IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELAN PHARMA INTERNATIONAL LIMITED and JAZZ PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ACTAVIS ELIZABETH LLC, ANCHEN PHARMACEUTICALS, INC., and ANCHEN INCORPORATED,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Elan Pharma International Limited ("Elan") and Jazz Pharmaceuticals, Inc. ("Jazz Pharmaceuticals") (collectively, "Plaintiffs"), for their Complaint against Defendants Actavis Elizabeth LLC ("Actavis"), Anchen Pharmaceuticals, Inc. "(Anchen Pharmaceuticals") and Anchen Incorporated ("Anchen") (together with Anchen Pharmaceuticals, "the Anchen Defendants") (collectively, "Defendants"), allege as follows:

PARTIES

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

2. Jazz Pharmaceuticals is a Delaware corporation having its principal place of business at 3180 Porter Drive, Palo Alto, CA 94304.

3. On information and belief, Actavis is a Delaware company having a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07207, and is engaged in the manufacture and sale of generic drug products.

4. On information and belief, Anchen Pharmaceuticals is a California corporation having a principal place of business at 9601 Jeronimo Road, Irvine, CA 92618-2025, and is engaged in the manufacture and sale of generic drug products.

5. On information and belief, Anchen is a Delaware corporation having a principal place of business at 9601 Jeronimo Road, Irvine, CA 92618-2025, and is engaged in the manufacture and sale of generic drug products. On information and belief, Anchen Pharmaceuticals is a wholly-owned subsidiary of Anchen.

6. On information and belief, the Anchen Defendants closely coordinate their commercial activities and hold themselves out to the marketplace as one company. For example, during prosecution of Anchen Pharmaceuticals' trademark application for the word mark ANCHEN with respect to pharmaceutical products (serial no. 77051871), representatives for Anchen Pharmaceuticals stated that, "Anchen Pharmaceuticals, Inc. and Anchen Incorporated, though separate legal entities, constitute a single source to the relevant public, and there is unity of control with respect to the nature and quality of the goods." On information and belief, the Anchen Defendants have also simultaneously shared senior corporate officers with the same titles, including Margaret Choy, Senior Vice President of Regulatory Affairs. Ms. Choy is the contact person listed in the Anchen Defendants' Paragraph IV Notice Letter to Plaintiffs, which is discussed below.

7. On information and belief, Anchen Pharmaceuticals is in the business of preparing generic pharmaceuticals that it distributes in the State of Delaware and throughout the United States. On information and belief, Anchen Pharmaceuticals conducts its North American operations, in part, through its parent company Anchen. On information and belief, together, the Anchen Defendants collaborate in the manufacture, marketing, and sale of many pharmaceutical

products (including generic drug products manufactured and sold pursuant to approved abbreviated new drug applications) within the United States generally, and the State of Delaware specifically.

NATURE OF ACTION

8. This is an action for infringement of United States Patent No. 7,465,462 (the "'462 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. 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.

11. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery, this Court has personal jurisdiction over the Anchen Defendants.

12. On information and belief, this Court has personal jurisdiction over Anchen Pharmaceuticals by virtue of its systematic and continuous contacts with the State of Delaware, including *inter alia* the supply of generic pharmaceutical drugs to the State of Delaware and a UCC lien filing in the State of Delaware.

13. On information and belief, Anchen Pharmaceuticals plans to continue to maintain continuous and systematic contacts with the State of Delaware, including but not limited to its aforementioned business of preparing generic pharmaceuticals that it distributes in the State of Delaware.

14. This Court has personal jurisdiction over Anchen because Anchen is a Delaware corporation, and because Anchen has had continuous and systematic contacts within this judicial district, including *inter alia* the supply of generic pharmaceutical drugs to the State of Delaware and a UCC lien filing in the State of Delaware.

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

FACTUAL BACKGROUND

16. On December 16, 2008, the '462 patent, entitled "Multiparticulate Controlled Release Selective Serotonin Reuptake Inhibitor Formulations," was duly and legally issued to Elan as assignee. Jazz Pharmaceuticals is the exclusive licensee under the '462 patent. A true and correct copy of the '462 patent is attached as Exhibit A.

17. On February 28, 2008, the United States Food And Drug Administration ("FDA") approved an new drug application ("NDA"), No. 22-033, for LUVOX CR® extended release capsules, which contain fluvoxamine maleate, under § 505(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a), for the treatment of social anxiety disorder and obsessive compulsive disorder. The '462 patent is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for LUVOX CR® capsules. Jazz Pharmaceuticals is the holder of NDA No. 22-033.

18. On information and belief, Actavis submitted to the FDA an abbreviated new drug application ("ANDA"), No. 91-482, 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 Fluvoxamine Maleate Extended-Release Capsules in 100 and 150 mg strengths, as generic versions of the LUVOX CR® 100 and 150 mg capsules.

