UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY

Plaintiff,

v.

ANCHEN PHARMACEUTICALS, INC. AND ANCHEN, INC.

Defendants.

Case No.
1:09-cv-1029 WTL -JMS

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Eli Lilly and Company ("Lilly") files this Complaint for patent infringement against Anchen Pharmaceuticals, Inc. and Anchen, Inc.(collectively "Defendants") under 35 U.S.C. § 271(e)(2). This patent action concerns the pharmaceutical drug product Cymbalta®. Plaintiff, Lilly, hereby states as follows.

JURISDICTION AND PARTIES

1. Lilly is an Indiana corporation that has its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. On information and belief, Anchen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of California, having a principal place of business at 9601 Jeronimo Road, Irvine, California. On information and belief, Anchen Pharmaceuticals, Inc. is a subsidiary and agent of Anchen, Inc. On information and belief, Anchen Pharmaceuticals, Inc. is a generic pharmaceutical company that develops, manufactures,

markets, and distributes generic pharmaceutical products for sale in the Southern District of Indiana and throughout the United States.

3. On information and belief, Anchen, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 9601 Jeronimo Road, Irvine, California. On information and belief, Anchen, Inc. is generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the Southern District of Indiana and throughout the United States through its subsidiary and agent Anchen Pharmaceuticals, Inc.

4. The Court has personal jurisdiction over Defendants because, on information and belief, they maintained continuous and systematic contacts with the State of Indiana, and Defendants have purposefully availed themselves of the benefits and protections of the laws of the State of Indiana.

5. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2). This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I FOR PATENT INFRINGEMENT

6. United States Patent No. 5,023,269 ("the '269 patent"), entitled "3-Aryloxy-3-Substituted Propanamines," was duly and legally issued to Lilly by the United States Patent and Trademark Office ("PTO") on June 11, 1991. The patent claims *inter alia*, the chemical compound duloxetine. The '269 patent expires on June 11, 2013. This expiration date includes

a five year term extension granted by the PTO pursuant to 35 U.S.C. § 156. A true and correct copy of the '269 patent is attached as Exhibit A. A true and correct copy of the term extension is attached as Exhibit B. Since its date of issue, Lilly has been, and continues to be, the owner of the '269 patent.

7. Lilly is the holder of New Drug Application ("NDA") No. 21-427 for the use of Cymbalta® for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and fibromyalgia. The United States Food and Drug Administration ("FDA") approved NDA No. 21-427 on August 3, 2004. Lilly lists the '269 patent in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-427.

8. Lilly manufactures and sells various dosage strengths of duloxetine in the United States under the brand name Cymbalta®.

9. On information and belief, Defendants filed or caused to be filed with the FDA, in Rockville, Maryland, ANDA No. 90-780, as amended, under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of "duloxetine hydrochloride delayed-release capsule, 20 mg, 30 mg, and 60 mg" ("Anchen's Duloxetine HCl Capsules") in the United States before the expiration of the '269 patent.

10. On information and belief, Defendants amended ANDA No. 90-780, which now contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification"), alleging that the claims of the '269 patent are invalid, unenforceable, and/or would not be infringed by Anchen's Duloxetine HCl Capsules.

11. Defendants sent or caused to be sent to Lilly a letter ("Anchen's Notice Letter") dated July 31, 2009, notifying Lilly that Defendants submitted or caused to be submitted an amendment to their pending ANDA No. 90-780 to include an additional paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of Anchen's Duloxetine HCl Capsules before the expiration of the '269 patent, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Lilly received Anchen's Notice Letter on or about August 4, 2009. Anchen's Notice Letter alleges that claims of the '269 patent are invalid over the prior art.

12. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 90-780, as amended, to the FDA to obtain approval for the commercial manufacture, use, or sale of Anchen's Duloxetine HCl Capsules in the United States before the expiration date of the '269 patent constitutes an act of infringement.

13. If ANDA No. 90-780 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of its Duloxetine HCl Capsules would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '269 patent under 35 U.S.C. § 271.

