IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| IN RE: ALFUZOSIN HYDROCHLORIDE PATENT LITIGATION | ) | MDL Docket No. 08-md-1941 GMS |

**MEMORANDUM OPINION**

## I. INTRODUCTION

After having conducted 2 days of a 5-day bench trial on the issues presented in this case, and after considering the testimonial and documentary evidence presented by both sides, and hearing the arguments of counsel for both sides, pursuant to Federal Rule of Civil Procedure 52(a)(1), the court is prepared to rule on the issue of patent infringement under 35 U.S.C. § 271(e)(2).

The court finds that the plaintiffs have proven by the preponderance of the evidence that the defendant, Mylan Pharmaceuticals, Inc.'s ("Mylan"), proposed 10 mg extended release alfuzosin hydrochloride tablets will infringe the asserted claims of the '491 patent. The court further finds that Mylan will induce infringement of the asserted claims of the '491 patent.

## II. FINDINGS OF FACT

The court makes the following factual findings:

1. This is a patent infringement action in which the plaintiffs contend that Mylan's proposed 10 mg alfuzosin hydrochloride product infringes the asserted claims of the '491 patent.

2. The application that led to the '491 patent was filed on May 27, 1986. The '491 patent claims priority from a foreign application filed in France on May 28, 1985.

3. The '491 patent was issued by the USPTO on April 28, 1987, to Synthelabo, a predecessor to the plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively, "sanofi-

aventis"). Synthelabo was the named assignee of the named inventor of the '491 patent, François Regnier. Sanofi-aventis is the owner of the entire right, title, and interest in the '491 patent.

4. The '491 patent claims a method for treating humans for dysuria by administering an effective non-toxic amount of alfuzosin or a pharmaceutically acceptable salt thereof.

5. Alfuzosin is an alpha$_1$-blocker that relaxes the smooth muscle in the lower urinary tract, including bladder neck and prostate, resulting in an improvement in urine flow and a reduction in the symptoms of benign prostatic hypertrophy or benign prostatic hyperplasia ("BPH"). Alfuzosin hydrochloride is a pharmaceutically acceptable salt of alfuzosin.

6. The '491 patent is subject to a term extension of 1,697 days, pursuant to 35 U.S.C. § 156, and is set to expire on January 18, 2011.

7. Sanofi-aventis holds an approved NDA No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended-release tablets, and is the exclusive distributor of Uroxatral® in the United States.

8. The '491 patent is listed in the FDA's Orange Book in connection with sanofi-aventis' Uroxatral® extended-release tablets.

9. On June 12, 2007, Mylan submitted an ANDA No. 79-014 to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of a 10 mg extended release generic Uroxatral® product. Mylan's ANDA names Uroxatral® as the reference listed drug.

10. On August 27, 2007, sanofi-aventis received a Paragraph IV Certification letter from Mylan notifying it that Mylan's ANDA includes a certification that the '491 patent is invalid, unenforceable, or will not be infringed by the commercial, manufacture, use or sale of the drug product described in Mylan's ANDA.

11. On September 21, 2007, sanofi-aventis filed its action for patent infringement against

Mylan.

12. On June 9, 2008, this action was consolidated for pretrial proceedings with other related suits by the Judicial Panel on Multidistrict Litigation.

## III. CONCLUSIONS OF LAW

The court makes the following conclusions of law:

### A. Direct Infringement

1. The application of a patent claim to an accused product is a fact-specific inquiry. *See Kustom Signals, Inc. v. Applied Concepts, Inc.*, 264 F.3d 1326, 1332 (Fed. Cir. 2001). Literal infringement is present only when each and every element set forth in the patent claims is found in the accused product. *See Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575-76 (Fed. Cir. 1995). The patent owner has the burden of proving infringement by a preponderance of the evidence. *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758 (Fed. Cir. 1984) (citing *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1361 (Fed. Cir. 1983)).

