UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,

Plaintiff,

v.

LUPIN LIMITED AND
LUPIN PHARMACEUTICALS, INC,

Defendants.

Civil Action No.:

1:08-cv-1596 LJM-JMS

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Eli Lilly and Company ("Lilly") files this Complaint for patent infringement against Lupin Limited and Lupin Pharmaceuticals, Inc. (referred to collectively as the "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, Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Virginia, having its principal place of business at Harborplace Tower, 111 South Calvert St., 21st Floor, Baltimore, Maryland 21202. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Lupin Limited. On information and belief, Lupin Pharmaceuticals, Inc. is the agent of Lupin Limited.

On information and belief, Lupin Pharmaceuticals, Inc., on behalf of Lupin Limited, sells and markets pharmaceutical products for distribution in the Southern District of Indiana and throughout the United States.

3. On information and belief, Lupin Limited, is an Indian company with its principal place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (W), Mumbai 400 051, India, and having a registered office at 159 CST Road, Kalina, Santacruz (East), Mumbai 400 098, India. On information and belief, Lupin Limited is a generic pharmaceutical company that manufactures generic drugs for sale and use in the Southern District of Indiana and throughout the United States, through Lupin Pharmaceuticals, Inc., its wholly owned subsidiary and agent.

4. The Court has personal jurisdiction over the Defendants because, on information and belief, they have maintained continuous and systematic contacts with the State of Indiana, and they 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, Lupin Limited and/or Lupin Pharmaceuticals, Inc. filed or caused to be filed with the FDA, in Rockville, Maryland, ANDA No. 90-694 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of "Duloxetine Hydrochloride Delayed-release Capsules (20 mg, 30 mg and 60 mg)" ("Lupin's Duloxetine HCl Capsules") in the United States before the expiration of the '269 patent.

10. On information and belief, ANDA No. 90-694 contains a Paragraph IV certification alleging that the claims of the '269 patent are either invalid or would not be infringed by Lupin's Duloxetine HCl Capsules.

11. Lupin Limited and/or Lupin Pharmaceuticals, Inc. sent or caused to be sent to Lilly a letter ("Lupin's Notice Letter") dated November 12, 2008, notifying Lilly that Defendants

filed ANDA No. 90-694, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Lilly received Lupin's Notice Letter on or about November 13, 2008. Lupin's Notice Letter alleges noninfringement of claims 3-7, 12-19, and 36-47 of the '269 patent. Lupin's Notice Letter also alleges that claims 1-2, 8-12, 20-35, and 48-51 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. 90-694 to the FDA to obtain approval for the commercial manufacture, use, or sale of Lupin's Duloxetine HCl Capsules in the United States before the expiration date of the '269 patent constitutes an act of infringement. If ANDA No. 90-694 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Lupin's Duloxetine HCl Capsules would infringe, either literally or under the doctrine of equivalents, one or more claims of the '269 patent under 35 U.S.C. § 271.

13. On information and belief, Defendants have filed ANDA No. 90-694, seeking authorization to commercially manufacture, use, offer for sale, and sell Lupin's Duloxetine HCl Capsules in the United States. On information and belief, Defendants know that physicians will use Lupin's 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).

14. On information and belief, Defendants had actual knowledge of the '269 patent prior to the filing of ANDA No. 90-694 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 Lupin'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 Lupin's

Duloxetine HCl Capsules constitute actual or threatened willful infringement and render this case exceptional under 35 U.S.C. § 285.

15. 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

16. Lilly realleges and incorporates by reference paragraphs 1-15.

17. 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).

18. On information and belief, Defendants have filed or caused to be filed ANDA No. 90-694 with the FDA, seeking authorization to commercially manufacture, market, use, offer for sale, and sell in the United States Lupin's Duloxetine HCl Capsules.

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

20. On information and belief, Defendants know that physicians prescribing or using Lupin's Duloxetine HCl Capsules according to the indications sought by Defendants will be using Lupin'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.

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

22. 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).

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

24. Defendants' infringing activities complained of herein are imminent and will begin following FDA approval of ANDA No. 90-694.

25. 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. 90-694 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Lupin'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 Lupin'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 Lupin's Duloxetine HCl Capsules shall be no earlier that 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. 90-694 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 Lupin's Duloxetine HCl Capsules within the United States, or importing Lupin'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: November 24, 2008 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