IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELAN CORPORATION, PLC and ELAN PHARMA INTERNATIONAL LTD.	)	
Plaintiff,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC.	)	
Defendant.	)	

COMPLAINT

Plaintiffs Elan Corporation, plc and Elan Pharma International Ltd. (collectively "Elan"), for their Complaint against Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), 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, Teva is a Delaware corporation having its principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454-1090.

4. On information and belief, Teva 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 Teva because, *inter alia*, Teva is a Delaware corporation and because of its continuous and systematic contacts within this judicial district.

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

FACTUAL BACKGROUND

9. 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.

10. 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.

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

12. On information and belief, Teva submitted to the FDA abbreviated new drug application ("ANDA") No. 202731 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 30 mg and 40 mg strengths, as generic versions of the FOCALIN® XR 30 mg and 40 mg capsules.

13. By letter dated March 11, 2011 (the "Teva Letter"), Teva advised Elan that it had submitted ANDA No. 202731 seeking approval to manufacture, use, or sell generic dexmethylphenidate hydrochloride extended-release capsules in the 30 mg and 40 mg strengths prior to the expiration of the '398 and '325 patents.

14. Elan previously litigated the '398 and '325 patents against Teva with respect to Teva's 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.

15. Elan has not previously litigated the '398 and '325 patents with respect to Teva's ANDA seeking approval to manufacture, use, or sell generic dexmethylphenidate hydrochloride extended-release capsules in the 30 mg and 40 mg strengths.

16. The Teva Letter also advised Elan that Teva's ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Teva's opinion, the manufacture, use, or sale of the proposed generic dexmethylphenidate hydrochloride extended-release capsules

described in Teva's ANDA will not infringe any claim of the '398 and '325 patents, and that those claims are invalid.

COUNT I

17. Plaintiffs incorporate each of the preceding paragraphs 1 to 16 as if fully set forth herein.

18. Teva's submission of ANDA No. 202731 to the FDA for dexmethylphenidate hydrochloride extended-release capsules in the 30 mg 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). Teva's commercial manufacture, offer for sale, or sale of the proposed generic for dexmethylphenidate hydrochloride extended-release capsules in the 30 mg and 40 mg strengths would infringe the '398 patent.

19. On information and belief, Teva was aware of the existence of the '398 patent and was aware that the filing of ANDA No. 202731 and certification with respect to the '398 patent constituted infringement of that patent. This is an exceptional case.

COUNT II

20. Plaintiffs incorporate each of the preceding paragraphs 1 to 16 as if fully set forth herein.

21. Teva's submission of ANDA No. 202731 to the FDA for dexmethylphenidate hydrochloride extended-release capsules in the 30 mg 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). Teva's commercial manufacture, offer for sale, or sale of the proposed generic for dexmethylphenidate hydrochloride extended-release capsules in the 30 mg and 40 mg strengths would infringe the '325 patent.

22. On information and belief, Teva was aware of the existence of the '325 patent and was aware that the filing of ANDA No. 202731 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 Teva 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. 202731 for dexmethylphenidate hydrochloride extended-release capsules in the 30 mg 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 Teva, its officers, agents, servants, and employees, and those persons in active concert or participation with 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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