UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,

Plaintiff,

v.

SANDOZ, INC,
Defendant.

Civil Action No.:

1:10-cv-1057 JMS-TAB

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 drug 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 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. § 355a, 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 in an order issued on August 17, 2009, in *Sun Pharmaceutical Industries Ltd. v. Eli Lilly and Co.*, No 2:07-cv-15087-GCS-RSW (E.D. Mich.). Pursuant to a Lilly motion under Fed. R. Civ. P. 54(b), the Court entered final judgment of invalidity on the '826 patent on October 29, 2009. Lilly filed its Notice of Appeal with the district court on October 30, 2009, and the United

States Court of Appeals for the Federal Circuit heard oral argument on Lilly's appeal on May 7, 2010. Lilly believes the Michigan court's ruling is incorrect and will be reversed on appeal.

7. 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.

8. Upon information and belief, Sandoz filed with the FDA in Rockville, Maryland, a New Drug Application No. 200-200 under 21 U.S.C. § 355(b) ("Application No. 200-200" or "B2 Application"), to obtain approval for the commercial manufacture, use, sale, and/or importation of Gemcitabine Hydrochloride Injection, 40 mg/mL (200 mg /5 mL, 1 g/25 mL, and 2 g/50 mL). Upon information and belief, Sandoz filed Application No. 200-200 to obtain approval to market these generic versions of Gemzar® before the expiration date of the '826 patent. Upon information and belief, Application No. 200-200 contains certifications pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), alleging that the claims of the '826 patent are invalid or would not be infringed.

9. Sandoz sent Lilly a letter ("Notice Letter") dated July 6, 2010, notifying Lilly that Sandoz filed Application No. 200-200 for Gemcitabine Hydrochloride Injection, 40 mg/mL (200 mg /5 mL, 1 g/25 mL, and 2 g/50 mL), and providing information pursuant to 21 U.S.C. § 355(b)(3). Lilly received the Notice Letter, sent by certified mail, on or about July 9, 2010. The Notice Letter alleges that claims 1, 2, 6, and 7 of the '826 patent are invalid under the doctrine of obviousness-type double patenting. The Notice Letter further states that claims 3, 4, and 5 of the '826 patent are not infringed.

10. Under 35 U.S.C. § 271(e)(2)(A), Sandoz's filing of its B2 Application seeking approval for the commercial manufacture, use, sale, and/or importation of its Gemcitabine

Hydrochloride Injection products before the expiration of the '826 patent constitutes an act of infringement. If Application No. 200-200 is approved by the FDA, Sandoz's commercial manufacture, use, offer to sell, sale, or importation of Gemcitabine Hydrochloride Injection products will infringe one or more claims of the '826 patent under 35 U.S.C. § 271(a)-(c).

11. Upon information and belief, Sandoz knows that physicians prescribing or using its Gemcitabine for Injection drug products according to the indications sought by Sandoz will be using them in a manner that will infringe one or more claims of the '826 patent.

12. 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

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

14. Upon information and belief, Sandoz has filed a B2 Application with the FDA, seeking authorization to commercially manufacture, use, sell, and/or import Gemcitabine Hydrochloride Injection drug products. Upon information and belief, Sandoz knows that doctors prescribing or using its Gemcitabine Hydrochloride Injection drug products 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.

15. Upon information and belief, Sandoz seeks approval of at least one indication for its Gemcitabine Hydrochloride Injection drug products.

16. Upon information and belief, Sandoz plans to begin manufacturing, marketing, offering to sell, selling, and/or importing its Gemcitabine Hydrochloride Injection drug products soon after the FDA approves such indications.

17. Such conduct will constitute 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. Sandoz's infringing activity complained of herein is imminent and will begin following FDA approval of Application No. 200-200.

19. 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 not invalid and not unenforceable;

(b) declaring that Sandoz would infringe one or more claims of United States Patent No. 5,464,826 by the threatened acts of manufacture, use, offer to sell, sale, and importation of its Gemcitabine Hydrochloride Injection drug products 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 Application No. 200-200 relating to Gemcitabine Hydrochloride Injection before the expiration of the six-month period of market exclusivity for the '826 patent granted under 21 U.S.C. § 355a, which follows the expiration of the patent;

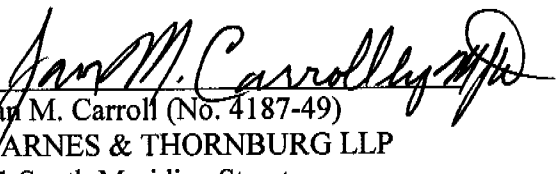
(d) enjoining Sandoz from the commercial manufacture, use, offer to sell, sale, or importation of its Gemcitabine Hydrochloride Injection drug products, in accordance with 35 U.S.C. § 271(e)(4)(B);

(e) declaring this to be an exceptional case and awarding attorney fees to Lilly 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: August 23, 2010

By: 

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