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Eli Lilly and Company

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY,	)	
	)	
Plaintiff,	)	Civil Action No. _____
	)	
v.	)	
	)	
ACTAVIS ELIZABETH LLC,	)	
	)	
Defendant.	)	
	)	

COMPLAINT

Plaintiff Eli Lilly and Company, (hereinafter "Lilly") for its Complaint against Defendant Actavis Elizabeth LLC (hereinafter "Actavis"), hereby alleges as follows:

Nature of the Action

1. This is a civil action for the infringement of United States Patent No. 5,658,590 ("the '590 patent"). This action relates to an Abbreviated New Drug Application ("ANDA") filed by Actavis with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Lilly's Strattera® drug products. This action arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq*.

Parties

2. Plaintiff Eli Lilly and Company is an Indiana corporation having a principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

3. Upon information and belief, Defendant Actavis Elizabeth LLC is a corporation organized under the laws of Delaware having a principal place of business at 200 Elmora Avenue, Elizabeth, NJ 07207.

Jurisdiction and Venue

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

5. Venue is proper in this judicial district pursuant to, *inter alia*, 28 U.S.C. §§ 1391(b) and/or 1400(b).

Plaintiff's Strattera® Products and Related Patent

6. On August 19, 1997, the '590 patent, titled "Treatment of Attention-Deficit/Hyperactivity Disorder," was duly and legally issued to John H. Heiligenstein and Gary D. Tollefson and assigned to Eli Lilly and Company. A true and correct copy of the '590 patent is attached hereto as Exhibit A. The '590 patent claims methods of treating attention-deficit/hyperactivity disorder with tomoxetine. Tomoxetine is now known as atomoxetine. The claims of the '590 patent are valid and enforceable. The '590 patent expires on May 26, 2017.

7. Strattera® is the commercial formulation of atomoxetine hydrochloride developed, manufactured, and sold by Lilly. Lilly submitted a New Drug Application to the FDA for Strattera® Capsules for the treatment of attention-deficit/hyperactivity disorder (NDA No. 21-411). NDA 21-411 was approved by the FDA on or about November 26, 2002, for Strattera® Capsules in strengths of Eq 10 mg, 18 mg, 25 mg, 40 mg, and 60 mg. Strattera® Capsules in strengths of Eq 80 mg and 100 mg were approved on or about February 14, 2005.

v.

8. The Food And Drug Administration Center For Drug Evaluation And Research Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book") lists the '590 patent for each of the strengths of Strattera® approved by the FDA under NDA No. 21-411.

9. Pursuant to 21 U.S.C. § 355a, Lilly is entitled to a six-month period of pediatric exclusivity for Strattera® beyond the date of expiration of the '590 patent.

Actavis' ANDA Filing

10. By letter dated June 27, 2007 (the "Actavis Notice Letter"), Actavis notified Lilly that Actavis had submitted ANDA No. 78-940 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) (the "Actavis ANDA"). The Actavis Notice Letter explained that the Actavis ANDA seeks approval to engage in the commercial manufacture, use or sale of generic Atomoxetine Hydrochloride Capsules, Eq 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg Atomoxetine (collectively the "Actavis Atomoxetine Capsules") — generic versions of each of the FDA-approved Strattera® Capsule strengths — before the expiration date of the '590 patent.

11. By filing the Actavis ANDA, Actavis has necessarily represented to the FDA that the Actavis Atomoxetine Capsules have the same active ingredient as Strattera®, have the same route of administration, dosage form, and strengths as Strattera®, are bioequivalent to Strattera®, and have the same or substantially the same proposed labeling as Strattera®.

12. In the Actavis Notice Letter, Actavis notified Lilly that the Actavis ANDA contains a "paragraph IV certification" with respect to the '590 patent. Actavis attached to the Actavis Notice Letter a statement asserting its opinion that the '590 patent is invalid, unenforceable, or will not be infringed by the Actavis Atomoxetine Capsules.

v.

13. This action is being brought before the expiration of forty-five days from the date Lilly received the Actavis Notice Letter, which Lilly received no earlier than June 28, 2007.

COUNT I

Infringement of the '590 Patent

14. Lilly incorporates the preceding paragraphs as if fully set forth herein.

15. Actavis' submission of the Actavis ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Actavis Atomoxetine Capsules prior to the expiration of the '590 patent constitutes infringement of one or more of the valid claims of the '590 patent under 35 U.S.C. § 271(e)(2)(A).

16. Actavis' commercial manufacture, use, offer to sell, sale, or importation of the Actavis Atomoxetine Capsules prior to the expiration of the '590 patent, or its inducement of or contribution to such conduct, would further infringe the '590 patent under 35 U.S.C. §§ 271(a), (b) and/or (c). Actavis' filing of the Actavis ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Atomoxetine Capsules upon receiving FDA approval create an actual case or controversy with respect to infringement of the '590 patent.

17. Upon FDA approval of the Actavis ANDA, Actavis will infringe the '590 patent by making, using, offering to sell, selling, or importing the Actavis Atomoxetine Capsules in the United States, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

18. Lilly will be irreparably harmed if Actavis' infringement is not enjoined. Lilly does not have an adequate remedy at law.

v.

Prayer for Relief

WHEREFORE, LILLY prays that this Court grant the following relief:

A. A declaration that the '590 patent is valid and enforceable;

B. A declaration that a claim or claims of the '590 patent are infringed by the manufacture, use, sale, offer for sale or importation of the Actavis Atomoxetine Capsules, that Actavis' submission of the Actavis ANDA is an act of infringement of the '590 patent, that Actavis' making, using, offering to sell, selling, or importing the Actavis Atomoxetine Capsules, and its inducement of such conduct by others, will infringe the '590 patent;

C. An Order providing that the effective date of any approval of the Actavis ANDA shall be a date which is not earlier than six months after the expiration of the '590 patent;

D. An Order permanently enjoining Actavis and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, using, offering to sell, selling, or importing the Actavis Atomoxetine Capsules and from inducing such conduct by others, until after six months after the expiration of the '590 patent;

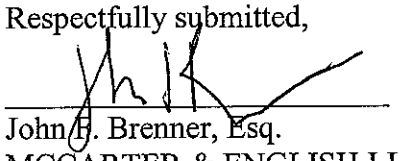
E. Damages or other monetary relief to Lilly if Actavis engages in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Atomoxetine Capsules, or in inducing such conduct by others, prior to six months after the expiration of the '590 patent, and that any such damages or monetary relief be trebled and awarded to Lilly with prejudgment interest;

F. Reasonable attorneys fees, filing fees, and reasonable costs of suit incurred by Lilly in this action; and

v.

G. Such further and other relief as this Court deems proper and just.

Respectfully submitted,



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Dated: August 9, 2007

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