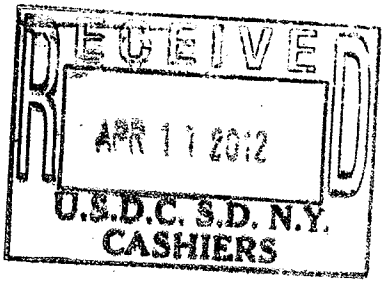
12 CV 2855

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK



ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA UK LIMITED,

Plaintiffs,

v.

INTELLIPHARMACEUTICS CORPORATION and INTELLIPHARMACEUTICS INTERNATIONAL INC.,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited (collectively, "AstraZeneca"), for their complaint against Defendants IntelliPharmaCeutics Corporation ("IPC") and IntelliPharmaCeutics International Inc. ("IPCI"), (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, IPC is a corporation organized and existing under the laws of Canada, having a place of business at 30 Worcester Road East, Toronto, Ontario, Canada, M9W 5X2. IPC 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, IPCI is a corporation organized and existing under the laws of Canada, having a place of business at 30 Worcester Road, Toronto, Canada, Ontario M9W 5X2. IPCI 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, IPC is a wholly-owned subsidiary of IPCI. IPC and IPCI both operate as a single, integrated business; both companies share a website, www.intellipharmaceutics.com; IPCI has released press statements regarding the status of IPC's ANDA No. 202-939; 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.

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), and 1400(b).

7. This Court has personal jurisdiction over IPCI because, on information and belief, IPCI regularly conducts business in this District, and counsel for IPCI has indicated in

submissions to the United States District Court for the District of New Jersey that IPCI will not contest personal jurisdiction in this Court.

8. This Court has personal jurisdiction over IPC because IPC regularly conducts business in this District, and has by letters dated May 18, 2011 and February 27, 2012 purporting to be notice pursuant to 21 U.S.C. § 355 (j)(2)(B) (the "First Notice Letter" and "Second Notice Letter", respectively, collectively, the "Notice Letters"), designated Davidson, Davidson & Kappel LLC 485 7th Avenue, New York, New York 10007 as its U.S Agent for service of process. Counsel for IPC has indicated in submissions to the United States District Court for the District of New Jersey that IPC will not contest personal jurisdiction in this Court.

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. Anchen Pharmaceuticals Inc.*, Civil Action No. 10-cv-1835 (JAP) (TJB) ("the Anchen actions"); *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"). 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 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.

10. AstraZeneca has also brought the following, related action in this Court: *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. IntelliPharmaCeutics Corporation and IntelliPharmaCeutics International Inc.*, Civil Action No. 11-cv-4498 (RJS)(KNF). This action involves the same patent-in-suit but involves different dosage units of IPC's proposed generic sustained release quetiapine products. There has not been any substantive discovery conducted in this case.

CLAIMS FOR RELIEF

Count 1: Infringement By IPC

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 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.

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

15. By the First Notice Letter, IPC notified AstraZeneca that IPC had submitted ANDA No. 202-939 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 patents, quetiapine fumarate extended release tablets in 150 mg, 200 mg, 300 mg and 400 mg strengths as generic versions of AstraZeneca's SEROQUEL XR® 150 mg, 200 mg, 300 mg and 400 mg extended release tablets.

16. By the Second Notice Letter IPC notified AstraZeneca that IPC had submitted ANDA No. 202-939 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 patents, quetiapine fumarate extended release tablets in 50 mg, 150 mg, 200 mg, 300 mg and 400 mg strengths as generic versions of AstraZeneca's SEROQUEL XR® 50 mg, 150 mg, 200 mg, 300 mg and 400 mg extended release tablets.

17. In the Notice Letters, IPC alleged that certain claims of the '437 patent will not be infringed by its proposed generic quetiapine fumarate extended release tablets. IPC did not allege in the Notice Letters that its proposed generic quetiapine fumarate extended release tablets will not infringe claims 1-2, 10 and 13-15 of the '437 patent.

18. IPC also alleged in the Notice Letters that the claims of the '437 patent are invalid for obviousness under 35 U.S.C. § 103(a) and for failure to meet the enablement requirement of 35 U.S.C. § 112, first paragraph.

19. IPC also alleged in the Notice Letters that the '437 patent is unenforceable in view of inequitable conduct during the prosecution of the application which issued as the '437 patent.

20. IPC has infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 202-939 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 IPC seeks approval under ANDA No. 202-939 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 IPC'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. 202-939 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 IPCI

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

25. On information and belief, IPCI initiates, directs and controls the activities of IPC with regard to ANDA No. 202-939 and the quetiapine fumarate extended release tablets described therein.

26. On information and belief, IPCI, through IPC as its agent, initiated, directed and controlled the preparation and filing of ANDA No. 202-939 with the FDA.

27. On information and belief, IPCI has infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by initiating, directing and controlling the preparation of ANDA No. 202-939.

28. On information and belief, in the event that the FDA approves ANDA No. 202-939, IPCI 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 IPCI, through IPC as its agent, seeks approval under ANDA No. 202-939 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 IPCI of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 202-939 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 IPCI'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. 202-939 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. 202-939, defendants were aware of the existence of the '437 patent, and, upon information and belief, were aware that the filing of ANDA No. 202-939, 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. The opinions set forth in the Notice Letters that the '437 patent is invalid and unenforceable are devoid of an objective, good faith basis in either the facts or the law.

36. Subsequent to filing ANDA 202-939, defendants become aware of the New Jersey District Court's decision in the related cases identified in paragraph 9. That decision sets forth the New Jersey Court'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 defendants on notice that their allegations of noninfringement and invalidity are devoid of an objective good faith basis and should not be maintained.

37. 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, AstraZeneca respectfully requests 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. 202-939 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 AstraZeneca is 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.

Respectfully submitted,

Dated: April 11, 2012

By: _____

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