has personal jurisdiction over Wockhardt USA, LLC because Wockhardt USA, LLC has purposefully 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, Wockhardt USA, LLC has had persistent and continuous contacts with this judicial district, including developing, distributing, marketing, and/or selling pharmaceutical products in this judicial district with the authorization, participation, or assistance of Wockhardt, Ltd.

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

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

11. On information and belief, Wockhardt USA, LLC is registered to do business in New Jersey and has appointed as its agent for receipt of service of process Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey 08628.

12. On information and belief, Wockhardt, Ltd. maintains an office in this judicial district.

13. Wockhardt, Ltd. and Wockhardt USA, LLC previously consented to personal jurisdiction in this district in prior patent cases. *E.g.*, Answer and Countercls. of Defs. Wockhardt Ltd. and Wockhardt USA LLC ¶ 8, *Aventis Pharms. Inc. v. Wockhardt Ltd.*, C.A. No. 07-5647 (D.N.J. June 4, 2010); Answer and Countercls. of Defs. Wockhardt Ltd. and Wockhardt USA LLC ¶ 9, *Sanofi Aventis U.S. LLC v. Wockhardt Ltd.*, C.A. No. 10-1471 (D.N.J. Apr. 22, 2010); Defs. Wockhardt USA LLC's and Wockhardt Ltd.'s Answer and Countercls. ¶¶ 13-14, *Nautilus Neurosciences, Inc. v. Wockhardt USA LLC*, C.A. No. 11-1997 (D.N.J. Apr. 29, 2011).

14. One related lawsuit is currently pending in this Court. On August 26, 2011, Abbott and Fournier filed suit in this Court against Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively "Mylan") seeking a judgment that each of the Patents-in-Suit is infringed by Mylan's filing of its ANDA No. 202856. *See Abbott Labs. v. Mylan Pharm. Inc.*, C.A. No. 11-4966-DMC-MCA (D.N.J.).

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

#### BACKGROUND

16. 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).

17. 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."

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

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

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

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

22. 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).

23. 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).

24. On information and belief, Wockhardt submitted ANDA No. 203497 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 ("Wockhardt's Tablets, 48 mg and 145 mg"), as generic versions of the TRICOR® 48 mg and 145 mg tablets. On information and belief, Wockhardt will market and/or

distribute Wockhardt's Tablets, 48 mg and 145 mg, if ANDA No. 203497 is approved by the FDA.

25. By letter dated October 18, 2011 (the "Wockhardt Letter"), Wockhardt advised Abbott and Fournier that it had submitted to the FDA ANDA No. 203497 seeking approval to manufacture, use, or sell Wockhardt's Tablets, 48 mg and 145 mg, prior to the expiration of the Patents-in-Suit.

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

#### COUNT I

27. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 26 hereof, as if fully set forth herein.

28. 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. Wockhardt's submission of ANDA No. 203497 for approval to sell Wockhardt'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, Wockhardt's Tablets, 48 mg and 145 mg infringe one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271.

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

30. Plaintiffs have no adequate remedy at law to redress Wockhardt's infringement.

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

32. Plaintiffs will be irreparably harmed if Wockhardt 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 Wockhardt's submission of ANDA No. 203497;

(b) an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 203497 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) be a date that is not earlier than the expiration date of each of the Patents-in-Suit, including any extensions;

(c) an injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Wockhardt and those acting in privity or concert with them 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 Wockhardt;

(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 lawsuit identified in Paragraph 14 of this Amended Complaint involving different defendants but the same Patents-in-Suit.

Respectfully submitted,

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