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AstraZeneca Pharmaceuticals LP and  
AstraZeneca UK Limited

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

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ASTRAZENECA PHARMACEUTICALS LP and		)
ASTRAZENECA UK LIMITED,		)
		)
	Plaintiffs,	)
		)
	v.	)
		)
SANDOZ INC.		)
		)
		)
	Defendant.	)
		)
		)
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Civil Action No. \_\_\_\_\_

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited (collectively, “AstraZeneca”), for their complaint against Defendant Sandoz Inc. (“Sandoz”), hereby allege as follows:

**THE PARTIES**

1. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware, having its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

2. Plaintiff AstraZeneca UK Limited is a company incorporated under the laws of England and Wales, having a registered office at 15 Stanhope Gate, W1K 1LN, London, England.

3. Upon information and belief, Defendant Sandoz is a company incorporated under the laws of the State of Colorado, having its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

**JURISDICTION AND VENUE**

4. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

**CLAIM FOR RELIEF: THE ‘288 PATENT**

5. AstraZeneca realleges paragraphs 1-4 above, as if set forth specifically here.

6. Plaintiff AstraZeneca UK Limited is the holder of New Drug Application (“NDA”) No. 20-639 by which the United States Food and Drug Administration (“FDA”) first

granted approval for 25, 50, 100, 150, 200, 300 and 400 mg tablets containing the active ingredient quetiapine (11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl]dibenzo[b,f][1,4]thiazepine) fumarate. These tablets, described in NDA No. 20-639, are prescribed and sold in the United States under the trademark SEROQUEL<sup>®</sup>.

7. AstraZeneca Pharmaceuticals LP is the owner of United States Patent No. 4,879,288 (“the ‘288 patent,” copy attached as Exhibit A), entitled “Novel Dibenzothiazepine Antipsychotic”, which was duly and legally issued by the United States Patent and Trademark Office on November 7, 1989 upon assignment from the inventors Edward J. Warawa and Bernard M. Migler. The ‘288 patent claims, *inter alia*, quetiapine fumarate, the active ingredient of SEROQUEL<sup>®</sup>, and methods of using that compound.

8. The ‘288 patent received a Patent Term Extension under 35 U.S.C. § 156, thereby extending its term for a period of 1,651 days from March 20, 2007. At present, unless an additional extension is granted, the ‘288 patent will expire on September 26, 2011.

9. By a letter dated March 22, 2007, purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B)(ii) (the “First Notice Letter”), Sandoz notified AstraZeneca that it had submitted Abbreviated New Drug Application (“ANDA”) No. 78-679 to the FDA under 21 U.S.C. § 355(j), seeking the FDA’s approval to commercially manufacture, use and sell quetiapine fumarate tablets in 25 mg strength as a generic version of the SEROQUEL<sup>®</sup> 25 mg product, prior to the expiration of the ‘288 patent. The First Notice Letter was addressed to AstraZeneca Pharmaceuticals and LP and AstraZeneca PLC, but not AstraZeneca UK Limited, the holder of NDA No. 20-639. On April 6, 2007, AstraZeneca filed a complaint against Sandoz in this Court for patent infringement based on the ANDA filing described in the First Notice Letter. That suit, Civil Action No. 3:07-cv-01632 (JAP)(TJB) (“the earlier action”), was

assigned to the Honorable Joel A. Pisano and Magistrate Tonianne J. Bongiovanni and consolidated with Civil Action No. 3:05-cv-05333 (JAP)(TJB). On July 9, 2008, a Final Judgment was entered in these actions in favor of AstraZeneca. Sandoz appealed that Final Judgment to the United States Court of Appeals for the Federal Circuit. That appeal is Docket Nos. 08-1480, -1481.

10. By a second letter dated February 18, 2009, purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B) (“Second Notice Letter,” copy attached as Exhibit B), Sandoz notified AstraZeneca that it had submitted an ANDA seeking the approval of the FDA to commercially manufacture, use and sell prior to the expiration of the ‘288 patent, quetiapine fumarate tablets in 50, 100, 150, 200, 300 and 400 mg strengths as generic versions of the SEROQUEL<sup>®</sup> 50, 100, 150, 200, 300 and 400 mg products, prior to the expiration of the ‘288 patent.

