UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,
Plaintiff,

v.

DR. REDDY'S LABORATORIES, LTD.
and DR. REDDY'S LABORATORIES, INC.,
Defendants.

Civil Action No.:

1:10-cv-1251 TWP -TAB

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Eli Lilly and Company ("Lilly") brings this action for patent infringement against Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") and Dr. Reddy's Laboratories, Inc. ("DRL Inc.") (collectively "Dr. Reddy") 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 DRL Ltd. is a public limited liability corporation organized and existing under the laws of India, having its principal place of business at 7-1-27, Ameerpet, Hyderabad, 500 016, India. Upon information and belief, DRL Ltd. is a generic pharmaceutical company that develops, manufactures, and markets generic pharmaceutical products, as well as bulk active pharmaceutical ingredients ("API"). Upon

information and belief, DRL Ltd. imports and ships those products and API into the United States for distribution and sale in the Southern District of Indiana and throughout the United States.

3. Upon information and belief, Defendant DRL Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 200 Somerset Corporate Boulevard, Building II, 7th Floor, Bridgewater, New Jersey 08807-2862. Upon information and belief, DRL Inc. is a wholly owned and directly controlled subsidiary of DRL Ltd. Upon information and belief, DRL Inc. is the exclusive agent in North America for DRL Ltd. and distributes and markets DRL Ltd.'s generic pharmaceutical products and API for sale in the Southern District of Indiana and throughout the United States.

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

5. This Court has personal jurisdiction over DRL Ltd. and DRL Inc. 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.

6. 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

7. 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 United States Food and Drug Administration ("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.

8. Claims 2 and 6-7 of the '826 patent were 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.) ("Michigan decision"). Lilly appealed the decision to the United States Court of Appeals for the Federal Circuit ("Federal Circuit"), and a three-judge panel affirmed the Michigan decision on July 28, 2010. Lilly has petitioned for rehearing and rehearing en banc, and a mandate has not yet issued from the Federal Circuit. Lilly's petition is supported by three amici curiae. Further, at the Federal Circuit's request, Sun has submitted a response to Lilly's petition for rehearing. The parties await the court's decision on Lilly's petition.

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, Dr. Reddy filed with the FDA in Rockville, Maryland, an Abbreviated New Drug Application ("ANDA") No. 91-365 under 21 U.S.C. § 355(j), to obtain approval for the commercial manufacture, use, sale, and/or importation of

Gemcitabine Hydrochloride for Injection, 200 mg base/vial and 1 gm base/vial. Upon information and belief, Dr. Reddy filed ANDA No. 91-365 to obtain approval to market these generic versions of Gemzar® before the expiration date of the '826 patent. Upon information and belief, ANDA No. 91-365 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.

11. Upon information and belief, DRL Ltd. participated in the submission of ANDA No. 91-365 or otherwise acted in concert with DRL Inc. in the submission of ANDA No. 91-365.

12. Upon information and belief, if ANDA No. 91-365 is approved, it is the intention of DRL Ltd. and DRL Inc. that the products will be distributed in the United States by or through DRL Inc.

13. DRL Inc. sent Lilly a letter ("Notice Letter") dated August 13, 2010, notifying Lilly that Dr. Reddy filed ANDA No. 91-365 for Gemcitabine Hydrochloride for Injection, 200 mg base/vial and 1 gm base/vial, and providing information pursuant to 21 U.S.C. § 355(b)(3). Lilly received the Notice Letter, sent by certified mail, on or about August 20, 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 3-5 of the '826 patent are not infringed.

14. Under 35 U.S.C. § 271(e)(2)(A), Dr. Reddy's filing of their ANDA seeking approval for the commercial manufacture, use, sale, and/or importation of Dr. Reddy's Gemcitabine Hydrochloride for Injection products before the expiration of the '826 patent constitutes an act of infringement. If ANDA No. 91-365 is approved by the FDA, Dr. Reddy's

commercial manufacture, use, offer to sell, sale, or importation of Gemcitabine Hydrochloride for Injection products will infringe one or more claims of the '826 patent under 35 U.S.C. § 271(a)-(c).

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

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

COUNT II FOR DECLARATORY JUDGMENT

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

18. Upon information and belief, Dr. Reddy has filed ANDA No. 91-365 with the FDA, seeking authorization to commercially manufacture, use, sell, and/or import Gemcitabine Hydrochloride for Injection drug products. Upon information and belief, Dr. Reddy knows that doctors prescribing or using their Gemcitabine Hydrochloride for Injection drug products according to the indications sought by Dr. Reddy 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.

19. Upon information and belief, DRL Ltd. participated in the submission of ANDA No. 91-365 or otherwise acted in concert with DRL Inc. in the submission of ANDA No. 91-365.

20. Upon information and belief, Dr. Reddy seeks approval of at least one indication for their Gemcitabine Hydrochloride for Injection drug products.

21. Upon information and belief, Dr. Reddy plans to begin manufacturing, marketing, offering to sell, selling, and/or importing their Gemcitabine Hydrochloride for Injection drug products soon after the FDA approves such indications.

22. 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).

23. Dr. Reddy's infringing activity complained of herein is imminent and will begin following FDA approval of ANDA No. 91-365.

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

WHEREFORE, Lilly demands judgment against Dr. Reddy as follows:

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

(b) declaring that Dr. Reddy 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 for Injection drug products prior to the expiration of said patent;

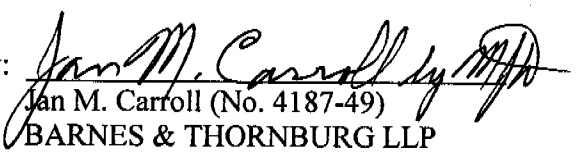
(c) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of Dr. Reddy's ANDA No. 91-365 relating to Gemcitabine Hydrochloride for Injection before the expiration of the six-month period of market exclusivity for the '826 patent granted under 21 U.S.C. § 355a, which follows the expiration of the patent;

(d) enjoining Dr. Reddy from the commercial manufacture, use, offer to sell, sale, or importation of their Gemcitabine Hydrochloride 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: October 1, 2010

By: 

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