

manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

Nature of the Action

5. This is a civil action for the infringement of United States Patent No. 4,661,491 ("the '491 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 Apotex Inc. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including through its sister corporation and agent Apotex Corp.

9. This Court has personal jurisdiction over Defendant Apotex Corp. by virtue of the fact that, *inter alia*, it is a Delaware corporation.

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

The '491 Patent

11. On April 28, 1987, the '491 patent, titled "Alfuzosine Compositions and Use," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff sanofi-aventis is the current assignee of the '491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application ("NDA") No. 21-287 on Uroxatral[®] brand alfuzosin hydrochloride extended release tablets, and is the exclusive distributor of Uroxatral[®] in the United States. The '491 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 '491 Patent by Defendants**

12. Upon information and belief, Apotex Inc. submitted Abbreviated New Drug Application ("ANDA") 79-013 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 79-013 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral[®] brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

13. Apotex Inc. alleged in ANDA 79-013 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs

received written notification of the § 505(j)(2)(A)(vii)(IV) allegation related to the '491 patent in ANDA 79-013 on or about October 25, 2007.

14. Apotex Inc.'s submission of ANDA 79-013 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Apotex Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

15. Apotex Corp. is jointly and severally liable for Apotex Inc.'s infringement of the '491 patent. Upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced Apotex Inc.'s submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

16. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Apotex Corp.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

17. This is an exceptional case under 35 U.S.C. § 285 because Defendants were aware of the existence of the '491 patent at the time of the submission of ANDA 79-013 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

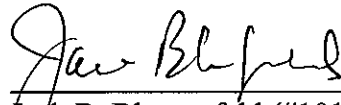
18. Plaintiffs will be irreparably harmed by Defendants infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, Plaintiffs pray for judgment as follows:

- A. That Defendants have infringed the '491 patent;
- B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Apotex Inc.'s ANDA identified in this Complaint shall not be earlier than the expiration date of the '491 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' Uroxatral® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '491 patent, prior to the expiration of the '491 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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December 6, 2007