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

ELI LILLY AND COMPANY,	
Plaintiff,	
v.	**Civil Action No.:**
SANDOZ, INC,	1:09-cv-1282 DFH -TAB
Defendant.	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Eli Lilly and Company ("Lilly") brings this action for patent infringement against Sandoz, Inc. ("Sandoz") under 35 U.S.C. § 271(e)(2). This action involves a patent for the use of the pharmaceutical product GEMZAR® as a treatment for susceptible neoplasms.

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. Upon information and belief, Defendant Sandoz is a corporation organized and existing under the laws of the State of Colorado, having its headquarters at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540, and having additional places of business at 2555 West Midway Boulevard, Broomfield, Colorado 80020, 227-15 North Conduit Avenue, Laurelton, New York 11413, and 4700 Sandoz Drive, Wilson, North Carolina 27893. Upon information and belief, Sandoz is a generic pharmaceutical company that develops,

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

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

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. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). 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. 5,464,826 ("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. The '826 patent was found invalid for obviousness-type double patenting on summary judgment in *Sun Pharmaceutical Industries Ltd. v. Eli Lilly and Co.*, Case No 2:07-cv-15087-GCS-RSW (E.D. Mich.), but the Court's August 17, 2009, order granting summary judgment on the issue has not been made final. Lilly believes the ruling is incorrect and will be reversed on appeal.

7. The '826 patent is similarly alleged to be invalid for, *inter alia*, obviousness-type double patenting in *Eli Lilly and Company v. SICOR Pharmaceuticals, Inc. et al.*, Case No. 06-CV-0238-SEB-JMS (S.D. Ind.). The Court held trial in that case between September 8, 2009, and September 22, 2009, and the parties await the Court's ruling on all issues.

8. 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.

9. Upon information and belief, Sandoz filed with the FDA, in Rockville, Maryland, an Abbreviated New Drug Application ("ANDA") No. 90-993 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 1 g base/vial, generic versions of Lilly's Gemzar® products. Upon information and belief, Sandoz filed ANDA No. 90-993 to obtain approval to market generic versions of Gemzar® before the expiration date of the '826 patent. Upon information and belief, ANDA No. 90-993 contains a certification 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.

10. Sandoz sent Lilly a letter ("Notice Letter") dated September 23, 2009, notifying Lilly that Sandoz filed ANDA No. 90-993 for Gemcitabine for Injection, 200 mg base/vial and 1 g 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 September 28, 2009. The Notice Letter alleges that claims 1, 2, 6, and 7 of the '826 patent are invalid under the judicial doctrine of obviousness-type double patenting. The Notice Letter further states that claims 3, 4, and 5 of the '826 patent are not infringed.

11. Under 35 U.S.C. § 271(e)(2)(A), Sandoz's submission to the FDA seeking approval for the commercial manufacture, use, sale, and/or importation of Sandoz's Gemcitabine for Injection before the expiration of the '826 patent constitutes an act of infringement. If ANDA No. 90-993 is approved by the FDA, Sandoz's using, offering to sell, or selling of Sandoz's Gemcitabine for Injection will infringe one or more claims of the '826 patent under 35 U.S.C. § 271(a)-(c).

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

13. Upon information and belief, Sandoz 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).

14. Lilly will be substantially and irreparably harmed by Sandoz'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. Upon information and belief, Sandoz 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 Sandoz 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.

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

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

19. 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).

20. Sandoz's infringing activity complained of herein is imminent and will begin following FDA approval of ANDA No. 90-993.

21. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Lilly and Sandoz concerning liability for infringement of the '826 patent. Sandoz's actions create a reasonable apprehension of irreparable harm and loss resulting from its threatened imminent actions.

WHEREFORE, Lilly demands judgment against Sandoz as follows:

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

(b) declaring that Sandoz 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 Sandoz's ANDA No. 90-993 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 Sandoz 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: October 14, 2009

By: Jan M. Carroll

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