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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.)	Civil Action No. _____
)	
TORRENT PHARMACEUTICALS LIMITED)	
and TORRENT PHARMA INC.,)	
)	
Defendants.)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited

(collectively, "AstraZeneca"), for their complaint against Defendant Torrent Pharmaceuticals Limited ("Torrent Ltd.") and Torrent Pharma. Inc. ("Torrent 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. Upon information and belief, Torrent Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at International Operations Division, 4th Floor, Torrent Tower, Off Ashram Road, Ahmedabad, Gujarat 380009 India. Upon information and belief, Torrent Ltd. is in the business of, among other things, manufacturing, marketing and selling generic copies of branded pharmaceutical products throughout the United States.

4. Upon information and belief, Torrent Inc. is a corporation organized and existing under the laws of Michigan, having its principal place of business at 5380 Holiday Terrace, Suite 40, Kalamazoo, Michigan 49009. Upon information and belief, Torrent Inc. is in the business of, among other things, manufacturing, marketing and selling generic copies of branded pharmaceutical products throughout the United States.

JURISDICTION AND VENUE

5. 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).

6. This Court has personal jurisdiction over Torrent Ltd. because Torrent 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, Torrent Ltd. 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. Thus, Torrent Ltd. is subject to general jurisdiction in New Jersey.

7. This Court has personal jurisdiction over Torrent Inc. because Torrent Inc. 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, Torrent Inc. 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. Thus, Torrent Inc. is subject to general jurisdiction in New Jersey.

8. Upon information and belief, Torrent Inc. is a wholly-owned subsidiary of Torrent Ltd., and is in the business of marketing and selling generic drugs throughout the United States; Torrent Ltd. and Torrent Inc. operate as a single, integrated business; both companies share a website, www.torrentpharma.com; Torrent Inc. is identified on the Torrent Ltd. website as a contact for “general inquiries” regarding US operations; and the companies collaborate in the manufacture, marketing, and sale of pharmaceutical products, including generic drug products manufactured and sold throughout the United States pursuant to approved abbreviated new drug applications.

9. Upon information and belief, Torrent Ltd. and Torrent Inc. have sold millions of dollars of pharmaceutical products nationwide. Upon information and belief, Torrent Inc. markets and sells pharmaceutical products manufactured by Torrent Ltd. in New Jersey.

10. Nine related lawsuits are currently pending in this Court. On July 28, 2008, AstraZeneca filed suit in this Court against Handa Pharmaceuticals, LLC and John Doe Entity (“Handa”) seeking a judgment that its U.S. Patent Nos. 4,879,288 (the “’288 patent”) and 5,948,437 (the “’437 patent,” a copy of which is attached hereto as Exhibit A) are infringed by Handa’s filing of its ANDA No. 90-482. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Handa Pharms., LLC and John Doe Entity*, Case No. 08-3773 (D.N.J.). On September 26, 2008, AstraZeneca filed suit in this Court against Accord Healthcare, Inc., Accord Health Care, Inc., Accord Healthcare Ltd., and Intas Pharmaceuticals, Ltd. seeking a judgment that the ’437 patent is infringed by the filing of its ANDA No. 90-681. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Accord Healthcare, Inc. and Intas Pharms., Ltd*, Case No. 08-4804 (D.N.J.). On October 28, 2008, AstraZeneca filed another suit in this Court against Handa seeking a judgment that both the ’288 and ’437 patents are infringed by Handa’s amendments to its ANDA No. 90-482. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Handa Pharms., LLC and John Doe Entity*, Case No. 08-5328 (D.N.J.). On December 8, 2008, AstraZeneca filed another suit in this Court against Handa seeking a judgment that both the ’288 and ’437 patents are infringed by another Handa amendment to its ANDA No. 90-482. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Handa Pharms., LLC and John Doe Entity*, Case No. 08-5997 (D.N.J.). On January 9, 2009, AstraZeneca filed suit in this Court against Biovail Laboratories International SRL, Biovail Corporation and BTA Pharmaceuticals, Inc. (“Biovail”) seeking a judgment that the ’288 and ’437 patents are infringed by Biovail’s filing of its ANDA No. 90-882. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Biovail Labs Int’l SRL, Biovail Corp. and BTA Pharms., Inc.*, Case No. 09-0128 (D.N.J.). On February 10, 2009, AstraZeneca filed another suit in this Court against Accord Healthcare, Inc.,

