UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No.:**
	)	
APP PHARMACEUTICALS, LLC and APP PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	**1:09-cv-1551 LJM-TAB**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Eli Lilly and Company ("Lilly") brings this action for patent infringement against APP Pharmaceuticals, LLC ("APP LLC") and APP Pharmaceuticals, Inc. ("APP Inc.") (collectively "Defendants") 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 APP LLC is a limited liability corporation organized and existing under the laws of the State of Illinois, having its headquarters and principal place of business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173, and registered to do business in the State of Indiana. Upon

information and belief, APP LLC is a wholly owned and directly controlled subsidiary of APP Inc. Upon information and belief, APP LLC distributes generic pharmaceutical products for sale in the Southern District of Indiana and throughout the United States.

3. Upon information and belief, Defendant APP Inc. is a corporation organized and existing under the laws of the State of Delaware, having its headquarters and principal place of business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173. Upon information and belief, APP Inc. is a generic pharmaceutical company that develops, manufactures, and distributes generic pharmaceutical products through and with its wholly owned and directly controlled subsidiary APP LLC.

4. Upon information and belief, APP Inc. uses and works with APP LLC to carry out its business of importing, manufacturing, selling, formulating, filling, labeling, and packaging finished dosage forms of generic drug products for distribution in the Southern District of Indiana and throughout the United States.

5. Upon information and belief, APP Inc. and APP LLC employ and/or seek to employ sales representatives in the State of Indiana and throughout the United States.

6. This Court has personal jurisdiction over Defendants because, on information and belief, they have maintained continuous and systematic contacts with the State of Indiana and have purposefully availed themselves of the benefits and protections of the laws of the State of Indiana.

7. 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

8. 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.

9. 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 believes the Michigan court's ruling is incorrect and will be reversed on appeal.

10. The '826 patent is similarly alleged to be invalid for, *inter alia*, obviousness-type double patenting 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.

11. 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.

12. Upon information and belief, APP LLC filed with the FDA, in Rockville, Maryland, an Abbreviated New Drug Application ("ANDA") No. 90-242 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, 1 g base/vial, and 2 g base/vial. Upon information and belief, APP LLC filed ANDA No. 90-242 to obtain approval to market these generic versions of Gemzar® before the expiration date of the '826 patent. Upon information and belief, ANDA No. 90-242 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.

13. Upon information and belief, APP Inc. participated in the submission of ANDA No. 90-242 or otherwise acted in concert with APP LLC in the submission of ANDA No. 90-242.

14. Upon information and belief, APP Inc. exercises control over APP LLC and conducts its U.S. generic drug product operations through and with APP LLC.

15. Upon information and belief, if ANDA No. 90-242 is approved, it is the intention of APP Inc. and APP LLC that the products will be distributed in the United States by or through APP Inc. and/or APP LLC.

16. APP LLC sent Lilly a letter ("Notice Letter") dated November 3, 2009, notifying Lilly that APP LLC filed ANDA No. 90-242 for Gemcitabine for Injection, 200 mg base/vial, 1 g base/vial, and 2 g base/vial, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Lilly received the Notice Letter, sent by Federal Express, on or about November 4, 2009. 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.

17. Under 35 U.S.C. § 271(e)(2)(A), APP LLC's filing of its ANDA seeking approval for the commercial manufacture, use, sale, and/or importation of Defendants' Gemcitabine for Injection before the expiration of the '826 patent constitutes an act of infringement. If ANDA No. 90-242 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale, or importation of Gemcitabine for Injection will infringe one or more claims of the '826 patent under 35 U.S.C. § 271(a)-(c).

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

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

COUNT II FOR DECLARATORY JUDGMENT

20. Lilly realleges and incorporates by reference paragraphs 1-19.

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

22. Upon information and belief, APP LLC seeks approval of at least one indication for Defendants' Gemcitabine for Injection drug products.

23. Upon information and belief, Defendants plan to begin manufacturing, marketing, offering to sell, selling, and/or importing their Gemcitabine for Injection drug products soon after the FDA approves such indications.

24. 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).

25. Defendants' infringing activity complained of herein is imminent and will begin following FDA approval of ANDA No. 90-242.

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

WHEREFORE, Lilly demands judgment against Defendants as follows:

(a) declaring United States Patent No. 5,464,826 not invalid and not unenforceable;

(b) declaring that Defendants 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 their Gemcitabine for Injection drug products prior to the expiration of said patent;

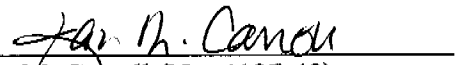
(c) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of APP LLC's ANDA No. 90-242 relating to Gemcitabine for Injection before the expiration of the six-month period of market exclusivity for the '826 patent granted under 21 U.S.C. § 355(a), which follows the expiration of the patent;

(d) enjoining Defendants from the commercial manufacture, use, offer to sell, sale, or importation of their Gemcitabine for 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: December 16, 2009

By: 

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