Andrew T. Berry
John E. Flaherty
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Of Counsel
Henry J. Renk
Bruce C. Haas
Steven C. Kline
FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112
(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. ACCORD HEALTHCARE, INC., AND INTAS PHARMACEUTICAL LTD, Defendants.	**Civil Action No. _____**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited (collectively, "AstraZeneca"), for their complaint against Defendants Accord Healthcare, Inc., Accord Healthcare Ltd. ("Accord"), and Intas Pharmaceutical Ltd. ("Intas") (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 15 Stanhope Gate, W1K 1LN, London England.

3. Upon information and belief, Defendant Accord is a corporation organized under the laws of North Carolina, having a place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703 and a former place of business at 8601 Six Forks Road, Suite 400, Raleigh, North Carolina 27615.

4. Upon information and belief, Intas is company organized under the laws of India, having a place of business at Chinubhai Centre off Nehru Bridge Ashram Road, Ahmedabad 380009, Gujarat, India.

5. Upon information and belief, Accord is a wholly-owned subsidiary of Intas.

6. Upon information and belief, the acts of Accord, complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, assistance of Intas.

JURISDICTION AND VENUE

7. Upon information and belief, Defendants sell various products and do business throughout the United States, including this District.

8. Defendants manufacture bulk pharmaceuticals and pharmaceutical products that are sold in this District and throughout the United States.

9. 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).

10. In its answer to an earlier complaint filed in this Court by AstraZeneca against Accord and Intas involving the same ANDA (Civil Action No. 3:08-cv-04804 (JAP)(TJB)), Defendants, for purposes of that lawsuit, waived their objection to venue and personal jurisdiction in this District.

CLAIMS FOR RELIEF

Count 1: Direct Infringement By Accord

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 United States Food and Drug Administration ("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 United States Patent No. 4,879,288 (the "'288 patent," a copy of which is attached hereto 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 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 United States Patent No. 5,948,437 (the "'437 patent," a copy of which is attached hereto as Exhibit B), 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 September 5, 2008, purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B) ("First Notice Letter"), Accord notified AstraZeneca that it had submitted to the FDA ANDA No. 90-681 seeking the approval of the FDA to commercially manufacture, use and sell, prior to the expiration of the '288 and '437 patents, quetiapine fumarate extended release tablets in 200, 300, and 400 mg strengths as generic versions of AstraZeneca's SEROQUEL XR® 200, 300, and 400 mg extended release tablets. On October 28, 2008, AstraZeneca filed a complaint against Defendants in this Court for patent infringement based on the ANDA filing described in the First Notice Letter. That suit, Civil Action No. 3:08-cv-04804

(JAP)(TJB) ("the earlier action"), is assigned to the Honorable Joel A. Pisano and Magistrate Tonianne J. Bongiovanni. The present action should be consolidated with the earlier action.

18. By a letter dated January 23, 2009, purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B) ("Second Notice Letter"), Accord notified AstraZeneca that it had submitted an amendment to its ANDA seeking the approval of the FDA to commercially manufacture, use and sell prior to the expiration of the '288 and '437 patents, quetiapine fumarate extended release tablets in 150 mg strength..

19. In the Second Notice Letter, Accord notified AstraZeneca that, as part of ANDA No. 90-482, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '437 patent.

20. In the Second Notice Letter, Accord alleged that claims 3-9, 11 and 12 of the '437 patent will not be infringed by the quetiapine fumarate extended release tablets that are the subject of ANDA No. 90-681. Accord did not allege in the Notice Letter that the quetiapine fumarate extended release tablets that are the subject of ANDA No. 90-681 will not infringe any claim of the '288 patent and claims 1-2, 10, and 13-15 of the '437 patent.

21. Accord also alleged in the Second Notice Letter that claims 1, 2, 10 and 13-15 of the '437 patent are invalid.

22. Accord has infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-681 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.

23. The quetiapine fumarate extended release tablets for which Accord seeks approval under ANDA No. 90-681 will infringe one or more claims of the '437 patent under 35 U.S.C. §271(a).

24. The commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 90-681 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

25. 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. 90-482 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: Direct Infringement By Intas

26. AstraZeneca realleges paragraphs 1-25 as if set forth specifically herein.

27. Upon information and belief, Intas initiates, directs and controls the activities of Accord with regard to ANDA No. 90-681 and the quetiapine fumarate extended release tablets described therein.

28. Upon information and belief, Intas, through Accord as its agent, initiated, directed and controlled the preparation and filing of ANDA No. 90-681 with the FDA.

29. Upon information and belief, Intas 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. 90-681.

30. Upon information and belief, in the event that the FDA approves ANDA No. 90-681, Intas 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.

31. The quetiapine fumarate extended release tablets for which Intas, through Accord as its agent, seeks approval under ANDA No. 90-681 will infringe one or more claims of the ‘437 patent under 35 U.S.C. §271(a).

32. The commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, by Intas of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 90-681 will infringe one or more claims of the ‘437 patent under 35 U.S.C. § 271(a).

33. 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. 90-482 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 Intas

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

35. Accord has directly infringed the ‘437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-681 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.

36. Upon information and belief, Intas knowingly and intentionally induced and/or aided and abetted Accord in the preparation and filing of ANDA No. 90-681.

37. Upon information and belief, Intas knowingly and intentionally induced and/or aided and abetted Accord in providing information and materials to the FDA in connection with ANDA No. 90-681.

38. Upon information and belief, Intas knowingly and intentionally induced and/or aided and abetted Accord in the development of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 90-681, and that will infringe the '437 patent under 35 U.S.C. § 271(a).

39. Upon information and belief, Intas has, under 35 U.S.C. § 271(b) induced Accord's direct infringement of the '437 patent by knowingly and intentionally inducing and/or aiding and abetting the preparation and filing of ANDA No. 90-681.

Count 4: Exceptional Case

40. AstraZeneca realleges paragraphs 1-39 as if set forth specifically herein.

41. Prior to filing ANDA No. 90-681, Defendants were aware of the existence of the '437 patent, and, upon information and belief, were aware that the filing of ANDA No. 90-482, including a Paragraph IV certification with respect to the '437 patent, infringed that patent.

42. The opinions set forth in the Notice Letters that the '437 patent is invalid, and/or not infringed are devoid of an objective, good faith basis in either the facts or the law.

43. This 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 the '437 patent has been infringed by Defendants;

(b) A judgment declaring that the effective date of any approval of ANDA No. 90-482 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 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 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.

Respectfully submitted,

Dated: February 10, 2009

By: s/ Andrew T. Berry

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

Attorneys for Plaintiffs
AstraZeneca Pharmaceuticals LP and
AstraZeneca UK Limited

Of Counsel
Henry J. Renk
Bruce C. Haas
Steven C. Kline
FITZPATRICK, CELLA,
HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112
(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)