IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELAN CORPORATION, PLC and ELAN PHARMA INTERNATIONAL LTD.,	)	
Plaintiffs,	)	C.A. No. 07-552-SLR
v.	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

AMENDED COMPLAINT

Plaintiffs Elan Corporation, plc and Elan Pharma International Ltd. (collectively "Elan"), for their Amended 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 a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454, 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 Teva because Teva is a Delaware corporation, and because Teva 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 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, Teva submitted to the FDA abbreviated new drug application ("ANDA") No. 78-908 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 and 20 mg strengths, as generic versions of the FOCALIN® XR 5, 10, 15 and 20 mg capsules.

12. By letter dated August 3, 2007 (the "Teva Letter"), Teva stated that it had submitted ANDA No. 78-908 seeking approval to manufacture, use, or sell generic dexmethylphenidate hydrochloride extended release capsules prior to the expiration of the '398 and '325 patents.

13. The Teva Letter also stated 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 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. 78-908 for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of its generic dexmethylphenidate hydrochloride extended release capsules prior to the expiration of the '398 patent, Teva 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 Teva's proposed generic dexmethylphenidate hydrochloride extended release 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, Teva 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. 78-908 for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of its generic dexmethylphenidate hydrochloride extended release capsules prior to the expiration of the '325 patent, Teva 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 Teva's proposed generic dexmethylphenidate hydrochloride extended release 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, Teva 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 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 Teva's ANDA No. 78-908 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 Teva 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 therof;

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

/s/ Jack B. Blumenfeld

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October 15, 2007
1266169

CERTIFICATE OF SERVICE

I hereby certify that on October 15, 2007 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

Thomas G. Whalen, Jr., Esquire
STEVENS & LEE

I further certify that I caused to be served copies of the foregoing document on October 15, 2007 upon the following in the manner indicated:

Thomas G. Whalen, Jr., Esquire
STEVENS & LEE, P.C.
1105 North Market Street
7th Floor
Wilmington, DE 19801

VIA ELECTRONIC MAIL and HAND DELIVERY

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)