



## **PARTY DEFENDANTS**

2. The Defendants, AstraZeneca Pharmaceuticals LP and AstraZeneca LP, are incorporated in Delaware with their principal place of business at U.S. Corporate Headquarters, AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, Wilmington, Delaware, 19897. Defendants transact business in Texas and nationwide by manufacturing, marketing, promoting, selling and distributing prescription drugs, including Seroquel.

## **VENUE**

3. Venue of this action lies in Dallas County on the basis of §17.47(b) of the DTPA because Defendants' acts and practices that violate these statutes occurred throughout Texas, including Dallas County, Texas.

## **PUBLIC INTEREST**

4. Because Plaintiff STATE OF TEXAS has reason to believe that Defendants have engaged in, and will continue to engage in, the unlawful practices set forth below, Plaintiff STATE OF TEXAS has reason to believe that Defendants have caused and will cause adverse effects to legitimate business enterprises which conduct their trade and commerce in a lawful manner in this State. Therefore, the Attorney General of the STATE OF TEXAS believes and is of the opinion that these proceedings are in the public interest.

## **ACTS OF AGENTS**

5. Whenever in this petition it is alleged Defendants did any act or thing, it is meant that Defendants performed or participated in such act or thing or that such act was performed by agents or employees of Defendants and in each instance, the agents or employees of Defendants were then authorized to and did in fact act on behalf of Defendants or otherwise acted under the guidance and direction of Defendants.

## **TRADE AND COMMERCE**

6. Defendants have, at all times described below, engaged in conduct which constitutes “trade” and “commerce” as those terms are defined by §17.45(6) of the DTPA.

## **NOTICE BEFORE SUIT**

7. Plaintiff informed Defendants herein at least seven (7) days before instituting this action of the alleged unlawful conduct of which complaint is now made.

## **BACKGROUND**

8. AstraZeneca manufactures, markets, and promotes Seroquel nationally and in Texas. Seroquel is a drug classified as an atypical antipsychotic.

9. While some experts hypothesized, as early as 1993, that atypical antipsychotics may reduce some of the side effects that traditional antipsychotics cause, there were early signs that these drugs, including Seroquel, produced dangerous side effects, including weight gain, hyperglycemia, diabetes, cardiovascular complications and other severe conditions.

10. Seroquel received approval from the U.S. Food and Drug Administration (hereinafter “FDA”), for the treatment of manifestations of psychotic disorders, including schizophrenia, on September 26, 1997.

11. FDA narrowed Seroquel’s label to “indicated for the treatment of schizophrenia” on March 27, 2001.

## **NATURE OF DEFENDANTS’ CONDUCT**

12. Texas permits physicians to prescribe FDA-approved drugs for conditions or diseases for which FDA approval has not been obtained when, through the exercise of independent professional judgment, the physician determines the drug in question is an appropriate treatment for an individual patient. This practice is referred to as “off-label prescribing.”

13. However, pharmaceutical manufacturers may not promote or market their products for any use not specifically approved by the FDA. This practice is known as “off-label marketing.”

14. Prior to late 2009, Seroquel was approved by the FDA only for the treatment of certain specific conditions in adults, primarily conditions related to Schizophrenia and Bipolar Mania.

15. Despite having narrow FDA approval for adults only, AstraZeneca promoted and marketed the drug for the treatment of a variety of conditions and to a variety of patient populations not included among the FDA-approved indications, including for anxiety, depression and post traumatic stress disorder, and to child and geriatric populations.

16. Through this off-label marketing, AstraZeneca aimed to enhance Seroquel’s market penetration across a wide range of diagnoses and patient populations.

17. AstraZeneca promoted Seroquel’s use in children and adolescents long before establishing that it was safe or effective for any use in this population.

18. AstraZeneca promoted Seroquel to treat dementia and Alzheimer’s disease in the elderly even though Seroquel has never been approved for the treatment of these conditions and AstraZeneca has not established that Seroquel is safe and effective for these uses.

