IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALKERMES PHARMA IRELAND LIMITED,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
MYLAN PHARMACEUTICALS INC.,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Alkermes Pharma Ireland Limited ("Alkermes"), for its Complaint against Defendant Mylan Pharmaceuticals Inc. ("Mylan"), 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, Mylan is a West Virginia corporation having its principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505.

3. On information and belief, Mylan is in the business of, among other things, manufacturing, marketing, distributing, and selling generic 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 Nos. 6,228,398 ("the '398 patent") and 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 Mylan because it purposefully avails itself of the privilege of selling its generic pharmaceutical products in the State of Delaware and can therefore reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, on information and belief, Mylan has expressly consented to jurisdiction by registering to do business in the State of Delaware and appointing an agent in Delaware for service of process. Mylan also conducts marketing and sales activities in the State of Delaware, including, but not limited to, the distribution, marketing, and/or sales of generic pharmaceutical products to Delaware residents that are continuous and systematic. Moreover, on information and belief, Mylan has invoked the benefits and protections afforded by the State of Delaware by bringing several lawsuits in this Court. *See, e.g., Mylan Pharms. Inc. v. Eurand Inc., et al.*, C.A. No. 10-306; *Mylan Pharms. Inc. v. Galderma Labs. Inc., et al.*, C.A. No. 10-892; *Mylan Pharms. Inc. v. Ethypharm SA, et al.*, C.A. No. 10-1064.

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

FACTUAL BACKGROUND

8. On May 8, 2001, the '398 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 '398 patent is attached as Exhibit A.

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

10. 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 '398 and '325 patents are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for FOCALIN® XR capsules.

11. On information and belief, Mylan submitted to the FDA abbreviated new drug application ("ANDA") No. 204266 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, 35, and 40 mg strengths, as generic versions of the FOCALIN® XR 5, 10, 15, 20, 25, 35, and 40 mg capsules.

12. By letter dated October 26, 2012 (the "Mylan Letter"), Mylan advised Alkermes that it had submitted ANDA No. 204266 seeking approval to manufacture, use, or sell generic dexmethylphenidate hydrochloride extended-release capsules in the 5, 10, 15, 20, 25, 35, and 40 mg strengths prior to the expiration of the '398 and '325 patents.

13. Alkermes and Mylan previously litigated the '398 and '325 patents with respect to Mylan's ANDA No. 202580 seeking approval to manufacture, use, or sell generic dexmethylphenidate hydrochloride extended-release capsules in the 30 mg strength. That

litigation was settled pursuant to a settlement agreement. *See Alkermes Pharma Ireland Limited v. Mylan Pharmaceuticals Inc.*, C.A. No. 11-281-SLR (D. Del.).

14. Alkermes and Mylan have not previously litigated the '398 and '325 patents with respect to Mylan's ANDA seeking approval to manufacture, use, or sell generic dexmethylphenidate hydrochloride extended-release capsules in the 5, 10, 15, 20, 25, 35, and 40 mg strengths.

15. The Mylan Letter also advised Alkermes that Mylan's ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Mylan's opinion, the claims of the '398 and '325 patents are invalid.

COUNT I

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

17. Mylan's submission of ANDA No. 204266 to the FDA for dexmethylphenidate hydrochloride extended-release capsules in the 5, 10, 15, 20, 25, 35, and 40 mg strengths, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '398 patent under 35 U.S.C. § 271(e)(2)(A). Mylan's commercial manufacture, offer for sale, or sale of the proposed generic for dexmethylphenidate hydrochloride extended-release capsules in the 5, 10, 15, 20, 25, 35, and 40 mg strengths would infringe the '398 patent.

18. On information and belief, Mylan was aware of the existence of the '398 patent and was aware that the filing of ANDA No. 204266 and certification with respect to the '398 patent constituted infringement of that patent. This is an exceptional case.

COUNT II

19. Alkermes incorporates each of the preceding paragraphs 1 to 18 as if fully set forth herein.

20. Mylan's submission of ANDA No. 204266 to the FDA for dexmethylphenidate hydrochloride extended-release capsules in the 5, 10, 15, 20, 25, 35, and 40 mg strengths, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '325 patent under 35 U.S.C. § 271(e)(2)(A). Mylan's commercial manufacture, offer for sale, or sale of the proposed generic for dexmethylphenidate hydrochloride extended-release capsules in the 5, 10, 15, 20, 25, 35, and 40 mg strengths would infringe the '325 patent.

21. On information and belief, Mylan was aware of the existence of the '325 patent and was aware that the filing of ANDA No. 204266 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 Mylan has infringed the '398 and '325 patents;

B. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 204266 for dexmethylphenidate hydrochloride extended-release capsules in the 5, 10, 15, 20, 25, 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 dates of the '398 patent and '325 patent, including any extensions;

C. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Mylan, its officers, agents, servants, and employees, and those persons in active

concert or participation with any of them, from infringement of the '398 and '325 patents for the full terms 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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