IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALKERMES PHARMA IRELAND LIMITED,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
SUN PHARMA GLOBAL FZE and SUN PHARMACEUTICAL INDUSTRIES, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiff Alkermes Pharma Ireland Limited ("Alkermes"), for its Complaint against Defendants Sun Pharma Global FZE ("Sun FZE") and Sun Pharmaceutical Industries, Inc. ("Sun Inc.") (collectively "Defendants"), alleges as follows:

PARTIES

1. Alkermes is an Irish corporation having its principal place of business at Connaught House, 1 Burlington Road, Dublin 4, Ireland.

2. On information and belief, Sun FZE is a limited liability company organized under the laws of the United Arab Emirates, having a principal place of business at Office #43, Block Y, SAIF Zone, P.O. Box 122304, Sharjah, United Arab Emirates. On information and belief, Sun FZE, itself and through its agent Sun Inc., sells various pharmaceutical products throughout the United States, including in the State of Delaware.

3. On information and belief, Sun Inc. is a Michigan corporation having its principal place of business at 1150 Elijah McCoy Drive, Detroit, Michigan 48202. On information and belief, Sun Inc. was formerly known as Caraco Pharmaceutical Laboratories, Ltd. and is in the

business of, among other things, manufacturing, marketing, distributing, and selling pharmaceutical products throughout the United States, including in the State of Delaware.

NATURE OF ACTION

4. This is an action for infringement of United States Patent No. 6,730,325 ("the '325 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Defendants because they have purposefully availed themselves of the privilege of selling their pharmaceutical products in the State of Delaware and, therefore, can reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, on information and belief, Defendants conduct marketing and sales activities in the State of Delaware, including, but not limited to, the distribution, marketing, and/or sales of pharmaceutical products to Delaware residents that are continuous and systematic.

7. Sun FZE has previously been sued in this district, has not challenged personal jurisdiction in those suits, and has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g., Aventis Pharma S.A. v. Sun Pharm. Indus. Ltd.*, No. 09-630-GMS, *AbbVie Inc. v. Sun Pharm. Indus. Ltd.*, No. 10-112-SLR, *UCB, Inc. v. Sun Pharma Global FZE*, No. 13-1218-LPS, *Teijin Ltd. v. Sun Pharma Global FZE*, No. 13-1852-SLR, *Sanofi v. Sun Pharma Global FZE*, No. 14-294-RGA, *AstraZeneca AB v. Sun Pharma Global FZE*, No. 14-694-GMS.

8. Sun Inc. has previously been sued in this district, has not challenged personal jurisdiction in those suits, and has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g., Pfizer Inc. v. Sun Pharma Global Inc.*, No. 09-313-GMS. Furthermore, on information and belief, under its former name, Caraco Pharmaceutical Laboratories, Ltd., Sun Inc. has held Delaware pharmaceutical wholesale licenses and distributor/manufacturer licenses for controlled substances that have since lapsed and has pending applications for Delaware pharmacy wholesale licenses. *See Sanofi v. Sun Pharma Global FZE*, No. 14-294-RGA, D.I. 19 at ¶ 14.

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

FACTUAL BACKGROUND

10. On May 4, 2004, the '325 patent, entitled "Multiparticulate Modified Release Composition," was duly and legally issued to Elan Corporation, plc ("Elan") as assignee. Elan's rights were subsequently transferred to Alkermes. A true and correct copy of the '325 patent is attached as Exhibit A.

11. On May 26, 2005, the United States Food And Drug Administration ("FDA") approved new drug application No. 21-802 for Focalin® XR capsules, which contain dexmethylphenidate hydrochloride, under § 505(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a), for the treatment of Attention Deficit Hyperactivity Disorder. The '325 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for Focalin® XR capsules.

12. On information and belief, Defendants submitted abbreviated new drug application ("ANDA") No. 206734 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 dexmethylphenidate hydrochloride extended-release capsules in the 5, 10, 15, 20, 25, 30, 35, and 40 mg strengths, as generic versions of the FOCALIN® XR 5, 10, 15, 20, 25, 30, 35, and 40 mg capsules.

13. By letters dated June 13, 2014, and June 17, 2014 (the "Notice Letters"), Defendants advised Alkermes that they had submitted ANDA No. 206734 seeking approval to manufacture, use, or sell generic dexmethylphenidate hydrochloride extended-release capsules in the 5, 10, 15, 20, 25, 30, 35, and 40 mg strengths prior to the expiration of the '325 patent.

14. The Notice Letters also advised Alkermes that Defendants' ANDA included a certification under 21 U.S.C. § 355(j)(2)(B)(ii) that, in Defendants' opinion, the claims of the '325 patent are invalid or unenforceable.

COUNT I

15. Alkermes incorporates each of the preceding paragraphs 1 to 14 as if fully set forth herein.

16. Defendants' submission of ANDA No. 206734 to the FDA for dexmethylphenidate hydrochloride extended-release capsules in the 5, 10, 15, 20, 25, 30, 35, and 40 mg strengths, including the § 505(j)(2)(B)(ii) allegations, constitutes infringement of the '325 patent under 35 U.S.C. § 271(e)(2)(A). Defendants' commercial manufacture, offer for sale, or sale of the proposed generic for dexmethylphenidate hydrochloride extended-release capsules in the 5, 10, 15, 20, 25, 30, 35, and 40 mg strengths would infringe the '325 patent.

17. On information and belief, Defendants were aware of the existence of the '325 patent and were aware that the filing of ANDA No. 206734 and certification with respect to the '325 patent constituted infringement of that patent. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Alkermes respectfully requests the following relief:

A. A judgment that Defendants have infringed the ’325 patent;

B. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 206734 for dexmethylphenidate hydrochloride extended-release capsules in the 5, 10, 15, 20, 25, 30, 35, and 40 mg strengths under § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the expiration date of the ’325 patent, including any extensions;

C. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from infringement of the ’325 patent for the full term thereof, including any extensions;

D. A declaration that this is an exceptional case and an award of reasonable 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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July 25, 2014
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