John E. Flaherty
Jonathan M.H. Short
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07109
(973) 622-4444

Of Counsel
Henry J. Renk
Bruce C. Haas
Steven C. Kline
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
(212) 218-2100

Charles E. Lipsey
Mark J. Feldstein
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
Two Freedom Square
11955 Freedom Drive
Reston, Virginia 20190
(571) 203-2700

Attorneys For Plaintiffs
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, v. OSMOTICA PHARMACEUTICAL CORPORATION, Defendant.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited (collectively, "AstraZeneca"), for their complaint against Defendant Osmotica Pharmaceutical Corporation ("Osmotica"), hereby allege as follows:

THE PARTIES

1. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws 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 2 Kingdom Street, London, England W2 6BD.

3. Osmotica is a corporation organized and existing under the laws of North Carolina, having its principal place of business at 1205 Culbreth Drive, Suite 200, Wilmington, North Carolina 28405. Osmotica is in the business of, among other things, manufacturing, marketing and selling generic copies of branded pharmaceutical products throughout the United States including in this District.

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), 1391(d), and 1400(b).

5. This Court has personal jurisdiction over Osmotica because Osmotica has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being haled into court here. In addition, Osmotica has had continuous and systematic contacts with this judicial district, including, on information and belief, selling pharmaceutical products in New Jersey and deriving substantial revenues from those sales. In fact, Osmotica has consented to personal jurisdiction in this Court in a related

action involving the same patent and subject matter, Civil Action No. 10-cv-4203 (JAP) (TJB). Thus, Osmotica Pharmaceuticals is subject to general jurisdiction in New Jersey.

6. AstraZeneca has brought the following actions in the United States District Court for the District of New Jersey: *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Handa Pharms., LLC and John Doe Entity,* Civil Action Nos. 08-cv-3773 (JAP) (TJB), 08-cv-5328 (JAP) (TJB) and 08-cv-5997 (JAP) (TJB) ("the Handa actions"); *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Accord Healthcare, Inc. and Intas Pharms., Ltd,* Civil Action Nos. 08-cv-4804 (JAP) (TJB) and 09-cv-0619 (JAP) (TJB) ("the Accord actions"); *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Biovail Labs Int'l SRL, Biovail Corp. and BTA Pharms., Inc.,* Civil Action No. 09-cv-0128 (JAP) (TJB) ("the Biovail action"); *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Anchen Pharmaceuticals Inc.,* Civil Action No. 10-cv-1835 (JAP) (TJB) ("the Anchen action"); *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Osmotica Pharmaceutical Corp.,* Civil Action No. 10-cv-4203 (JAP) (TJB) ("the Osmotica action"); *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.*, Civil Action Nos. 10-cv-4205 (JAP) (TJB) and 10-cv-4971 (JAP) (TJB) ("the Torrent actions"); and *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Mylan Pharmaceuticals Inc. and Mylan Inc.*, Civil Action No. 10-cv-5519 (JAP) (TJB) ("the Mylan action") (collectively "the pending actions"). All of the pending actions involve a claim by AstraZeneca of infringement of the same AstraZeneca United States patent that is involved in the present action. All of the pending actions are still currently pending in this Court before the Honorable Joel A. Pisano and Magistrate Judge Tonianne J. Bongiovanni. All pretrial proceedings in the pending actions are being coordinated, and a consolidated trial is now

scheduled to begin on October 3, 2011. The present action should be coordinated and consolidated for trial with the pending actions.

CLAIMS FOR RELIEF

Count 1: Direct Infringement By Osmotica

7. AstraZeneca realleges paragraphs 1-6 above as if set forth specifically herein.

8. Plaintiff AstraZeneca Pharmaceuticals LP is the holder of New Drug Application ("NDA") No. 22-047, by which the FDA first granted approval for 50 mg, 150 mg, 200 mg, 300 mg and 400 mg extended release tablets containing the active ingredient quetiapine (11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl] dibenzo [b,f][1,4] thiazepine) fumarate. The quetiapine fumarate extended release tablets described in NDA No. 22-047 are sold by AstraZeneca in the United States under the trademark SEROQUEL XR®.

9. Plaintiff AstraZeneca Pharmaceuticals LP is the owner of the '288 patent, 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 XR®, and methods of using that compound.

10. The '288 patent will expire on September 26, 2011.

11. Plaintiff AstraZeneca UK Limited is the owner of the '437 patent, entitled "Pharmaceutical Compositions Using Thiazepine," which was duly and legally issued by the United States Patent and Trademark Office on September 7, 1999 upon assignment from the inventors Bhavnish V. Parikh, Robert J. Timko and William J. Addicks. The '437 patent claims,

inter alia, sustained release formulations of quetiapine fumarate, including SEROQUEL XR® extended release tablets, and processes for preparing and using such formulations.

