UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,

Plaintiff,

v.

ACTAVIS TOTOWA LLC and ACTAVIS ELIZABETH LLC,

Defendants.

Case No.:

1:10-cv-0836TWP-TAB

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Eli Lilly and Company ("Lilly") brings this action for patent infringement against Actavis Totowa LLC ("Actavis Totowa") and Actavis Elizabeth LLC ("Actavis Elizabeth") (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 Actavis Totowa is a limited liability corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 101 East Main Street, Little Falls, New Jersey 07424. Upon

information and belief, Actavis Totowa is a wholly owned and directly controlled subsidiary of Actavis Group hf., a global pharmaceutical company, which is headquartered at Dalshrauni 1, 220 Hafnarfirdi, Iceland. Upon information and belief, Actavis Totowa is a generic pharmaceutical company that produces and markets generic pharmaceutical products for sale in the Southern District of Indiana and throughout the United States.

3. Upon information and belief, Defendant Actavis Elizabeth is a limited liability corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07207. Upon information and belief, Actavis Elizabeth is a wholly owned and directly controlled subsidiary of Actavis, Inc., which is headquartered at 60 Columbia Road, Suite 8, Morristown, New Jersey 07960. Actavis Inc. is a wholly owned and directly controlled subsidiary of Actavis Group hf., a global pharmaceutical company, which is headquartered at Dalshrauni 1, 220 Hafnarfirdi, Iceland. Upon information and belief, Actavis Elizabeth is a generic pharmaceutical company that produces and markets generic pharmaceutical products for sale in the Southern District of Indiana and throughout the United States.

4. 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.

5. 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

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. § 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.

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, and the United States Court of Appeal 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.

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, Actavis Totowa filed with the FDA, in Rockville, Maryland, an Abbreviated New Drug Application ("ANDA") No. 79-160 under 21 U.S.C. § 355(j), to obtain approval for the commercial manufacture, use, sale, and/or importation of Gemcitabine Hydrochloride Injection, Eq. 1 gm and 200 mg base/vial. Upon information and

belief, Actavis Totowa filed ANDA No. 79-160 to obtain approval to market these generic versions of Gemzar® before the expiration date of the '826 patent. Upon information and belief, ANDA No. 79-160 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. Upon information and belief, Actavis Elizabeth participated in the submission of ANDA No. 79-160 or otherwise acted in concert with Actavis Totowa in the submission of ANDA No. 79-160.

11. Upon information and belief, if ANDA No. 79-160 is approved, it is the intention of Actavis Totowa and Actavis Elizabeth that the products will be distributed in the United States by or through Actavis Totowa and/or Actavis Elizabeth.

12. Actavis Elizabeth sent Lilly a letter ("Notice Letter") dated May 14, 2010, notifying Lilly that Actavis Totowa filed ANDA No. 79-160 for Gemcitabine Hydrochloride Injection, Eq. 1 gm and 200 mg 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 May 17, 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.

13. Under 35 U.S.C. § 271(e)(2)(A), Actavis Totowa's filing of its ANDA seeking approval for the commercial manufacture, use, sale, and/or importation of Defendants' Gemcitabine Hydrochloride Injection before the expiration of the '826 patent constitutes an act of infringement. If ANDA No. 79-160 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale, or importation of Gemcitabine Hydrochloride Injection will infringe one or more claims of the '826 patent under 35 U.S.C. § 271(a)-(c).

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

15. 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

16. Lilly realleges and incorporates by reference paragraphs 1-15.

17. Upon information and belief, Actavis Totowa has filed an ANDA with the FDA, seeking authorization to commercially manufacture, use, sell, and/or import Gemcitabine Hydrochloride Injection drug products. Upon information and belief, Defendants know that doctors prescribing or using Defendants' Gemcitabine Hydrochloride Injection drug products according to the indications sought by Actavis Totowa 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.

18. Upon information and belief, Actavis Totowa seeks approval of at least one indication for Defendants' Gemcitabine Hydrochloride Injection drug products.

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

20. 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).

21. Defendants' infringing activity complained of herein is imminent and will begin following FDA approval of ANDA No. 79-160.

22. 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 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 Actavis Totowa's ANDA No. 79-160 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 Defendants from the commercial manufacture, use, offer to sell, sale, or importation of their 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: June 30, 2010

By: Jan M. Carroll

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