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

ELI LILLY AND COMPANY

Plaintiff,

v.

SUN PHARMACEUTICAL INDUSTRIES LTD.

Defendant.

Civil Action No.:

1:06-cv-1721-SEB-VSS

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Eli Lilly and Company ("Lilly") brings this action for patent infringement against Sun Pharmaceutical Industries Ltd. ("Sun"). This action involves a patent for the use of the pharmaceutical drug product Gemzar® as a treatment for susceptible neoplasms.

JURISDICTION AND PARTIES

1. Lilly is an Indiana corporation, having 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. Upon information and belief, Defendant Sun is an Indian corporation having its principal place of business at Acme Plaza, Kurla Road, Andheri (E), Mumbai 400 059. Upon information and belief, Sun develops and markets generic pharmaceuticals.

3. This Court has personal jurisdiction over Sun under Fed. R. Civ. P. 4(k)(2) because this action arises under federal law and, upon information and belief, Sun is not subject to the jurisdiction of the courts of general jurisdiction of any state and the exercise of personal jurisdiction over Sun is consistent with the Constitution and the laws of the United States.

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) 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). Venue is proper under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I FOR PATENT INFRINGEMENT

5. United States Patent No. 5,464,826 ("the '826 patent"), entitled "Method of Treating Tumors in Mammals with 2',2'-Difluoronucleosides," was duly and legally issued to Lilly by the United States Patent and Trademark Office on November 7, 1995. The '826 patent expires on November 7, 2012, followed by a six-month period of market exclusivity granted by the FDA under 21 U.S.C. § 355(a), ending on May 7, 2013. A true and correct copy of the '826 patent is attached as Exhibit A. Lilly has been the owner of the '826 patent since it issued.

6. Lilly is the holder of approved New Drug Application No. 20-509 for the use of Gemzar® as a treatment for non-small cell lung cancer, pancreatic cancer, breast cancer, and ovarian cancer.

7. Upon information and belief, Sun filed with the FDA, in Rockville, Maryland, an Abbreviated New Drug Application ("ANDA") No. 78-433 under 21 U.S.C. § 355(j), to obtain approval for the commercial manufacture, use, sale, and/or importation of Gemcitabine for Injection, 200 mg base/vial and 1g base/vial, a generic version of Lilly's Gemzar® products.

Upon information and belief, Sun filed ANDA No. 78-433 to obtain approval to market generic versions of Gemzar® before the expiration date of the '826 patent. Upon information and belief, ANDA No. 78-433 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the '826 patent are invalid or would not be infringed.

8. Sun sent Lilly a letter ("Notice Letter") dated October 17, 2006, notifying Lilly that Sun filed ANDA No. 78-433 for Gemcitabine for Injection, 200 mg base/vial and 1g base/vial, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Lilly received the Notice Letter, sent by certified mail, on or about October 20, 2006. The Notice Letter alleges that claims 1, 2, 6, and 7 of the '826 patent are invalid over the prior art. The Notice Letter further states that claims 3, 4, and 5 of the '826 patent are not infringed.

9. Under 35 U.S.C. § 271(e)(2)(A), Sun's submission to the FDA seeking approval for the commercial manufacture, use, sale, and/or importation of Sun's Gemcitabine for Injection before the expiration of the '826 patent constitutes an act of infringement. If ANDA No. 78-433 is approved by the FDA, Sun's using, offering to sell, or selling of Sun's Gemcitabine for Injection will infringe one or more claims of the '826 patent under 35 U.S.C. § 271(a)-(c).

10. Upon information and belief, doctors prescribing or using Sun's Gemcitabine for Injection according to the indications sought by Sun will be using it in a manner that will infringe one or more claims of the '826 patent.

11. Upon information and belief, Sun did not exercise due care in analyzing the '826 patent and presenting arguments in the paragraph IV certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), and Notice Letter, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii).

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

COUNT II FOR DECLARATORY JUDGMENT

13. Lilly realleges and incorporates by reference paragraphs 1-12.

14. Upon information and belief, Sun has filed an ANDA with the FDA, seeking authorization to commercially manufacture, use, sell, and/or import its Gemcitabine for Injection drug product. Upon information and belief, doctors prescribing or using the Gemcitabine for Injection drug product according to the indications sought by Sun will be using it in a manner that will infringe one or more claims of the '826 patent, either literally or under the doctrine of equivalents.

15. Upon information and belief, Sun seeks approval of at least one indication for the Gemcitabine for Injection drug product.

16. Upon information and belief, Sun plans to begin marketing, offering to sell, and selling the Gemcitabine for Injection drug product soon after the FDA approves such indications.

17. Such conduct will constitute direct infringement of one or more claims of the '826 patent under 35 U.S.C. § 271(a), inducement of infringement of the '826 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

18. Sun's infringing activity complained of herein is imminent and will begin following FDA approval of ANDA No. 78-433.

19. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Lilly and Sun concerning liability for infringement of the '826

patent. Sun's actions create a reasonable apprehension of irreparable harm and loss resulting from its threatened imminent actions.

WHEREFORE, Lilly demands judgment against Sun as follows:

(a) declaring United States Patent No. 5,464,826 valid and enforceable;

(b) declaring that Sun would infringe one or more claims of United States Patent No. 5,464,826 by the threatened acts of using, offering to sell, or selling its Gemcitabine for Injection drug product prior to the expiration of said patent;

(c) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of Sun's ANDA No. 78-433 relating to Gemcitabine for Injection before the expiration of the six-month period of market exclusivity for the '826 patent granted under 21 U.S.C. § 355(a), which follows the expiration of the patent;

(d) enjoining Sun from using, offering to sell, or selling its Gemcitabine for Injection drug product, in accordance with 35 U.S.C. § 271(e)(4)(B);

(e) declaring this to be an exceptional case and awarding Lilly attorney's fees under 35 U.S.C. §§ 285 and 271(e)(4); and

(f) awarding Lilly any further and additional relief as this Court deems just and proper.

Respectfully submitted,

Dated: December 1, 2006 By: Jan M. Carroll

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