12. The '437 patent will expire on May 28, 2017.

13. By letter dated July 30, 2010 purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B) (the "First Notice Letter"), Osmotica notified AstraZeneca that it had submitted ANDA No. 201424 to the FDA seeking the approval of the FDA to commercially manufacture, market, use and sell, prior to the expiration of the '437 patents, quetiapine fumarate extended release tablets in 200 mg, 300 mg and 400 mg strengths as generic versions of AstraZeneca's SEROQUEL XR® 200 mg, 300 mg and 400 mg extended release tablets. AstraZeneca has already filed suit on the First Notice Letter. It is Civil Action No. 3:10-cv-4203 (JAP) (TJB) and is assigned to the Honorable Joel A. Pisano and Magistrate Judge Tonianne J. Bongiovanni. AstraZeneca believes this action should be consolidated with that pending action.

14. By letter dated April 18, 2011 purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B) (the "Second Notice Letter"), Osmotica notified AstraZeneca that it had submitted ANDA No. 202587 to the FDA seeking the approval of the FDA to commercially manufacture, market, use and sell, prior to the expiration of the '437 patents, quetiapine fumarate extended release tablets in 50 mg and 150 mg strengths as generic versions of AstraZeneca's SEROQUEL XR® 50 mg and 150 mg extended release tablets.

15. In the Second Notice Letter, Osmotica alleged that certain claims of the '437 patent will not be infringed by its proposed generic quetiapine fumarate extended release tablets. Osmotica did not allege in the Second Notice Letter that its proposed generic quetiapine fumarate extended release tablets will not infringe claims 1-2 and 11-14 of the '437 patent.

16. Osmotica also alleged in the Second Notice Letter that claims 1-2 and 10-15 of the '437 patent are invalid for failure to meet the 35 U.S.C. § 103(a) obviousness requirement.

17. Osmotica has infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 202587 seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '437 patent, or the use of which is claimed in the '437 patent, prior to the expiration of that patent.

18. The quetiapine fumarate extended release tablets for which Osmotica seeks approval under ANDA No. 202587 will infringe one or more claims of the '437 patent under 35 U.S.C. §271(a).

19. The commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, of Osmotica's quetiapine fumarate extended release tablets will directly or indirectly infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a), (b) or (c).

20. 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 ANDA No. 202587 be a date that is not earlier than the later of May 28, 2017, the expiration date of the '437 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled.

Count 2: Exceptional Case

21. AstraZeneca realleges paragraphs 1-20 as if set forth specifically herein.

22. Prior to filing ANDA No. 202587, defendant was aware of the existence of the '437 patent, and, upon information and belief, was aware that the filing of ANDA No.

202587, including a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '437 patents, infringed that patent.

23. The opinions set forth in the Second Notice Letter that the '437 patent is invalid are devoid of an objective, good faith basis in either the facts or the law.

24. 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 '437 patent remains valid and enforceable, and that this patent has been infringed by Defendant;

(b) A judgment declaring that the effective date of any approval of ANDA No. 202587 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date that is not earlier than the later of May 28, 2017, the expiration date of the '437 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled;

(c) A permanent injunction against any infringement of the '437 patent by Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them;

(d) A judgment that this is an exceptional case, and that Plaintiffs are entitled to an award of its reasonable attorney fees pursuant to 35 U.S.C. § 285;

(e) To the extent that Defendants have committed any acts with respect to the subject matter claimed in the '437 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 29, 2011

Respectfully submitted,

By: /s/ John E. Flaherty

John E. Flaherty
Jonathan M.H. Short
MCCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 639-2097
(973) 624-7070 (Facsimile)

Of Counsel
Henry J. Renk
Bruce C. Haas
Steven C. Kline
FITZPATRICK, CELLA,
HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
(212) 218-2100
(212) 218-2200 (Facsimile)

Charles E. Lipsey
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FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER LLP
Two Freedom Square
11955 Freedom Drive
Reston, VA 20190
(571) 203-2700
(202) 408-4400 (Facsimile)

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AstraZeneca UK Limited

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matters in controversy are not the subject of any other action pending in any other court or of any pending arbitration or administrative proceeding, with the exception of the related lawsuits identified in Paragraph 6 of this Complaint involving different defendants but the same patents-in-suit.

Dated: April 29, 2011

Respectfully submitted,

By: /s/ John E. Flaherty

John E. Flaherty
Jonathan M.H. Short
MCCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 639-2097
(973) 624-7070 (Facsimile)

Of Counsel
Henry J. Renk
Bruce C. Haas
Steven C. Kline
FITZPATRICK, CELLA,
HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
(212) 218-2100
(212) 218-2200 (Facsimile)

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GARRETT & DUNNER LLP
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Reston, VA 20190
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AstraZeneca Pharmaceuticals LP and
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