

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELAN CORPORATION, PLC and)	
ELAN PHARMA INTERNATIONAL LTD.,)	
)	
Plaintiffs,)	C.A. No. _____
)	
v.)	
)	
ACTAVIS SOUTH ATLANTIC LLC,)	
)	
Defendant.)	

COMPLAINT

Plaintiffs Elan Corporation, plc and Elan Pharma International Ltd. (collectively “Elan”), for their Complaint against Defendant Actavis South Atlantic LLC (“Actavis”), allege as follows:

PARTIES

1. Elan Corporation, plc is an Irish corporation having its principal place of business at Treasury Building, Lower Grand Canal St., Dublin 2, Ireland.
2. Elan Pharma International Ltd. is an Irish corporation having its principal place of business at Monksland, Athlone County, Westmeath, Ireland. Elan Pharma International Ltd. is a subsidiary of Elan Corporation, plc.
3. On information and belief, Actavis is a Delaware company having a place of business at 13800 NW 2nd Street, Suite 190, Fort Lauderdale, FL 33325, and is engaged in the manufacture and sale of generic drug products.

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 Actavis because Actavis is a Delaware company, and because Actavis has had continuous and systematic contacts within this judicial district.

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 as assignee. Elan owns all rights to the ‘398 patent, including the right to sue for infringement thereof. 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 owns all rights to the ‘325 patent, including the right to sue for infringement thereof. 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 dexamethylphenidate 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, Actavis submitted to the FDA abbreviated new drug application ("ANDA") No. 79-108 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 dexamethylphenidate hydrochloride capsules in the 5, 10, 15 and 20 mg strengths, as generic versions of the FOCALIN® XR 5, 10, 15 and 20 mg capsules.

12. By letter dated September 26, 2007 (the "Actavis Letter"), Actavis stated that it had submitted ANDA No. 79-108 seeking approval to manufacture, use, or sell generic dexamethylphenidate hydrochloride capsules prior to the expiration of the '398 and '325 patents.

13. The Actavis Letter also stated that Actavis' ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Actavis's opinion, the manufacture, use or sale of the proposed generic dexamethylphenidate hydrochloride capsules described in its ANDA will not infringe any valid claim of the '398 and '325 patents.

COUNT I

14. Plaintiffs incorporate each of the preceding paragraphs 1 to 13 as if fully set forth herein.

15. By filing ANDA No. 79-108 for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of its generic dexamethylphenidate hydrochloride capsules prior to the expiration of the '398 patent, Actavis has committed an act of infringement of the '398 patent under 35 U.S.C. § 271(e)(2).

16. The commercial manufacture, use or sale of Actavis' proposed generic dexamethylphenidate hydrochloride capsules in the United States before the expiration of the '398 patent would infringe one or more claims of that patent.

17. On information and belief, Actavis was aware of the existence of the '398 patent and was aware that the filing of its ANDA and certification with respect to the '398 patent constituted infringement of that patent. This is an exceptional case.

COUNT II

18. Plaintiffs incorporate each of the preceding paragraphs 1 to 13 as if fully set forth herein.

19. By filing ANDA No. 79-108 for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of its generic dexamethylphenidate hydrochloride capsules prior to the expiration of the '325 patent, Actavis has committed an act of infringement of the '325 patent under 35 U.S.C. § 271(e)(2).

20. The commercial manufacture, use or sale of Actavis' proposed generic dexamethylphenidate hydrochloride capsules in the United States before the expiration of the '325 patent would infringe one or more claims of that patent.

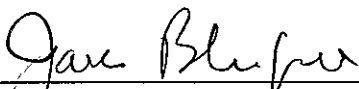
21. On information and belief, Actavis was aware of the existence of the '325 patent and was aware that the filing of its ANDA and certification with respect to the '325 patent constituted infringement of that patent. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request 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 Actavis' ANDA No. 79-108 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), be a date which is not earlier than the expiration date of the '398 and '325 patents or any expiration of exclusivity to which Elan is or becomes entitled;
- C. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Actavis and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from infringement of the '398 and '325 patents for the full terms thereof;
- 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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