UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA

ELI LILLY AND COMPANY, Plaintiff, vs. ACCORD HEALTHCARE, INC., Defendant.	Civil Action No. 1:11-cv-261

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 covering formulations of the pharmaceutical olanzapine, Zyprexa®, a prescription drug widely used to treat schizophrenia and acute manic episodes associated with bipolar mania.

JURISDICTION AND PARTIES

1. Lilly is an Indiana corporation, having 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 its 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). 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. 5,919,485 ("the '485 patent"), entitled "Oral 2-Methyl-thieno-benzodiazepine Formulation," was duly and legally issued to Lilly by the United States Patent and Trademark Office on July 6, 1999. The '485 patent expires on March 24, 2015, 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 September 24, 2015. A true and correct copy of the '485 patent is attached as Exhibit A. Lilly has been the owner of the '485 patent since it issued.

6. Lilly is the holder of a New Drug Application approved by the United States Food and Drug Administration ("FDA") for the use of olanzapine, Zyprexa®, to treat schizophrenia and acute manic episodes associated with bipolar mania.

7. Upon information and belief, Accord filed with the FDA in Rockville, Maryland, an Abbreviated New Drug Application ("ANDA") No. 202391 under 21 U.S.C. § 355(j), to obtain approval for the commercial manufacture, use, sale, and/or importation of Olanzapine Tablets 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg. Upon information and belief, Accord filed ANDA No. 202391 to obtain approval to market these generic versions of Zyprexa® before the expiration date of the '485 patent. Upon information and belief, ANDA No. 202391 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the '485 patent are invalid or would not be infringed.

8. Accord sent Lilly a letter ("Notice Letter") dated February 17, 2011, notifying Lilly that Accord filed ANDA No. 202391 for Olanzapine Tablets 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II). Lilly received the Notice Letter, sent by Federal Express and certified mail, on or about February 18, 2011. The Notice Letter alleges that claims 1-16 and 18 of the '485 patent are invalid as obvious. The Notice Letter further states that claims 17 and 19 of the '485 patent are not infringed.

9. 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 Olanzapine Tablet drug products before the expiration of the '485 patent constitutes an act of infringement. If ANDA No. 202391 is approved by the FDA, the sale of Accord's Olanzapine Tablet drug products will infringe one or more claims of the '485 patent under 35 U.S.C. § 271(a).

10. 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.

WHEREFORE, Lilly demands judgment against Accord as follows:

(a) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of Accord's ANDA No. 202391 relating to Olanzapine Tablets before the expiration of the six-month period of market exclusivity for the '485 patent granted under 21 U.S.C. § 355a, which follows the expiration of the patent;

(b) enjoining Accord from the commercial manufacture, use, offer to sell, sale, or importation of its Olanzapine Tablet drug products, in accordance with 35 U.S.C. § 271(e)(4)(B); and

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

Respectfully submitted, this 4th day of April, 2011.

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