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
Michael P. McGraw
Robert J. Czarnecki, Jr.
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
(212) 218-2100

Charles E. Lipsey
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. LUPIN LTD. and LUPIN PHARMACEUTICALS, INC., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited (collectively, "AstraZeneca"), for their complaint against Defendants Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals, Inc. ("LPI") (collectively, "Lupin"), 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, Lupin Ltd. is a corporation organized and existing under the laws of India, having a place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India. Lupin Ltd. is in the business of, among other things, manufacturing and marketing generic copies of branded pharmaceutical products throughout the United States including in this District.

4. On information and belief, LPI is a corporation organized under the laws of the Commonwealth of Virginia, having a principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202, and is a wholly-owned subsidiary of Lupin Ltd. LPI is in the business of, among other things, manufacturing and marketing generic copies of branded pharmaceutical products throughout the United States including in this District.

5. On information and belief, Lupin Ltd. and LPI hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic pharmaceutical products.

JURISDICTION AND VENUE

6. 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), 1400(a) and 1400(b).

7. This Court has personal jurisdiction over Lupin Ltd. because Lupin Ltd. 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, on information and belief, Lupin Ltd. has had continuous and systematic contacts with this judicial district, including: (1) engaging in the business of filing with the United States Food and Drug Administration Abbreviated New Drug Applications to sell various products in the United States, including within this judicial district, (2) directly or indirectly, and in partnership and agency with its subsidiary LPI, conducting business within this judicial district, (3) directly or indirectly, and in partnership and agency with its subsidiary LPI, manufacturing, marketing, shipping, using, offering to sell, selling, distributing causing others to use, offer to sell or sell generic pharmaceutical products throughout the United States and in this judicial district, and (4) this judicial district is a likely destination of its generic products. Thus, Lupin Ltd. is subject to general jurisdiction in New Jersey.

8. This Court has personal jurisdiction over LPI because LPI 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, on information and belief, LPI has had continuous and systematic contacts with this judicial district, including: (1) directly or indirectly, and in partnership and agency with its parent corporation Lupin Ltd., conducting business within this judicial district, and (2) directly or indirectly, and in partnership and agency with its parent corporation Lupin Ltd., manufacturing, marketing, shipping, using, offering to sell, selling, distributing causing others to use, offer to sell or sell generic pharmaceutical

products throughout the United States and in this judicial district. Thus, LPI is subject to general jurisdiction in New Jersey.

9. AstraZeneca has brought the following related 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 Laboratories International SRL, Biovail Corporation and BTA Pharmaceuticals, Inc.*, Civil Action No. 09-cv-128 (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) and 11-cv-2484 (JAP) (TJB) ("the Osmotica actions"); *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) and 11-cv-2483 (JAP)(TJB) ("the Mylan actions") (collectively "the closed actions"). All of these closed actions involve a claim by AstraZeneca of infringement of AstraZeneca's United States Patent No. 5,948,437 ("the '437 patent"), the same patent that is involved in the present action. The Handa and Accord actions were settled on the eve of trial. The Anchen, Osmotica, Torrent and Mylan actions were tried before the Honorable Joel A. Pisano in October 2011. In a March 29, 2012

Opinion, Judge Pisano found all asserted claims of the ’437 patent valid and infringed. Appeals from the Osmotica, Torrent and Mylan decisions are presently pending before the United States Court of Appeals for the Federal Circuit.

10. AstraZeneca has also brought the following, related actions in the United States District Court for the Southern District of New York: *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. IntelliPharmaCeutics Corporation and IntelliPharmaCeutics International Inc.*, Civil Action Nos. 11-cv-4498 (RJS)(KNF) and 12-cv-2855 (RJS)(KNF). These actions also involved the same patent-in-suit. These actions were settled and dismissed.

11. AstraZeneca has brought the following related actions in the United States District Court for the District of New Jersey: *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Amneal Pharmaceuticals, LLC, Amneal Holdings, LLC, Amneal Pharmaceuticals Holding Company, LLC, Amneal Pharmaceuticals of New York, LLC, and Amneal Pharmaceuticals Co. India Private Limited,* Civil Action No. 12-cv-4841 (JAP) (TJB) (“the Amneal action”). This action also involves the same patent-in-suit. Amneal has answered AstraZeneca’s complaint and AstraZeneca has responded to Amneal’s counterclaims. A Scheduling Conference is presently set for December 13, 2012.

CLAIMS FOR RELIEF

Count 1: Direct Infringement By Lupin Ltd.

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

13. 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®.

