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AstraZeneca Pharmaceuticals LP and  
AstraZeneca UK Limited

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

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

**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 mg, 100 mg, 200 mg and 300 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®.

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®, 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 “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® 25 mg product, prior to the expiration of the ’288 patent.

10. In its 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.

11. In its Notice Letter, Sandoz alleged that claim 4 of the '288 patent will not be infringed by the Quetiapine Fumarate Tablets that are the subject of its ANDA No. 78-679, and that claims 6 and 8 of the '288 patent will not be infringed by the intended uses of that product. However, Sandoz did not allege in its Notice Letter that the Quetiapine Fumarate Tablets that are the subject of its ANDA No. 78-679 will not infringe claims 1-3, 5 or 7 of the '288 patent.

12. Sandoz alleged in its Notice Letter 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. Upon information and belief, 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.

15. Upon information and belief, the commercial manufacture, use, sale, offer for sale, or 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 the 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 September 26, 2011, the current expiration date of the '288 patent, or any other expiration of 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 Notice Letter, of the factual and legal bases for its opinion regarding the validity of the '288 patent is devoid of an objective good faith basis in either the facts or the law.

19. 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 expiration of the period of exclusivity provided by the '288 patent, and no earlier than September 26, 2011, the current expiration date of the '288 patent;

(b) A judgment declaring that the '288 patent remains valid, enforceable, and has been infringed by Sandoz;

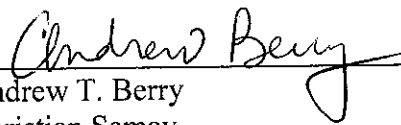
(c) A permanent injunction against any infringement of the '288 patent by Sandoz, its officers, agents, attorneys, and employees, and/or those acting in privity or concert with Sandoz;

(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.

Dated: April 6, 2007

  
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