

2011 MAR 10 A 9 03

CLERK-SUPERIOR COURT  
SAN DIEGO COUNTY, CA

1 KAMALA D. HARRIS  
Attorney General of California  
2 DANIEL A. OLIVAS  
Supervising Deputy Attorney General  
3 ALBERT NORMAN SHELDEN  
State Bar No. 46277  
4 JUDITH FIORENTINI  
Deputy Attorneys General  
5 State Bar No. 201747  
110 West A Street, Suite 1100  
6 San Diego, CA 92101  
P.O. Box 85266  
7 San Diego, CA 92186-5266  
Telephone: (619) 645-2207  
8 Fax: (619) 645-2062  
E-mail: [judith.fiorentini@doj.ca.gov](mailto:judith.fiorentini@doj.ca.gov)  
9 *Attorneys for Plaintiff*

10 SUPERIOR COURT OF THE STATE OF CALIFORNIA  
11 FOR THE COUNTY OF SAN DIEGO.

12  
13  
14  
15 **THE PEOPLE OF THE STATE OF  
CALIFORNIA,**

16 Plaintiff,

17 v.

18 **ASTRAZENECA PHARMACEUTICALS  
19 LP; and ASTRAZENECA LP,**

20  
21 Defendants.

Case No. **37-2011-00087378-CU-MC-CTL**

**COMPLAINT FOR INJUNCTION, CIVIL  
PENALTIES AND OTHER EQUITABLE  
RELIEF**

ASSIGN TO MASTER CALENDAR

22  
23  
24 Plaintiff, the People of the State of California, ("Plaintiff" or the "People"), by its attorney,  
25 Kamala D. Harris, Attorney General of the State of California, by Judith Fiorentini and Albert  
26 Norman Shelden, Deputy Attorneys General, is informed and believes and thereupon alleges as  
27 follows:  
28

1 **JURISDICTION AND VENUE**

2 1. This action is by the People of the State of California, by Kamala D. Harris, Attorney  
3 General of the State of California, pursuant to the provisions of California Business and  
4 Professions Code Sections 17200, *et seq.* and 17500, *et seq.*

5 2. Defendants AstraZeneca Pharmaceutical LP, and AstraZeneca LP (“Defendants”), at  
6 all relevant times have transacted business in the City and County of San Diego and elsewhere in  
7 the State of California. The violations of law alleged herein have been and are being carried out  
8 within the City and County of San Diego and elsewhere in the State of California. This Court has  
9 jurisdiction over the Defendants and venue for this action properly lies in San Diego, California,  
10 because Defendant transacts business in San Diego, California.

11 **PARTIES**

12 3. Plaintiff is the People of the State of California (hereinafter “People”).

13 4. AstraZeneca Pharmaceuticals, LP, and AstraZeneca, LP (hereinafter “AstraZeneca”)  
14 are the Defendants in this case. AstraZeneca is incorporated in Delaware. AstraZeneca’s U.S.  
15 Corporate Headquarters and principal place of business is 1800 Concord Pike, Wilmington, DE  
16 19897. AstraZeneca transacts business in San Diego and elsewhere in California and nationwide  
17 by manufacturing, marketing, promoting, selling and distributing prescription drugs, including  
18 Seroquel.®

19 **BACKGROUND**

20 5. AstraZeneca manufactures, markets, and promotes Seroquel® nationally and in  
21 California. Seroquel® is a drug classified as an atypical antipsychotic.

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

26 //

27 //

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

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

6                                       **ASTRAZENECA’S MARKETING OF SEROQUEL®**

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

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

15           11.    Before late 2009, Seroquel® was approved by the FDA only for the treatment of  
16 certain specific conditions in adults, primarily conditions related to Schizophrenia and Bipolar  
17 Mania.

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

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

25           14.    AstraZeneca promoted Seroquel’s® use in children and adolescents long before  
26 establishing that it was safe or effective for any use by this population.  
27  
28



1 a. AstraZeneca has violated Business and Professions Code section 17500 as  
2 alleged in paragraph 19 of the above First Cause of Action which paragraph is incorporated as  
3 though fully set forth by reference.

4 b. AstraZeneca, in the course of marketing, promoting, selling, and distributing  
5 the prescription drug Seroquel® has engaged in a course of unfair competition which constitutes  
6 unlawful, unfair, or fraudulent business acts or practices and unfair, deceptive, untrue or  
7 misleading advertising, and is therefore in violation of Business and Professions Code section  
8 17200 by promoting Seroquel® for uses that have not been shown to be safe or effective and by  
9 failing to adequately disclose the risks associated with Seroquel's® use.

10 **PRAYER FOR RELIEF**

11 **WHEREFORE**, Plaintiff prays that:

12 1. An injunction be issued pursuant to Business and Professions Code sections 17203  
13 and 17535 restraining and enjoining Defendants and their agents, employees, and all other  
14 persons or entities, corporate or otherwise, in active concert or participation with any of them,  
15 from violating Business and Professions Code sections 17200 or 17500 in their promotional and  
16 marketing practices, sampling practices, and dissemination of information in connection with the  
17 marketing and sale of Seroquel®.

18 2. Pursuant to Business and Professions Code sections 17206 and 17536, Defendants be  
19 assessed a civil penalty of Two Thousand Five Hundred (\$2,500) for each violation of Business  
20 and Professions Code sections 17200 and 17500, as proved at trial.

21 3. The Court order Defendant to pay the Plaintiff's attorneys fees and costs.

22 4. That Plaintiff is given such other and further relief as the nature of this case may  
23 require and that this Court deems equitable and proper to fully and successfully dissipate the  
24 effects of the alleged violations of Business and Professions Code sections 17200 and 17500.

25 //

26 //

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

Dated: March 10, 2011

Respectfully Submitted,

KAMALA D. HARRIS  
Attorney General of California  
DANIEL A. OLIVAS  
Supervising Deputy Attorney General  
ALBERT NORMAN SHELDEN  
JUDITH FIORENTINI  
Deputy Attorneys General



JUDITH FIORENTINI  
Deputy Attorney General  
*Attorneys for Plaintiff*