2. "Under [35 U.S.C.] § 271(e)(2)(A), a court must determine whether, if the drug were approved based upon the ANDA, the manufacture, use, or sale of that drug would infringe the patent in the conventional sense." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

3. Sanofi-aventis has carried its burden of showing by a preponderance of the evidence that Mylan literally infringes the asserted claims of the '491 patent.

4. In reaching this conclusion, the court credits the testimony of Dr. O'Leary. At trial, Dr. O'Leary testified that, based on the court's claim construction and his claim-by-claim analysis of the '491 patent and the information included in Mylan's ANDA, the proposed use of Mylan's generic product "absolutely will infringe claims 1 through 5 of the '491 patent." (Trial Tr. at 310:23-24.)

5. With respect to the only independent claim, claim 1, Dr. O'Leary concluded that Mylan's proposed product met every limitation because it: (1) is intended to be administered to humans; (2) is indicated for the signs and symptoms of BPH; (3) contains alfuzosin hydrochloride, a pharmaceutically acceptable salt of alfuzosin; and (4) will be effective in treating painful or difficult urination. (Id. at 301:25-304:19.) Dr. O'Leary also testified that Mylan's proposed generic infringes dependent claims 2-5 of the '491 patent. (Id. at 305:2-310:24.) In reaching his conclusions, Dr. O'Leary noted that Mylan's proposed product label was "virtually identical" to both the claims of the '491 patent and the package insert for Uroxatral. (Id. at 303:1-3; 311:12-17.) Mylan did not effectively challenge or directly refute Dr. O'Leary's conclusions in this regard on cross-examination.

6. Based on the factual record in this case, the documentary and testimonial evidence presented at trial, including the expert testimony on the issue of infringement, the court is persuaded that the plaintiffs have, indeed, proven by a preponderance of the evidence that manufacture, use, or sale of Mylan's proposed generic alfuzosin hydrochloride product would infringe the asserted claims of the '491 patent.

**B. Inducement**

7. Under Section 271(b) "[w]hoever actively induces infringement of a patent shall be liable as an infringer." To establish liability under section 271(b), a patent holder must prove that once the defendant knew of the patent, it "actively and *knowingly* aid[ed] and abett[ed] another's direct infringement." *DSU Med. Corp. v JMS Co., Ltd.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (citation omitted) (emphasis in original). The "mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." *Id.* (citing *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003)).

8. Sanofi-aventis has carried its burden of showing by a preponderance of the evidence that Mylan induces infringement of the asserted claims of the '491 patent.

9. In reaching this conclusion, the court again credits the testimony of Dr. O'Leary. At trial, Dr. O'Leary testified that Mylan knew of the '491 patent, because it referenced that patent in its Paragraph IV Certification notice letter. (Tr. at 312:5-17; See PTX-4.)

10. Dr. O'Leary further testified that Mylan's proposed label instructs physicians and patients how to use its generic Uroxatral® product. (Id. at 312:18-20; see Id. at 327:16-25.) As Dr. O'Leary testified, Mylan instructs pharmacists to dispense the label leaflet with each prescription. (Id. at 312:25-313:5; PTX 67 at Mylan0000089.) The label leaflet also instructs patients to read it before they use Mylan's generic alfuzosin hydrochloride product. (PTX 67 at Mylan0000090; Tr. at 332:3-23.) Dr. O'Leary further noted that the only use for which Mylan tells doctors to prescribe and patients to use its generic alfuzosin hydrochloride product is for the treatment of the symptoms of BPH. (Tr. at 313:18-24; see Id. at 335:16-20; PTX 67 at Mylan0000079.) Thus, Dr. O'Leary concluded that Mylan will induce infringement of claims 1-5 of the '491 patent. Again, Mylan did not effectively challenge or directly refute Dr. O'Leary's conclusions in this regard on cross-examination.

11. Based on the factual record in this case, the documentary and testimonial evidence presented at trial, including the expert testimony on the issue of inducement of infringement, the court is persuaded that the plaintiffs have, indeed, proven by a preponderance of the evidence that Mylan will induce infringement of the asserted claims of the '491 patent.

Dated: May 14, 2010

CHIEF, UNITED STATES DISTRICT JUDGE