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

ALKERMES PHARMA IRELAND
LIMITED and FOURNIER
LABORATORIES IRELAND LTD.,

Plaintiffs,

v.

WOCKHARDT, LTD. AND
WOCKHARDT USA, LLC

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Alkermes Pharma Ireland Limited (“Alkermes”) and Fournier Laboratories Ireland Ltd. (“Fournier”) for their 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. 7,276,249 (“the ’249 patent”) and 7,320,802 (“the ’802 patent”). This action arises out of Defendants’ filing of an Abbreviated New Drug Application (“ANDA”) seeking approval to sell generic copies of the highly successful TRICOR® 48 mg and 145 mg products prior to the expiration of Plaintiffs’ patents.

THE PARTIES

2. Plaintiff Alkermes Pharma Ireland Limited is an Irish corporation having a principal place of business at Monksland, Athlone, Co. Westmeath, Ireland.

3. Plaintiff Fournier Laboratories Ireland Ltd. is an Irish corporation having a principal place of business at Anngrove, Carrigtwohill, Co. Cork, Ireland.

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 400 051, 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 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, NJ 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.*, *Aventis Pharms. Inc. v. Wockhardt Ltd.*, C.A. No. 07-5647, Answer and Counterclaims of Defendants Wockhardt Limited and Wockhardt USA, LLC at 3 (D.N.J. June 4, 2010); *Sanofi Aventis U.S. LLC v. Wockhardt Ltd.*, C.A. No. 10-1471, Answer and Counterclaims of Defendants Wockhardt Limited and Wockhardt USA LLC at 3-4 (D.N.J. Apr. 22, 2010); *Nautilus Neurosciences, Inc. v. Wockhardt USA LLC*, C.A. No. 11-1997, Defendants Wockhardt USA LLC's and Wockhardt Ltd.'s Answer and Counterclaims at 4 (D.N.J. Apr. 29, 2011).

14. One related lawsuit is currently pending in this Court. On August 26, 2011, Alkermes (formerly known as EDT Pharma Holdings Ltd.) 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. 20-2856. *See Alkermes Pharma Ireland Ltd. v. Mylan Pharm. Inc.*, C.A. No. 11-4967-JLL-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. On October 2, 2007, the '249 patent, entitled "Nanoparticulate Fibrate Formulations," was duly and legally issued to Elan Pharma International, Ltd. ("Elan") and Fournier as assignees. Elan's rights were subsequently transferred to Alkermes. A true and correct copy of the '249 patent is attached as Exhibit A.

17. On January 22, 2008, the '802 patent, entitled "Methods of Treatment Using Nanoparticulate Fenofibrate Compositions," was duly and legally issued to Elan and Fournier as assignees. Elan's rights were subsequently transferred to Alkermes. A true and correct copy of the '802 patent is attached as Exhibit B.

18. On November 5, 2004, the FDA approved New Drug Application ("NDA") No. 21-656 for TRICOR® tablets, which contain fenofibrate, under § 505(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a), as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia and to reduce elevated LDL-C, Total-C, triglycerides, and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidemia.

19. The '249 and '802 patents are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for TRICOR® tablets.

20. 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 the 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.

21. By letter dated October 18, 2011 (the "Wockhardt Letter"), Wockhardt advised Elan and Fournier that it had submitted ANDA No. 203497 to the FDA seeking approval to manufacture, use, or sell fenofibrate tablets in the 48 mg and 145 mg dosages prior to the expiration of the '249 and '802 patents.

22. The Wockhardt Letter also advised Elan 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 '249 and '802 patents 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

23. Plaintiffs incorporate each of the preceding paragraphs 1 to 22 as if fully set forth herein.

24. Wockhardt's submission of ANDA No. 203497 to the FDA for fenofibrate tablets in the 48 mg and 145 mg dosages, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '249 patent under 35 U.S.C. § 271(e)(2)(A). Wockhardt's commercial manufacture, offer for sale, or sale of the proposed generic for fenofibrate tablets in the 45 mg and 148 mg dosages would infringe the '249 patent.

25. On information and belief, Wockhardt was aware of the existence of the '249 patent and was aware that the filing of ANDA No. 203497 and certification with respect to the '249 patent constituted infringement of that patent. This is an exceptional case.

COUNT II

26. Plaintiffs incorporate each of the preceding paragraphs 1 to 25 as if fully set forth herein.

27. Wockhardt's submission of ANDA No. 203497 to the FDA for fenofibrate tablets in the 48 mg and 145 mg dosages, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '802 patent under 35 U.S.C. § 271(e)(2)(A). Wockhardt's commercial manufacture, offer for sale, or sale of the proposed generic for fenofibrate tablets in the 45 mg and 148 mg dosages would infringe the '802 patent.

28. On information and belief, Wockhardt was aware of the existence of the '802 patent and was aware that the filing of ANDA No. 203497 and certification with respect to the '802 patent constituted infringement of that patent. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

- A. A judgment that Wockhardt has infringed the '249 and '802 patents;
- B. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Wockhardt's ANDA No. 203497 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), be a date which is not earlier than the expiration dates of the '249 and '802 patents, including any extensions;
- C. An injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Wockhardt and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from infringement of the '249 and '802 patents for the full terms thereof, including any extensions;

- D. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;
- E. Costs and expenses in this action; and
- F. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

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Dated: December 2, 2011

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is the subject of *Alkermes Pharma Ireland Limited and Fournier Laboratories Ireland Ltd. v. Mylan Pharmaceuticals Inc. and Mylan Inc.*, 11-cv-04967-JLL-MCA (D.N.J.).

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Dated: December 2, 2011