

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SANOFI-AVENTIS and)
SANOFI-AVENTIS U.S. LLC,)
)
Plaintiffs,)
)
v.)
)
WOCKHARDT LIMITED and)
WOCKHARDT USA, INC.,)
)
Defendants.)

C.A. No. _____

COMPLAINT

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (“sanofi-aventis U.S.”), for their Complaint against Defendants Wockhardt Limited and Wockhardt USA, Inc., hereby allege as follows:

Parties

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Upon information and belief, Wockhardt USA, Inc. is a Delaware Corporation, and a wholly-owned subsidiary and agent of Wockhardt Limited, having a principal place of business at 135 Route 202/206, Bedminster, New Jersey 07921.

4. Upon information and belief, Defendant Wockhardt Limited is an Indian Corporation having a place of business at Wockhardt Towers, Bandra-Kurla Complex, Bandra

(East), Mumbai - 400 051. Upon information and belief, Defendant Wockhardt Limited manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Wockhardt USA, Inc.

Nature of the Action

5. This is a civil action for the infringement of United States Patent No. 6,149,940 (“the ‘940 patent”) (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

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. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to a Delaware company, Plaintiff sanofi-aventis U.S. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

8. This Court has personal jurisdiction over Defendant Wockhardt USA, Inc. by virtue of the fact that, *inter alia*, Wockhardt USA, Inc. is a Delaware Corporation.

9. This Court has personal jurisdiction over Defendant Wockhardt Limited by virtue of, *inter alia*, (1) its presence in Delaware through its subsidiary and agent Wockhardt USA, Inc.; and (2) its systematic and continuous contact with Delaware, including through its subsidiary and agent Wockhardt USA, Inc.

10. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The '940 Patent

11. On November 21, 2000, the '940 patent, titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate," was duly and legally issued by the PTO. Plaintiff sanofi-aventis and Jagotec AG are the current assignees of the '940 patent. Plaintiff sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent. Pursuant to that license, sanofi-aventis has the right to unilaterally bring and proceed with this action in its own name. Jagotec has also consented to sanofi-aventis bringing this action. The '940 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

Acts Giving Rise to this Action Infringement of the '940 Patent by Defendants

12. Upon information and belief, Wockhardt Limited, through its subsidiary and agent Wockhardt USA, Inc., submitted Abbreviated New Drug Application ("ANDA") 90-221 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 90-221 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis's Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

13. Wockhardt Limited alleged in ANDA 90-221 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of

sanofi-aventis's Uroxatral® brand product. Plaintiffs received written notification of ANDA 90-221 on or about February 20, 2008.

14. Wockhardt Limited's submission of ANDA 90-221 to the FDA, through Wockhardt USA, Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Wockhardt Limited's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

15. Wockhardt USA, Inc. is jointly and severally liable for any infringement of the '940 patent. Upon information and belief, Wockhardt USA, Inc. participated in, contributed to, aided, abetted and/or induced Wockhardt Limited's submission of ANDA 90-221 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

16. Wockhardt USA, Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 90-221 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Wockhardt USA, Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis's Uroxatral® brand product would infringe the '940 patent.

17. This is an exceptional case under 35 U.S.C. § 285 because Wockhardt Limited and Wockhardt USA, Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 90-221 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

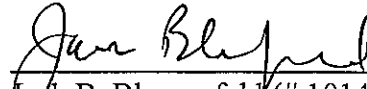
18. Plaintiffs will be irreparably harmed by Wockhardt Limited's and Wockhardt USA, Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, Plaintiffs pray for judgment as follows:

- A. That Defendants have infringed the '940 patent;
- B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Wockhardt Limited's ANDA identified in this Complaint shall not be earlier than the expiration date of the '940 patent, including any extensions;
- C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling the proposed generic version of sanofi-aventis's Uroxatral® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '940 patent, prior to the expiration of the '940 patent, including any extensions;
- D. That this case is exceptional under 35 U.S.C. § 285;
- E. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and
- F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

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