11. In its Second Notice Letter, Sandoz notified AstraZeneca that, as part of its ANDA No. 78-679, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ‘288 patent.

12. In its Second Notice Letter, Sandoz alleged that the ‘288 patent is “unenforceable in view of inequitable conduct committed during the prosecution of the application that matured into the ‘288 patent.” However, Sandoz did not allege in its Second Notice Letter that the quetiapine fumarate tablets that are the subject of its ANDA No. 78-679 will not infringe the ‘288 patent or that the ‘288 patent is invalid.

13. Sandoz has infringed the ‘288 patent under 35 U.S.C. § 271(e)(2)(A) by filing its ANDA No.78-679, seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the ‘288 patent (or the use of which is claimed in

the '288 patent) prior to the expiration of the patent.

14. The quetiapine fumarate tablets for which Sandoz seeks approval in its ANDA No. 78-679 will infringe the '288 patent under 35 U.S.C. § 271(a).

15. The commercial manufacture, use, sale or offer for sale within the United States or the importation into the United States, of the quetiapine fumarate tablets for which Sandoz seeks approval in its ANDA No. 78-679 will infringe the '288 patent under 35 U.S.C. § 271.

16. AstraZeneca is entitled to full relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Sandoz's ANDA No. 78-679 be a date that is not earlier than the later of September 26, 2011, the expiration date of the '288 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled.

17. Sandoz was aware of the existence of the '288 patent and, upon information and belief, was aware that the filing of its ANDA and certification with respect to the '288 patent constituted an act of infringement of that patent.

18. Sandoz's statement, in its Second Notice Letter, of the factual and legal bases for its opinion regarding the enforceability of the '288 patent is devoid of an objective good faith basis in either the facts or the law.

19. In its Second Notice Letter, Sandoz stated as follows:

"The '288 patent is unenforceable in view of inequitable conduct committed during the prosecution of the application that matured into the '288 patent. Generally speaking, at the same time as it was mischaracterizing the prior art, the patent applicant was withholding information concerning the true state of the prior art, and thereby procured the '288 patent by inequitable conduct. Thus, the '288 patent is unenforceable and the Sandoz Product does not infringe any claim of the '288 patent. This is illustrated

by AstraZeneca's predecessor-in-interest's argument to the patent examiner that the prior art references did not disclose that any compound was an atypical antipsychotic. This was not accurate, because the patent on fluperlapine effectively described it as an atypical antipsychotic. According to a published article, the inventors knew that fluperlapine had been reported to be an atypical antipsychotic."

This statement directly contradicts arguments advanced by Sandoz and its co-Defendant-Appellant, Teva, in *AstraZeneca Pharmaceuticals LP v. Teva Pharmaceuticals USA, Inc. et al.*, Docket Nos. 08-1480, -1481.

20. This case is an exceptional one, and AstraZeneca is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request the following relief:

- (a) A judgment declaring that the effective date of any approval of Sandoz's ANDA No. 78-679 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the later of September 26, 2011, the date of expiration or date of the '288 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled;
- (b) A judgment declaring that the '288 patent remains valid, enforceable, and has been infringed by Sandoz;
- (c) A permanent injunction against any infringement of the '288 patent by Sandoz, its officers, agents, attorneys, and employees, and/or those acting in privity or concert with Sandoz;
- (d) A judgment that this is an exceptional case, and that Plaintiffs are entitled to an award of reasonable attorney fees pursuant to 35 U.S.C. § 285;

(e) To the extent that Sandoz has committed any acts with respect to the subject matter claimed in the '288 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which this Court should treble pursuant to 35 U.S.C. § 284;

(f) Costs and expenses in this action; and

(g) Such other relief as this Court may deem proper.

Respectfully submitted,

Dated: February 26, 2009

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