19. By letter dated August 24, 2009 (the "Actavis Letter"), Actavis advised Plaintiffs that it had submitted ANDA No. 91-482 seeking approval to manufacture, use, or sell generic Fluvoxamine Maleate Extended-Release Capsules prior to the expiration of the '462 patent.

20. The Actavis Letter also advised Plaintiffs 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 Fluvoxamine Maleate Extended-Release Capsules described in its ANDA will not infringe any valid claim of the '462 patent.

21. On information and belief, the Anchen Defendants submitted to the FDA abbreviated an ANDA, No. 91-476, 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 Fluvoxamine Maleate Extended-Release Capsules in the 100 and 150 mg strengths, as generic versions of the LUVOX CR® 100 and 150 mg capsules.

22. By letter dated September 1, 2009 (the "Anchen Letter"), the Anchen Defendants advised Plaintiffs that they had submitted ANDA No. 91-476 seeking approval to manufacture, use, or sell generic Fluvoxamine Maleate Extended-Release Capsules prior to the expiration of the '462 patent.

23. The Anchen Letter advised Plaintiffs that the Anchen Defendants' ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in the Anchen Defendants' opinion, the manufacture, use or sale of the proposed generic Fluvoxamine Maleate Extended-Release Capsules described in their ANDA will not infringe any valid claim of the '462 patent.

COUNT I

24. Plaintiffs incorporate each of the preceding paragraphs 1 to 23 as if fully set forth herein.

25. By submitting ANDA No. 91-482 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of its generic Fluvoxamine Maleate Extended-Release Capsules prior to the expiration of the '462 patent, Actavis has committed an act of infringement of the '462 patent under 35 U.S.C. § 271(e)(2).

26. The commercial manufacture, use or sale of Actavis' proposed generic Fluvoxamine Maleate Extended-Release Capsules in the United States before the expiration of the '462 patent would infringe one or more claims of that patent.

27. On information and belief, Actavis was aware of the existence of the '462 patent and was aware that the filing of its ANDA and certification with respect to the '462 patent constituted infringement of that patent. This is an exceptional case.

COUNT II

28. Plaintiffs incorporate each of the preceding paragraphs 1 to 27 as if fully set forth herein.

29. By submitting ANDA No. 91-476 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of its generic Fluvoxamine Maleate Extended-Release Capsules prior to the expiration of the '462 patent, the Anchen Defendants, acting jointly in submitting ANDA No. 91-476 and both being actively involved in that submission, have committed an act of infringement of the '462 patent under 35 U.S.C. § 271(e)(2).

30. The commercial manufacture, use or sale of the Anchen Defendants' proposed generic Fluvoxamine Maleate Extended-Release Capsules in the United States before the expiration of the '462 patent would infringe one or more claims of that patent.

31. On information and belief, the Anchen Defendants were aware of the existence of the '462 patent and was aware that the filing of its ANDA and certification with respect to the '462 patent constituted infringement of that patent. This is an exceptional case.

COUNT III

32. Plaintiffs incorporate each of the preceding paragraphs 1 to 31 as if fully set forth herein.

33. On information and belief, Anchen jointly filed and/or was actively involved in submitting ANDA No. 91-476 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale throughout the United States, including the State of Delaware, of the Anchen Defendants' generic Fluvoxamine Maleate Extended-Release Capsules prior to the expiration of the '462 patent. Upon information and belief, Anchen will participate in the manufacture, marketing, and sale of the Anchen Defendants' generic Fluvoxamine Maleate Extended-Release Capsules if they are approved by the FDA. Anchen thus actively induced Anchen Pharmaceuticals to submit ANDA No. 91-476 to the FDA.

34. The commercial manufacture, use or sale of the Anchen Defendants' proposed generic Fluvoxamine Maleate Extended-Release Capsules in the United States before the expiration of the '462 patent would infringe one or more claims of that patent.

35. By actively inducing submission of ANDA No. 91-476, Anchen has committed an act of infringement with respect to the '462 patent under 35 U.S.C. § 271(b).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Actavis has infringed the '462 patent;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(a) that the effective date of any approval of Actavis' ANDA No. 91-482 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 '462 patent or any extension of exclusivity to which Plaintiffs are or become 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 '462 patent for the full term thereof;

D. A judgment that the Anchen Defendants, individually and/or collectively, have infringed the '462 patent;

E. A judgment that Anchen induced Anchen Pharmaceuticals to infringe the '462 patent;

F. An order pursuant to 35 U.S.C. § 271(e)(4)(a) that the effective date of any approval of the Anchen Defendants' ANDA No. 91-476 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 '462 patent or any extension of exclusivity to which Plaintiffs are or become entitled;

G. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining the Anchen Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from infringement of the '462 patent for the full term thereof;

H. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

I. Costs and expenses in this action; and

J. Such other and further relief as the Court may deem just and proper.

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October 6, 2009