14. 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. A copy of the '437 patent is attached an Exhibit A. 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.

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

16. By letter dated September 29, 2012 purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B) (the "Notice Letter"), Lupin Ltd. notified AstraZeneca that it had submitted ANDA No. 204203 to the U.S. Food and Drug Administration ("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 200 mg strengths as generic versions of AstraZeneca's SEROQUEL XR® 200 mg extended release tablets. AstraZeneca received this letter on October 1, 2012.

17. In the Notice Letter, Lupin Ltd. alleged that certain claims of the '437 patent will not be infringed by its proposed generic quetiapine fumarate extended release tablets. Lupin Ltd. did not allege in the Notice Letter that its proposed generic quetiapine fumarate extended release tablets will not infringe claims 1, 10 and 13-14 of the '437 patent.

18. Lupin Ltd. also alleged in the Notice Letter that certain claims of the ’437 patent are invalid for obviousness under 35 U.S.C. § 102. Lupin Ltd. did not allege in the Notice Letter that claims 3-9, 11, 12 and 15 of the ’437 patent are invalid.

19. Lupin Ltd. has infringed the ’437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 204203 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.

20. The quetiapine fumarate extended release tablets for which Lupin Ltd. seeks approval under ANDA No. 204203 will infringe one or more claims of the ’437 patent under 35 U.S.C. §271(a).

21. The commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, by Lupin Ltd. of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 204203 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 Lupin Ltd.’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).

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. 204203 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 LPI

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

25. On information and belief, Lupin Ltd. initiates, directs and controls the activities of its subsidiary company, LPI with regard to ANDA No. 204203 and the quetiapine fumarate extended release tablets described therein.

26. On information and belief, LPI, under the control of Lupin Ltd. was involved with the preparation and filing of ANDA No. 204203 with the FDA.

27. On information and belief, LPI has infringed the ’437 patent under 35 U.S.C. § 271(e)(2)(A) by its involvement with the preparation and filing of ANDA No. 204203.

28. On information and belief, in the event that the FDA approves ANDA No. 204203, LPI 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 products for which LPI, through Lupin Ltd. as its parent company, seeks approval under ANDA No. 204203 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 LPI of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 204203 will infringe one or more claims of the ‘437 patent under 35 U.S.C. § 271(a).

31. The commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, of LPI’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).

32. 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. 204203 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: Exceptional Case

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

34. Prior to filing ANDA No. 204203, Lupin was aware of the existence of the ’437 patent, and, upon information and belief, was aware that the filing of ANDA No. 204203, 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.

35. Prior to sending the Notice Letter, Lupin was aware of Judge Pisano’s decision in the related cases identified in paragraph 15. In fact, Lupin acknowledged the decision in the Notice Letter. That decision sets forth Judge Pisano’s opinion that the ’437 patent remains valid and is infringed by other generic drug manufactures that had been seeking approval to market and sell generic sustained-release quetiapine. That decision put Lupin on notice that their allegations of non-infringement and invalidity are devoid of an objective good faith basis in either the facts or the law and should not be maintained.

36. 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. 204203 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 their 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: November 5, 2012

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
Michael P. McGraw
Robert J. Czarnecki, Jr.
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
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 following related lawsuits, identified in Paragraphs 9 and 11 of this Complaint involving different defendants but the same patent-in-suit:

- *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Osmotica Pharmaceutical Corp.*, Civil Action No. 10-cv-4203 (JAP) (TJB) and 11-cv-2484 (JAP) (TJB), currently on appeal to the Federal Circuit;
- *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) , currently on appeal to the Federal Circuit;
- *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Mylan Pharmaceuticals Inc. and Mylan Inc.*, Civil Action No. 10-cv-5519 (JAP) (TJB) and 11-cv-2483 (JAP)(TJB), currently on appeal to the Federal Circuit; and
- *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Amneal Pharmaceuticals, LLC, Amneal Holdings, LLC, Amneal Pharmaceuticals Holding Company, LLC, Amneal Pharmaceuticals of New York, LLC, and Amneal Pharmaceuticals Co. India Private Limited,* Civil Action No. 12-cv-4841 (JAP) (TJB), pending.

Dated: November 5, 2012

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
Michael P. McGraw
Robert J. Czarnecki, Jr.
FITZPATRICK, CELLA,
HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
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Charles E. Lipsey
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER LLP
Two Freedom Square
11955 Freedom Drive
Reston, VA 20190
(571) 203-2700
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Attorneys for Plaintiffs
AstraZeneca Pharmaceuticals LP and
AstraZeneca UK Limited