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14 Elan Pharma International Limited
15 and Jazz Pharmaceuticals, Inc.

16 UNITED STATES DISTRICT COURT
17 FOR THE CENTRAL DISTRICT OF CALIFORNIA
18 SOUTHERN DIVISION

19 ELAN PHARMA INTERNATIONAL
20 LIMITED and JAZZ
21 PHARMACEUTICALS, INC.,

22 Plaintiffs,

23 v.

24 ANCHEN PHARMACEUTICALS,
25 INC. and ANCHEN
26 INCORPORATED,


27 Defendants.

Case No. SACV09-01193 CJC (MLGx)

COMPLAINT FOR PATENT
INFRINGEMENT

FILED BY FAX

28 Plaintiffs Elan Pharma International Limited ("Elan") and Jazz
Pharmaceuticals, Inc. ("Jazz Pharmaceuticals") (collectively, "Plaintiffs"), for their
Complaint against Defendants Anchen Pharmaceuticals, Inc. ("Anchen
Pharmaceuticals") and Anchen, Inc. ("Anchen") (collectively, "Defendants"),
allege as follows:

BY: 
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CLERK U.S. DISTRICT COURT
CENTRAL DIST. OF CALIF.
SANTA ANA

FILED

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t/s

1 **JURISDICTION**

2 1. This is an action for infringement of United States Patent
3 No. 7,465,462 (the “462 patent”). This action is based upon the Patent Laws of
4 the United States, 35 U.S.C. § 100 *et seq.* This Court has jurisdiction over the
5 subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6 **PARTIES**

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

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

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

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

19 6. On information and belief, the Defendants closely coordinate their
20 commercial activities and hold themselves out to the marketplace as one company.
21 For example, during prosecution of Anchen Pharmaceuticals’ trademark
22 application for the word mark ANCHEN with respect to pharmaceutical products
23 (serial no. 77051871), representatives for Anchen Pharmaceuticals stated that,
24 “Anchen Pharmaceuticals, Inc. and Anchen Incorporated, though separate legal
25 entities, constitute a single source to the relevant public, and there is unity of
26 control with respect to the nature and quality of the goods.” On information and
27 belief, the Defendants have also simultaneously shared senior corporate officers
28 with the same titles, including Margaret Choy, Senior Vice President of Regulatory

1 Affairs. Ms. Choy is the contact person listed in the Defendants' Paragraph IV
2 Notice Letter to Plaintiffs, which is discussed below.

3 7. On information and belief, Anchen Pharmaceuticals is in the business
4 of preparing generic pharmaceuticals that it distributes in the State of California
5 and throughout the United States. On information and belief, Anchen
6 Pharmaceuticals conducts its North American operations, in part, through its parent
7 company Anchen. On information and belief, together, the Defendants collaborate
8 in the manufacture, marketing, and sale of many pharmaceutical products
9 (including generic drug products manufactured and sold pursuant to approved
10 abbreviated new drug applications) within the United States generally, and the
11 State of California specifically.

12 **PERSONAL JURISDICTION AND VENUE**

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

16 9. On information and belief, this Court has personal jurisdiction over
17 Anchen by virtue of its systematic and continuous contacts with the State of
18 California and within this judicial district, including *inter alia* the supply of generic
19 pharmaceutical drugs to the State of California including this judicial district.

20 10. On information and belief, Anchen plans to continue to maintain
21 continuous and systematic contacts with the State of California and within this
22 judicial district, including but not limited to its aforementioned business of
23 preparing generic pharmaceuticals that it distributes in the State of California
24 including this judicial district.

25 11. On information and belief, this Court has personal jurisdiction over
26 Anchen Pharmaceuticals because Anchen Pharmaceuticals is a California
27 corporation, and because Anchen Pharmaceuticals has had continuous and
28

1 systematic contacts within this judicial district, including *inter alia* the supply of
2 generic pharmaceutical drugs to the State of California.

3 12. Venue is proper in this judicial district pursuant to 28 U.S.C.
4 §§ 1391(c) and 1400(b).

5 **FACTS RELEVANT TO ALL CAUSES**

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

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

19 15. On information and belief, Defendants submitted to the FDA an
20 ANDA, No. 91-476, under § 505(j) of the Federal Food, Drug and Cosmetic Act,
21 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture,
22 use, and sale of Fluvoxamine Maleate Extended-Release Capsules in the 100 and
23 150 mg strengths, as generic versions of the LUVOX CR® 100 and 150 mg
24 capsules.

25 16. The filing of ANDA No. 91-476 by Defendants constituted an act of
26 infringement pursuant to 35 U.S.C. 271(e)(2)(A).

27 17. By letter dated September 1, 2009 (the "Anchen Letter"), Defendants
28 advised Plaintiffs that they had submitted ANDA No. 91-476 seeking approval to

1 manufacture, use, or sell generic Fluvoxamine Maleate Extended-Release Capsules
2 prior to the expiration of the '462 patent.

