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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

<p>SANDOZ, INC.</p> <p style="text-align: center;">Plaintiff</p> <p style="text-align: center;">v.</p> <p>ELI LILLY AND COMPANY,</p> <p style="text-align: center;">Defendant.</p>	<p>Civil Action No. _____</p>
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COMPLAINT FOR DECLARATORY JUDGMENT
OF INVALIDITY AND NONINFRINGEMENT

Plaintiff, Sandoz, Inc. ("Sandoz"), by way of its complaint against defendant, Eli Lilly and Company ("Lilly"), alleges as follows:

Nature Of The Action

1. This is an action seeking declaratory judgment that U.S. Patent No. 5,658,590 ("the '590 patent"), is invalid and not infringed. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) and 28 U.S.C. §§ 2201 and 2202. Venue is proper in this District under 28 U.S.C. § 1391. The action relates to an Abbreviated New Drug Application ("ANDA") filed by Sandoz with the United States Federal Drug Administration ("FDA") for approval to market generic versions of Lilly's Strattera® drug products.

The Parties

2. Sandoz is a corporation organized and existing under the laws of the State of Colorado, having a place of business at 506 Carnegie Center, Princeton, NJ 08540 in this District.

3. Lilly is an Indiana corporation having its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. On information

and belief, Lilly sells its products in this District, and is therefore doing business in this District.

Background

4. On August 19, 1997, the United States Patent and Trademark Office issued U.S. Patent No. 5,658,590 (the "'590 patent"), entitled "Treatment Of Attention-Deficit/Hyperactivity Disorder", a copy of which is attached hereto as Exhibit A. The '590 patent purports to claim methods of treating attention-deficit/hyperactivity disorder ("ADHD") with tomoxetine, a substance now known as atomoxetine.

5. Straterra® is a commercial formulation of atomoxetine hydrochloride made and sold by Lilly. Lilly submitted a new drug application ("NDA") to the FDA for Straterra capsules for the treatment of ADHD as NDA No. 21-411, approved by the FDA on or about November 26, 2002. Additional capsules of different strengths were later approved on or about February 14, 2005.

6. On or about June 27, 2007, Actavis Elizabeth LLC ("Actavis") notified Lilly that it 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) (hereafter "the Actavis ANDA"). The Actavis ANDA seeks approval to engage in the commercial

manufacture, use and sale of atomoxetine hydrochloride capsules at various strengths as a generic version of the FDA approved Straterra capsules, indicating that such generic atomoxetine hydrochloride would be sold before the expiration of the '590 patent. At the same time, Actavis advised Lilly that, in its opinion, the '590 patent is invalid, unenforceable, and/or will not be infringed by the Actavis atomoxetine hydrochloride capsules.

7. On August 1, 2007, Sandoz notified Lilly that Sandoz had submitted ANDA No. 79-018 seeking approval to engage in the commercial manufacture, use and sale of generic atomoxetine hydrochloride at various dosage levels before the expiration of the '590 patent. At the same time, Sandoz explained that, in its opinion, the '590 patent is invalid or will not be infringed by the Sandoz atomoxetine hydrochloride capsules.

8. On August 8, 2007, Lilly filed suit against Actavis in the United States District Court for the Southern District of Indiana, Indianapolis Division, Case No. 1:07-CV-1023-DFH-TAB. In that complaint, Lilly alleged that the Actavis ANDA constitutes infringement of the '590 patent under 35 U.S.C. § 271 (e)(2)(A). Lilly alleges also that Actavis' filing of the Actavis ANDA and its intention to engage in the commercial manufacture, use and sale of Actavis' atomoxetine hydrochloride capsules upon receipt of FDA approval creates an

actual case or controversy with respect to infringement of the '590 patent. On August 9, 2007 Lilly filed a corresponding suit in the United States District Court for the District of New Jersey, Case No. 2:07-CV-03770.

COUNT I

Declaratory Judgment Of Patent Invalidity and Noninfringement

9. Sandoz repeats and re-alleges herein the allegations of Paragraphs 1-7.

10. Lilly has acknowledged, in its complaint filed against Actavis, that the submission of the Actavis ANDA and its stated intention to engage in the commercial manufacture, use and sale of atomoxetine hydrochloride capsules creates an actual case or controversy with respect to infringement of the '590 patent.

11. Sandoz has submitted its own ANDA for approval to engage in the commercial manufacture, use or sale of atomoxetine hydrochloride capsules. Sandoz has notified Lilly of its intention to engage in the commercial manufacture, use and sale of atomoxetine hydrochloride capsules at various dosage levels before expiration of the '590 patent. In view of Lilly's filing suit against Actavis for its intention to make, use and sell atomoxetine hydrochloride capsules, Lilly has

created an actual case or controversy against Sandoz with respect to infringement of the '590 patent. Therefore, there exists a substantial controversy between Lilly as the owner of the '590 patent and Sandoz by reason of its submission of its ANDA with respect to the validity and infringement of the '590 patent of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

12. The '590 patent and its claims are invalid for failing to comply with the requirements of the patent laws of the United States, including 35 U.S.C. §§ 101, et seq.

13. Sandoz has not infringed, is not infringing and will not infringe, either directly or indirectly, any claim of the '590 patent.

WHEREFORE, Sandoz seeks entry of a judgment:

- (A) U.S. Patent No. 5,658,590 is invalid for failing to comply with the requirements of the patent laws;
- (B) U.S. Patent No. 5,658,590 has not been infringed either directly or indirectly by Sandoz;
- (C) Awarding Sandoz its costs and reasonable attorney fees; and

(D) Awarding Sandoz such other and further relief as justice may require.

SANDOZ, INC.

/s/Eric I. Abraham

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