IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALKERMES PHARMA IRELAND LIMITED,	)	
Plaintiff,	)	
	)	C.A. No. _____
v.	)	
ACTAVIS, INC. and ACTAVIS SOUTH ATLANTIC LLC,	)	
Defendants.	)	

COMPLAINT

Plaintiff Alkermes Pharma Ireland Limited ("Alkermes"), for its Complaint against Defendants Actavis, Inc. and Actavis South Atlantic LLC (collectively, "Actavis"), alleges as follows:

PARTIES

1. Alkermes is an Irish corporation having its principal place of business at Monksland, Athlone, County Westmeath, Ireland.

2. On information and belief, Actavis, Inc. is a Delaware corporation having its principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960.

3. On information and belief, Actavis South Atlantic LLC is a Delaware company having its principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07207. On information and belief Actavis South Atlantic LLC is a subsidiary of Actavis, Inc.

4. On information and belief, Actavis 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

5. 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

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 Actavis, Inc. because, *inter alia*, Actavis, Inc. is a Delaware corporation and because of its continuous and systematic contacts within this judicial district.

8. This Court has personal jurisdiction over Actavis South Atlantic LLC because, *inter alia*, Actavis South Atlantic LLC is a Delaware company and because of its continuous and systematic contacts within this judicial district.

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

FACTUAL BACKGROUND

10. 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.

11. 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.

12. 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.

13. On information and belief, Actavis submitted to the FDA abbreviated new drug application ("ANDA") No. 203614 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 25 mg and 35 mg strengths as generic versions of the FOCALIN® XR 25 mg and 35 mg capsules.

14. By letter dated February 3, 2012 (the "Actavis Letter"), Actavis advised Alkermes that it had submitted ANDA No. 203614 seeking approval to manufacture, use, or sell generic dexmethylphenidate hydrochloride extended release capsules in the 25 mg and 35 mg strengths prior to the expiration of the '398 and '325 patents.

15. Elan previously litigated the '398 and '325 patents against Actavis South Atlantic LLC with respect to its ANDA seeking approval to manufacture, use, or sell generic dexmethylphenidate hydrochloride extended release capsules in the 5, 10, 15 and 20 mg strengths. That litigation was settled pursuant to a settlement agreement.

16. Alkermes is currently litigating the '398 and '325 patents against Actavis with respect to ANDA No. 79-108 seeking approval to manufacture, use, or sell generic

dexmethylphenidate hydrochloride extended release capsules in the 40 mg strength. Alkermes' complaint in that action was filed on November 4, 2011. *See Alkermes Pharma Ireland Limited v. Actavis, Inc. and Actavis South Atlantic LLC*, C.A. No. 11-1098-SLR (D. Del.).

17. Alkermes has not previously litigated the '398 and '325 patents against Actavis with respect to ANDA No. 203614 seeking approval to manufacture, use, or sell generic dexmethylphenidate hydrochloride extended release capsules in the 25 mg and 35 mg strengths.

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

COUNT I

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

20. Actavis' submission of ANDA No. 203614 to the FDA for dexmethylphenidate hydrochloride extended release capsules in the 25 mg and 35 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). Actavis' commercial manufacture, offer for sale, or sale of the proposed generic for dexmethylphenidate hydrochloride extended release capsules in the 25 mg and 35 mg strengths would infringe the '398 patent.

21. On information and belief, Actavis was aware of the existence of the '398 patent and was aware that the filing of ANDA No. 203614 and certification with respect to the '398 patent constituted infringement of that patent. This is an exceptional case.

COUNT II

22. Alkermes incorporates each of the preceding paragraphs 1 to 21 as if fully set forth herein.

23. Actavis' submission of ANDA No. 203614 to the FDA for dexmethylphenidate hydrochloride extended release capsules in the 25 mg and 35 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). Actavis' commercial manufacture, offer for sale, or sale of the proposed generic for dexmethylphenidate hydrochloride extended release capsules in the 25 mg and 35 mg strengths would infringe the '325 patent.

24. On information and belief, Actavis was aware of the existence of the '325 patent and was aware that the filing of ANDA No. 203614 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 Actavis 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. 203614 for dexmethylphenidate hydrochloride extended release capsules in the 25 mg and 35 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 Actavis, 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.

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