19. AstraZeneca also masked, withheld, or failed to disclose negative information contained in scientific studies concerning the safety and efficacy of Seroquel.

20. AstraZeneca failed to adequately disclose the risks associated with Seroquel’s use by, among other things, minimizing the risk of hyperglycemia and diabetes mellitus and failing to communicate important information regarding neuroleptic malignant syndrome, tardive dyskinesia, and the risk of bolded cataracts.

## **VIOLATIONS OF TEXAS DECEPTIVE TRADE PRACTICES-CONSUMER PROTECTION ACT**

21. Defendants, as set forth above, in the course and conduct of trade and commerce, has directly and indirectly engaged in false, misleading, and deceptive acts and practices declared unlawful by §17.46 (a) and (b) of the Texas Deceptive Trade Practices-Consumer Protection Act, including but not limited to:

- A. Causing confusion or misunderstanding as to the approval of the drug Seroquel manufactured by Defendants, in violation of § 17.46(b)(2) of the DTPA;
- B. Representing that Defendants' drug Seroquel has benefits which it does not have, in violation of § 17.46(b)(5) of the DTPA;
- C. Representing that Defendants' drug Seroquel is of a particular standard, quality, or grade, if it is of another, in violation of § 17.46(b)(7) of the DTPA;
- D. Failing to disclose that Defendants' drug Seroquel had increased risks, when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed, in violation of § 17.46(b)(24) of the DTPA; and
- E. Failing to disclose negative information found in scientific studies about the safety and effectiveness of Defendants' drug Seroquel, when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed, in violation of § 17.46(b)(24) of the DTPA.

### **INJURY TO CONSUMERS**

22. By means of the foregoing unlawful acts and practices which were producing causes of injury to the persons affected, Defendants have acquired money or other property from identifiable persons to whom such money or property should be restored, or who in the alternative are entitled to an award of damages.

### **CONTINUING VIOLATIONS**

23. Defendants have violated and could continue to violate the laws as hereinabove alleged. Defendants, unless restrained by this Honorable Court, could continue violating the laws

of the State of Texas. Defendants have violated and could continue to violate the Deceptive Trade Practices-Consumer Protection Act.

### **PRAYER**

24. WHEREFORE, PREMISES CONSIDERED, the STATE OF TEXAS prays that Defendants be cited according to law to appear and answer herein and that upon final hearing a PERMANENT INJUNCTION be issued restraining and enjoining Defendants and its agents, servants, employees, representatives, subsidiaries, divisions, successors, and assigns from making the representations, doing the acts, and engaging in the practices set out in the preceding paragraphs as well as from making the following representations and doing the following acts and engaging in the following practices in the pursuit and conduct of trade or commerce within the State of Texas as follows:

- A. Causing confusion or misunderstanding as to the approval of the drug Seroquel manufactured by Defendants;
- B. Representing that Defendants' drug Seroquel has benefits which it does not have;
- C. Representing that Defendants' drug Seroquel is of a particular standard, quality, or grade, if it is of another;
- D. Failing to disclose that Defendants' drug Seroquel had increased risks, when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed; and
- E. Failing to disclose negative information found in scientific studies about the safety and effectiveness of Defendants' drug Seroquel, when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed.

25. The STATE OF TEXAS further prays, that upon final hearing, this Court order Defendants to pay civil penalties of not more than \$20,000.00 per violation, as provided in §17.47(c)(1) of the DTPA.

26. The STATE OF TEXAS further prays that the Office of the Attorney General be awarded their investigative costs, court costs, reasonable attorneys' fees, expenses, and witness fees pursuant to the laws of the State of Texas including the TEX. GOV'T CODE ANN. §402.006(c).

27. The STATE OF TEXAS further prays that upon final hearing that this Court grants all other relief to which the State may be justly entitled.

Respectfully submitted,

**Plaintiff State of Texas**

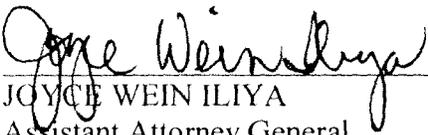
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