14. On information and belief, Defendants filed and amended ANDA No. 90-780, seeking authorization to commercially manufacture, use, offer for sale, and sell their Duloxetine HCl Capsules in the United States. On information and belief, Defendants know that physicians will use their Duloxetine HCl Capsules in accordance with the indications sought by Defendants, and will therefore infringe one or more claims of the '269 patent under 35 U.S.C. § 271(b) and/or (c).

15. On information and belief, Defendants had actual knowledge of the '269 patent prior to the filing and amendment of ANDA No. 90-780 and their actions in analyzing the '269 patent and in presenting arguments in their paragraph IV certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), and in Anchen's Notice Letter, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), and their threatened manufacture, use, sale, offer for sale and/or importation of Anchen's Duloxetine HCl Capsules render this case exceptional under 35 U.S.C. § 285 and constitute actual or threatened willful infringement.

16. Lilly will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Lilly has no adequate remedy at law.

COUNT II FOR DECLARATORY JUDGMENT

17. Lilly realleges and incorporates by reference paragraphs 1-16.

18. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

19. On information and belief, Defendants filed or caused to be filed ANDA No. 90-780 with the FDA, seeking authorization to commercially manufacture, market, use, offer for sale, and sell in the United States their Duloxetine HCl Capsules.

20. On information and belief, Defendants seek approval of at least one indication claimed in the '269 patent for its Duloxetine HCl Capsules.

21. On information and belief, Defendants know that physicians prescribing or using Anchen's Duloxetine HCl Capsules according to the indications sought by Defendants will be using Anchen's Duloxetine HCl Capsules in a manner that would infringe one or more claims of the '269 patent, either literally or under the doctrine of equivalents.

22. On information and belief, Defendants plan to begin marketing, selling, and offering to sell in the United States their Duloxetine HCl Capsules soon after the FDA has approved such indications.

23. Such conduct will constitute infringement of one or more claims of the '269 patent under 35 U.S.C. § 271(a), (b), and/or (c).

24. Defendants' infringing activities have been and will continue to be done in willful disregard of Lilly's patent rights.

25. Defendants' infringing activities complained of herein are imminent and will begin following FDA approval of ANDA No. 90-780.

26. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Lilly and Defendants as to liability for the infringement of the '269 patent. Defendants' actions have created in Lilly a reasonable apprehension of irreparable harm and loss resulting from defendants' threatened imminent actions.

PRAYER FOR RELIEF

WHEREFORE, Lilly respectfully requests that this Court enter judgment in its favor as follows:

a) declare that United States Patent No. 5,023,269 is valid and enforceable;

b) declare that, under 35 U.S.C. § 271(e)(2)(A), Defendants infringed United States Patent No. 5,023,269 by submitting ANDA No. 90-780, as amended, to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Anchen's Duloxetine HCl Capsules prior to the expiration of the said patent;

c) declare that Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Anchen's Duloxetine HCl Capsules prior to the expiration of United States Patent No. 5,023,269 would constitute infringement of the said patent;

d) order that the effective date of any FDA approval of Anchen's Duloxetine HCl Capsules shall be no earlier than the expiration date of United States Patent No. 5,023,269 and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

e) enjoin Defendants, and all persons acting in concert with Defendants, from seeking, obtaining, or maintaining approval of ANDA No. 90-780 until the expiration of United States Patent No. 5,023,269;

f) enjoin Defendants, and all persons acting in concert with Defendants, from commercially manufacturing, using, offering for sale, or selling Anchen's Duloxetine HCl Capsules within the United States, or importing Anchen's Duloxetine HCl Capsules into the United States, until the expiration of United States Patent No. 5,023,269, in accordance with 35 U.S.C. § 271(e)(4)(B);

g) declare this to be an exceptional case and award Lilly its cost, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

h) award Lilly any further appropriate relief under 35 U.S.C. § 271(e)(4); and

i) award Lilly any further and additional relief that this Court deems just and proper.

Respectfully submitted,

Dated: August 20, 2009

By: Jan M. Carroll

Jan M. Carroll, No. 4187-49
BARNES & THORNBURG LLP
11 South Meridian Street
Indianapolis, IN 46204-3535
(317) 236-1313

Attorney for Plaintiff,
Eli Lilly and Company