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Attorneys for Plaintiff
ELI LILLY AND COMPANY

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY,

Plaintiff,

v.

IMPAX LABORATORIES, INC.,

Defendant.

Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Eli Lilly and Company (“Lilly”) files this Complaint for patent infringement against Impax Laboratories, Inc. (“Impax”) 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, Impax is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 30831 Huntwood

Avenue, Hayward, California 94544, and having a regular and established place of business at 3735 Castor Avenue, Philadelphia Pennsylvania 19124. On information and belief, Impax is a pharmaceutical company that manufactures, sells, and/or markets generic drug products for sale and use in New Jersey and throughout the United States.

3. The Court has personal jurisdiction over Impax because, on information and belief, it has maintained continuous and systematic contacts with the State of New Jersey, and it has purposefully availed itself of the benefits and protections of the laws of the State of New Jersey.

4. 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

5. 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.

6. 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.

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

8. On information and belief, Impax filed or caused to be filed with the FDA, in Rockville, Maryland, Abbreviated New Drug Application (“ANDA”) No. 90-669 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” (“Impax’s Duloxetine HCl Capsules”) in the United States before the expiration of the ’269 patent.

9. On information and belief, ANDA No. 90-669 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 either invalid or would not be infringed by Impax’s Duloxetine HCl Capsules.

10. Impax sent or caused to be sent to Lilly a letter (“Impax’s Notice Letter”) dated October 28, 2008, notifying Lilly that Impax filed ANDA No. 90-669, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Lilly received Impax’s Notice Letter on or about October 29, 2008. Impax’s Notice Letter alleges noninfringement of all valid and enforceable claims of the ’269 patent. Impax’s Notice Letter also alleges that claims 1-2, 8-11, 20-35, and 48-51 of the ’269 patent are invalid over the prior art.

11. Under 35 U.S.C. § 271(e)(2)(A), Impax's submissions of ANDA No. 90-669 to the FDA to obtain approval for the commercial manufacture, use, or sale of Impax's Duloxetine HCl Capsules in the United States before the expiration date of the '269 patent constitutes an act of infringement. If ANDA No. 90-669 is approved by the FDA, Impax's commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of its 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.

12. On information and belief, Impax has filed ANDA No. 90-669, seeking authorization to commercially manufacture, use, offer for sale, and sell its Duloxetine HCl Capsules in the United States. On information and belief, Impax knows that physicians will use its Duloxetine HCl Capsules in accordance with the indications sought by Impax, and will therefore infringe one or more claims of the '269 patent under 35 U.S.C. §§ 271(b) and/or (c).

13. On information and belief, Impax had actual knowledge of the '269 patent prior to the filing of ANDA No. 90-669 and its actions in analyzing the '269 patent and in presenting arguments in its paragraph IV certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), and in Impax's Notice Letter, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), and its threatened manufacture, use, sale, offer for sale and/or importation of Impax's Duloxetine HCl Capsules constitute actual or threatened willful infringement and render this case exceptional under 35 U.S.C. § 285.

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

COUNT II FOR DECLARATORY JUDGMENT

15. Lilly realleges and incorporates by reference paragraphs 1-14.
16. 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).
17. On information and belief, Impax has filed or caused to be filed ANDA No. 90-669 with the FDA, seeking authorization to commercially manufacture, market, use, offer for sale, and sell in the United States its Duloxetine HCl Capsules.
18. On information and belief, Impax seeks approval of at least one indication claimed in the '269 patent for its Duloxetine HCl Capsules.
19. On information and belief, Impax knows that physicians prescribing or using Impax's Duloxetine HCl Capsules according to the indications sought by Impax will be using Impax'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.
20. On information and belief, Impax plans to begin marketing, selling, and offering to sell its Duloxetine HCl Capsules soon after the FDA has approved such indications.
21. 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).
22. Impax's infringing activities have been and will continue to be done in willful disregard of Lilly's patent rights.

23. Impax's activities complained of herein are imminent and will begin following FDA approval of the Defendants' ANDA.

24. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Lilly and Impax as to liability for the infringement of the '269 patent. Impax's actions have created in Lilly a reasonable apprehension of irreparable harm and loss resulting from Impax's 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), Impax infringed United States Patent No. 5,023,269 by submitting ANDA No. 90-669 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Impax's Duloxetine HCl Capsules prior to the expiration of the said patent;
- c) declare that Impax's commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Impax'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 Impax'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 Impax, and all persons acting in concert with Impax, from seeking, obtaining, or maintaining approval of ANDA No. 90-669 until the expiration of United States Patent No. 5,023,269;
- f) enjoin Impax, and all persons acting in concert with Impax, from commercially manufacturing, using, offering for sale, or selling Impax's Duloxetine HCl Capsules within the United States, or importing Impax'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,

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Dated: December 12, 2008