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. MYLAN PHARMCEUTICALS INC. and MYLAN INC., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited (collectively, "AstraZeneca"), for their complaint against Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Defendants"), 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. On information and belief, Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") is a corporation organized under the laws of the State of West Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

4. On information and belief, Mylan Inc. is a corporation organized under the laws of the State of Pennsylvania, having an office and place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

5. On information and belief, Mylan Pharmaceuticals is a wholly owned subsidiary of Mylan Inc., and the acts of Mylan Pharmaceuticals complained of herein were and are aided and abetted by, and done with the cooperation, participation, and assistance of, Mylan Inc. On information and belief, Mylan Pharmaceuticals and Mylan Inc. have officers or directors in common.

6. Upon information and belief, Mylan Pharmaceuticals and Mylan Inc. are both in the business of, among other things, manufacturing, marketing and selling generic copies of branded pharmaceutical products throughout the United States.

JURISDICTION AND VENUE

7. 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).

8. Mylan Pharmaceuticals is registered to do business in the State of New Jersey. Its agent for service of process in New Jersey is Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey 08628. Mylan Pharmaceuticals has submitted to jurisdiction in this judicial district in numerous patent cases, and sells various products and does business throughout the United States, including in this judicial district. This Court has personal jurisdiction over Mylan Pharmaceuticals by virtue of, *inter alia*, the above-mentioned facts.

9. Mylan Inc. is registered to do business in the State of New Jersey. Its agent for service of process in New Jersey is Corporation Service Company, 860 Bear Tavern Road, West Trenton, NJ 08628. Mylan Inc. has submitted to jurisdiction in this judicial district in numerous patent cases, and sells various products and does business throughout the United States, including in this judicial district. This Court has personal jurisdiction over Mylan Inc. by virtue of, *inter alia*, the above-mentioned facts.

10. 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"); and *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") (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. The present action should be coordinated with the pending actions.

CLAIMS FOR RELIEF

Count 1: Infringement By Mylan Pharmaceuticals

11. AstraZeneca realleges paragraphs 1-10 above as if set forth specifically herein.

12. 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®.

13. Plaintiff AstraZeneca Pharmaceuticals LP is the owner of U.S. Patent No. 4,879,288 (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.

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

15. Plaintiff AstraZeneca UK Limited is the owner of U.S. Patent No. 5,948,437 (the "'437 patent", attached hereto as Exhibit A), 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.

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

17. By letter dated October 14, 2010 purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B) (the "Notice Letter"), Mylan Pharmaceuticals notified AstraZeneca that it had submitted ANDA No. 202228 to the FDA seeking the approval of the FDA to commercially manufacture, market, use and sell, prior to the expiration of the '437 patent, quetiapine fumarate extended release tablets in the 200 mg strength as generic versions of AstraZeneca's SEROQUEL XR® 200 mg extended release tablets.

18. In the Notice Letter, Mylan Pharmaceuticals alleged that claims 12 and 13 of the '437 patent will not be infringed by its proposed generic quetiapine fumarate extended

release tablets. Mylan Pharmaceuticals did not allege in the Notice Letter that its proposed generic quetiapine fumarate extended release tablets will not infringe claims 1-11, 14 and 15 of the '437 patent.

19. Mylan Pharmaceuticals also alleged in the Notice Letter that claims 1-15 of the '437 patent are invalid for obviousness under 35 U.S.C. §103(a).

20. Mylan Pharmaceuticals has infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 202228 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.

21. The quetiapine fumarate extended release tablets for which Mylan Pharmaceuticals seeks approval under ANDA No. 202228 will infringe one or more claims of the '437 patent under 35 U.S.C. §271(a).

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

23. 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. 202228 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: Infringement By Mylan Inc.

24. AstraZeneca realleges paragraphs 1-23 as if set forth specifically herein.

25. Upon information and belief, Mylan Inc. initiates, directs and controls the activities of Mylan Pharmaceuticals with regard to ANDA No. 202228 and the quetiapine fumarate extended release tablets described therein.

26. Upon information and belief, Mylan Inc., through Mylan Pharmaceuticals as its agent, initiated, directed and controlled the preparation and filing of ANDA No. 202228 with the FDA.

27. Upon information and belief, Mylan Inc. has infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by initiating, directing and controlling the preparation and filing of ANDA No. 202228.

28. Upon information and belief, in the event that the FDA approves ANDA No. 202228, Mylan Inc. stands to benefit directly from such approval by being able to commercially manufacture and distribute the quetiapine fumarate extended release tablets that are the subject of the ANDA.

29. The quetiapine fumarate extended release tablets for which Mylan Inc., through Mylan Pharmaceuticals as its agent, seeks approval under ANDA No. 202228 will infringe one or more claims of the '437 patent under 35 U.S.C. §271(a).

30. The commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, by Mylan Inc., through Mylan Pharmaceuticals as its agent, of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 202228 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

31. 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. 202228 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 3: Inducement of Infringement By Mylan Inc.

32. AstraZeneca realleges paragraphs 1-31 above as if set forth specifically herein.

33. Mylan Pharmaceuticals has directly infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 202228 seeking FDA approval under 21 U.S.C. § 355(j) 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 the patent.

34. Upon information and belief, Mylan Inc. knowingly and intentionally induced and/or aided and abetted Mylan Pharmaceuticals in the preparation and filing of ANDA No. 202228.

35. Upon information and belief, Mylan Inc. knowingly and intentionally induced and/or aided and abetted Mylan Pharmaceuticals in providing information and materials to the FDA in connection with ANDA No. 202228.

36. Upon information and belief, Mylan Inc. knowingly and intentionally induced and/or aided and abetted Mylan Pharmaceuticals in the development of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 202228, and that will infringe the '437 patent under 35 U.S.C. § 271(a).

37. Upon information and belief, Mylan Inc. has, under 35 U.S.C. § 271(b) induced Mylan Pharmaceuticals' direct infringement of the '437 patent by knowingly and intentionally inducing and/or aiding and abetting the preparation and filing of ANDA No. 202228.

Count 4: Exceptional Case

38. AstraZeneca realleges paragraphs 1-37 as if set forth specifically herein.

39. Prior to filing ANDA No. 202228, Defendants were aware of the existence of the '437 patent, and, upon information and belief, were aware that the filing of ANDA No. 202228, including a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '437 patent, infringed that patent.

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

41. 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 Defendants;

(b) A judgment declaring that the effective date of any approval of ANDA No. 202228 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: October 22, 2010

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

Attorneys for Plaintiffs
AstraZeneca Pharmaceuticals LP and
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 10 of this Complaint involving the same patent-in-suit.

Dated: October 22, 2010

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

Attorneys for Plaintiffs
AstraZeneca Pharmaceuticals LP and
AstraZeneca UK Limited