UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No.:**
	)	
HOSPIRA, INC.,	)	
	)	
Defendant.	)	**1:10-cv-0346 RLY-DML**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Eli Lilly and Company ("Lilly") brings this action for patent infringement against Hospira, Inc. ("Hospira") under 35 U.S.C. § 271(e)(2). This action involves two patents. The first patent concerns the pharmaceutical drug product GEMZAR®. The second patent concerns the use of this pharmaceutical product 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 Hospira is a Delaware corporation having its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045. Upon information and belief, Hospira 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 Hospira 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. 4,808,614 ("the '614 patent), entitled "Difluoro Antivirals and Intermediate Therefor," was duly and legally issued to Lilly by the United States Patent and Trademark Office on February 28, 1989. The '614 patent expires on May 15, 2010, followed by a six-month period of market exclusivity granted by the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355a, ending on November 15, 2010. A true and correct copy of the '614 patent is attached as Exhibit A. Lilly has owned the '614 patent since it issued.

6. 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 B. Lilly has been the owner of the '826 patent since it issued.

7. 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. Lilly's appeal is fully briefed and awaiting oral argument to be scheduled. Lilly believes the Michigan court's ruling is incorrect and will be reversed on appeal.

8. The '614 and '826 patents are alleged to be invalid for, *inter alia*, obviousness-type double patenting and obviousness in *Eli Lilly and Co. v. SICOR Pharmaceuticals, Inc. et al.*, 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.

9. 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.

10. Upon information and belief, Hospira filed with the FDA, in Rockville, Maryland, a New Drug Application No. 200-795 under 21 U.S.C. § 355(b) ("Application No. 200-795" or "B2 Application"), to obtain approval for the commercial manufacture, use, sale, and/or importation of gemcitabine hydrochloride injection, 200 mg/5.3 ml, 1 g/26.3 ml, and 2 g/52.6 ml. Upon information and belief, Hospira filed Application No. 200-795 to obtain approval to market these generic versions of Gemzar® before the expiration date of the '614 and '826 patents. Upon information and belief, Application No. 200-795 contains certifications

pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), alleging that the claims of the '614 and '826 patents are invalid or would not be infringed.

11. Hospira sent Lilly a letter ("Notice Letter") dated February 12, 2010, notifying Lilly that Hospira filed Application No. 200-795 for gemcitabine hydrochloride injection, 200 mg/5.3 ml, 1 g/26.3 ml, and 2 g/52.6 ml, and providing information pursuant to 21 U.S.C. § 355(b)(3). Lilly received the Notice Letter, sent by facsimile and certified mail, on or about February 16, 2010. The Notice Letter alleges noninfringement of claims 3-6, 9-10, and 13-14 of the '614 patent and claims 3-5 of the '826 patent. The Notice Letter further alleges that claims 1-2, 7-8, and 11-14 of the '614 patent are invalid for one reason (obviousness), and that claims 1-2 and 6-7 of the '826 patent are invalid for two reasons (obviousness-type double patenting and obviousness).

12. Under 35 U.S.C. § 271(e)(2)(A), Hospira's filing of its B2 Application seeking approval for the commercial manufacture, use, sale, and/or importation of its gemcitabine hydrochloride injection before the expiration of the '614 and '826 patents constitutes an act of infringement. If Application No. 200-795 is approved by the FDA, Hospira's commercial manufacture, use, offer to sell, sale, or importation of gemcitabine hydrochloride injection will infringe one or more claims of the '614 patent and the '826 patent under 35 U.S.C. § 271(a)-(c).

13. Upon information and belief, Hospira knows that physicians prescribing or using its gemcitabine hydrochloride injection drug products according to the indications sought by Hospira will be using them in a manner that will infringe one or more claims of the '614 patent and the '826 patent.

14. Lilly will be substantially and irreparably harmed by Hospira'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, Hospira 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, Hospira know that doctors prescribing or using its gemcitabine hydrochloride injection drug products according to the indications sought by Hospira will be using them in a manner that will infringe one or more claims of the '614 patent and the '826 patent, either literally or under the doctrine of equivalents.

17. Upon information and belief, Hospira seeks approval of at least one indication for its gemcitabine hydrochloride injection drug products.

18. Upon information and belief, Hospira 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.

19. Such conduct will constitute direct infringement of one or more claims of the '614 patent under 35 U.S.C. § 271(a), inducement of infringement of the '614 and '826 patents under 35 U.S.C. § 271(b), and contributory infringement of the '826 patent under 35 U.S.C. § 271(c).

20. Hospira's infringing activity complained of herein is imminent and will begin following FDA approval of Application No. 200-795.

21. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Lilly and Hospira concerning liability for infringement of the '614 and '826 patents. Hospira's actions create a reasonable apprehension of irreparable harm and loss resulting from its threatened imminent actions.

WHEREFORE, Lilly demands judgment against Hospira as follows:

(a) declaring United States Patent Nos. 4,808,614 and 5,464,826 not invalid and not unenforceable;

(b) declaring that Hospira would infringe one or more claims of United States Patent No. 4,808,614 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) declaring that Hospira 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;

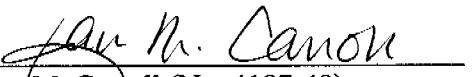
(c) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of Hospira's Application No. 200-795 relating to gemcitabine hydrochloride injection before the expiration of the six-month periods of market exclusivity for the '614 and '826 patents granted under 21 U.S.C. § 355a, which follow the expiration of the patent;

(d) enjoining Hospira 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); and

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

Respectfully submitted,

Dated: March 23, 2010

By: 

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