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

8 19. Under the Hatch-Waxman Act of 1984, an owner of a patented drug
9 must file an action in federal court within 45 days of receiving a letter such as the
10 Anchen Letter ("45-day window") in order to receive certain benefits under the
11 Act, including a stay of approval of the generic drug for up to 30 months during the
12 pendency of litigation, as appropriate. 21 U.S.C. § 355 (c)(3)(c).

13 20. On October 6, 2009, within the 45-day window, Plaintiffs filed and
14 served an action against Defendants for infringement of the patent-in-suit in the
15 United States District Court for the District of Delaware, Civil Action No. 09-744
16 (the "Delaware Action"). A copy of the Complaint in the Delaware Action is
17 attached hereto as Exhibit B.

18 21. Defendants are both properly subject to personal jurisdiction in the
19 District of Delaware. Upon information and belief, Plaintiffs understand that
20 Defendants may nevertheless contest personal jurisdiction in Delaware. The
21 Hatch-Waxman Act does not squarely address the consequences of the grant of a
22 motion to dismiss for lack of personal jurisdiction in a plaintiff's chosen forum. It
23 is possible that such a dismissal could result in a plaintiff losing the benefit of the
24 30-month stay of ANDA approval even if the plaintiff refilled the action in another
25 jurisdiction, since the refilling would occur after the 45-day window. Therefore,
26 district courts have countenanced the filing of additional "protective suits" within
27 the 45-day window to ensure a plaintiff will not lose the benefits of the 30-month
28 stay should the court in the chosen forum dismiss the action for lack of personal

1 jurisdiction. See e.g., Adams Respiratory Therapeutics, Inc. v. Perrigo Co., No.
2 1:07-cv-993, 2007 WL 4284877 (W.D. Mich. Dec. 3, 2007); see also PDL
3 Biopharma, Inc. v. Sun Pharm. Indus., Ltd., No. 07-11709, 2007 WL 2261386
4 (E.D. Mich. Aug. 6, 2007); Celgene Corp. v. Abrika Pharms., Inc., No. 06-5818
5 (SDW), 2007 WL 1456156 (D.N.J. May 17, 2007).

6 22. Accordingly, although Plaintiffs believe the District of Delaware has
7 personal jurisdiction over Defendants, and Delaware is their preferred choice of
8 forum to litigate the claims for relief set forth in this Complaint, Plaintiffs seek the
9 Court's indulgence and file this Complaint as a "protective suit" to protect
10 Plaintiffs' rights under the Hatch-Waxman Act in the event the District of
11 Delaware were to determine that there is no personal jurisdiction over one or both
12 Defendants in Delaware.

13 **COUNT I**
14 **(Infringement of the '462 Patent Under 35 U.S.C. § 271(e)(2)**
against Defendants)

15 23. Plaintiffs incorporate each of the preceding paragraphs 1 to 22 as if
16 fully set forth herein.

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

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

27 26. On information and belief, the Defendants were aware of the
28 existence of the '462 patent and was aware that the filing of their ANDA and

1 certification with respect to the '462 patent constituted infringement of that patent.
2 This is an exceptional case.

3
4 **COUNT II**
5 **(Inducement of Infringement of the '462 Patent**
6 **Under 35 U.S.C. § 271(b) against Anchen)**

7 27. Plaintiffs incorporate each of the preceding paragraphs 1 to 26 as if
8 fully set forth herein.

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

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

22 30. By actively inducing submission of ANDA No. 91-476, Anchen has
23 committed an act of infringement with respect to the '462 patent under 35 U.S.C. §
24 271(b).

25 **PRAYER FOR RELIEF**

26 WHEREFORE, Plaintiffs respectfully request that the Court enter Judgment
27 in their favor and against Defendants on their Complaint as follows:

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

1 B. A judgment that Anchen induced Anchen Pharmaceuticals to
2 infringe the '462 patent;

3 C. An order pursuant to 35 U.S.C. § 271(e)(4)(a) that the effective
4 date of any approval of Defendants' ANDA No. 91-476 under § 505(j) of the
5 Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), be a date which is not
6 earlier than the expiration date of the '462 patent or any extension of exclusivity to
7 which Plaintiffs are or become entitled;

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

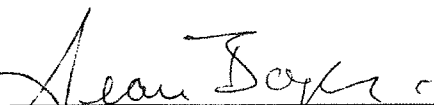
12 E. A declaration that this is an exceptional case and an award of
13 reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

14 F. Costs and expenses in this action; and

15 G. Such other and further relief as the Court may deem just and
16 proper.

17 Date: October 14, 2009

KING & SPALDING LLP

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19 By: 
20 Sean M. Boyle

21 *Attorneys for Plaintiffs*
22 *Elan Pharma International Limited*
23 *and Jazz Pharmaceuticals, Inc.*
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