**UNITED STATES DISTRICT COURT**
**MIDDLE DISTRICT OF NORTH CAROLINA**
**CIVIL ACTION NO.: 1:10-CV-781**

ELI LILLY AND COMPANY,

Plaintiff,

vs.

ACCORD HEALTHCARE, INC.,

Defendant.

## COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Eli Lilly and Company ("Lilly") brings this action for patent infringement against Accord Healthcare, Inc. ("Accord") 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 Accord Healthcare, Inc. is a corporation organized and existing under the laws of the State of North Carolina, having its principal place of business at 1009 Slater Road, Suite 210B, Durham, North

Carolina 27703. Upon information and belief, Accord is a generic pharmaceutical company that produces and markets generic pharmaceutical products for sale in the Middle District of North Carolina and throughout the United States.

3. This Court has personal jurisdiction over Accord because, on information and belief, Accord is a North Carolina corporation and has principal place of business in the Middle District of North Carolina.

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 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.

6. 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 Company*, 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.

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, Accord filed with the FDA in Rockville, Maryland, an Abbreviated New Drug Application ("ANDA") No. 91-594 under 21 U.S.C. § 355(j), to obtain approval for the commercial manufacture, use, sale, and/or importation of Gemcitabine Hydrochloride 200 mg base/vial, 1 g base/vial, and 2 g base/vial. Upon information and belief, Accord filed ANDA No. 91-594 to obtain approval to market these generic versions of Gemzar® before the expiration date of the '826 patent. Upon information and belief, ANDA No. 91-594 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.

9. Accord sent Lilly a letter ("Notice Letter") dated September 1, 2010, notifying Lilly that Accord filed ANDA No. 91-594 for Gemcitabine Hydrochloride 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 certified mail, on or about September 4, 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), Accord's filing of its ANDA seeking approval for the commercial manufacture, use, sale, and/or importation of its Gemcitabine Hydrochloride drug products before the expiration of the '826 patent constitutes an act of infringement. If ANDA No. 91-594 is approved by the FDA, the sale of Accord's Gemcitabine Hydrochloride drug products will infringe one or more claims of the '826 patent under 35 U.S.C. § 271(a)-(c).

11. Upon information and belief, Accord knows that physicians prescribing or using its Gemcitabine Hydrochloride drug products according to the indications sought by Accord 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 Accord'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, Accord has filed ANDA No. 91-594 with the FDA, seeking authorization to commercially manufacture, use, sell, and/or import Gemcitabine Hydrochloride drug products. Upon information and belief, Accord knows that doctors prescribing or using its Gemcitabine Hydrochloride drug products according to the indications sought by Accord will be using them in a manner that will infringe one or more claims of the '826 patent.

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

16. Upon information and belief, Accord plans to selling its Gemcitabine Hydrochloride drug products soon after the FDA approves ANDA No. 91-594.

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. Accord's infringing activity complained of herein is imminent and will begin following FDA approval of ANDA No. 91-594.

19. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Lilly and Accord concerning liability for

infringement of the '826 patent. Accord's actions create a reasonable apprehension of irreparable harm and loss resulting from its threatened imminent actions.

WHEREFORE, Lilly demands judgment against Accord as follows:

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

(b) declaring that Accord would infringe one or more claims of United States Patent No. 5,464,826 by the threatened act of sale of its Gemcitabine Hydrochloride 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 Accord's ANDA No. 91-594 relating to Gemcitabine Hydrochloride 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 Accord from the sale of its Gemcitabine Hydrochloride 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, this the 19th day of October, 2010.

NELSON MULLINS RILEY & SCARBOROUGH LLP

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