and Intas Pharmaceutical Ltd seeking a judgment that the '437 patent is infringed by the amendment to its ANDA No. 90-681. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Accord Healthcare, Inc. and Intas Pharms., Ltd*, Case No. 09-0619 (D.N.J.). On April 8, 2010, AstraZeneca filed suit in this Court against Anchen Pharmaceuticals (“Anchen”) seeking a judgment that the '437 patent is infringed by Anchen’s filing of its ANDA No. 90-757. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Anchen Pharmaceuticals Inc.*, Case No. 10-1835 (D.N.J.). On August 16, 2010, AstraZeneca filed suit in this Court against Osmotica Pharmaceutical Corporation (“Osmotica”) seeking a judgment that the '437 patent is infringed by Osmotica’s filing of its ANDA No.201424. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Osmotica Pharmaceutical Corp.*, Case No. 10-4203 (D.N.J.). On August 16, 2010, AstraZeneca filed suit in this Court against Defendants seeking a judgment that the '437 patent is infringed by the filing of ANDA No. 201996. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.*, Case No. 10-4205 (D.N.J.). Each of these actions is assigned to the Honorable Joel A. Pisano and Magistrate Judge Tonianne J. Bongiovanni and these cases are coordinated for discovery and claim construction purposes. To the extent possible, AstraZeneca believes this action should be coordinated and should proceed concurrently with these pending actions.

CLAIMS FOR RELIEF

Count 1: Direct Infringement By Torrent Ltd.

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 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 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.

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

17. By letter dated July 17, 2010 purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B) ("First Notice Letter"), Torrent Ltd. notified AstraZeneca that it had submitted ANDA No. 201996 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 150, 200, 300 and 400 mg strengths as generic versions of

AstraZeneca's SEROQUEL XR[®] 150, 200, 300 and 400 mg extended release tablets. On August 16, 2010 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. 10-cv-4205 (JAP)(TJB)("the first action"), is assigned to the Honorable Joel A. Pisano and Magistrate Judge Tonianne J. Bongiovanni. The present action should be consolidated with the first action.

18. By letter dated September 15, 2010 purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B) ("Second Notice Letter"), Torrent Ltd. notified AstraZeneca that it had submitted ANDA No. 202000 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 strength as generic versions of AstraZeneca's SEROQUEL XR[®] 50 mg extended release tablets.

19. In the Second Notice Letter, Torrent Ltd. alleged that the claims of the '437 patent will not be infringed by its proposed generic quetiapine fumarate extended release tablets.

20. Torrent Ltd. also alleged in the Second Notice Letter that at least claim 1 of the '437 patent is invalid for failure to meet the written description requirement and/or the enablement requirement under 35 U.S.C. § 112.

21. Torrent Ltd. has infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 202000 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.

22. The quetiapine fumarate extended release tablets for which Torrent Ltd. seeks approval under ANDA No. 202000 will infringe one or more claims of the '437 patent under 35 U.S.C. §271(a).

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

24. 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. 202000 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 Torrent Inc.

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

26. Upon information and belief, Torrent Ltd. initiates, directs and controls the activities of Torrent Inc. with regard to ANDA No. 202000 and the quetiapine fumarate extended release tablets described therein.

27. Upon information and belief, Torrent Inc., through Torrent Ltd. as its agent, initiated, directed and controlled the preparation and filing of ANDA No. 202000 with the FDA.

28. Upon information and belief, Torrent 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. 202000.

29. Upon information and belief, in the event that the FDA approves ANDA No. 202000, Torrent 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.

30. The quetiapine fumarate extended release tablets for which Torrent Inc., through Torrent Ltd. as its agent, seeks approval under ANDA No. 202000 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, by Torrent Inc. of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 202000 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

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. 202000 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 Torrent Inc.

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

34. Torrent Ltd. has directly infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 202000 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.

35. Upon information and belief, Torrent Inc. knowingly and intentionally induced and/or aided and abetted Torrent Ltd. in the preparation and filing of ANDA No. 202000.

36. Upon information and belief, Torrent Inc. knowingly and intentionally induced and/or aided and abetted Torrent Ltd. in providing information and materials to the FDA in connection with ANDA No. 202000.

37. Upon information and belief, Torrent Inc. knowingly and intentionally induced and/or aided and abetted Torrent Ltd. in the development of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 202000, and that will infringe the '437 patent under 35 U.S.C. § 271(a).

38. Upon information and belief, Torrent Inc. has, under 35 U.S.C. § 271(b) induced Torrent Ltd. direct infringement of the '437 patent by knowingly and intentionally inducing and/or aiding and abetting the preparation and filing of ANDA No. 202000.

Count 4: Exceptional Case

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

40. Prior to filing ANDA No. 202000, defendants were aware of the existence of the '437 patent, and, upon information and belief, was aware that the filing of ANDA No. 202000, 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.

41. The opinions set forth in the Second Notice Letter 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.

42. 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. 202000 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: September 28, 2010

Respectfully submitted,

By: /s/ John E. Flaherty

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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 patents-in-suit.

Dated: September 28, 2010

Respectfully submitted,

By: /s/ John E. Flaherty

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