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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA UK LIMITED, Plaintiffs, v. HANDA PHARMACEUTICALS, LLC and JOHN DOE ENTITY Defendants.	**Civil Action No. _____**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited (collectively, "AstraZeneca"), for their complaint against Defendants Handa Pharmaceuticals, LLC ("Handa") and John Doe Entity (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 Handa Pharmaceuticals, LLC ("Handa") is a corporation organized under the laws of California, having a place of business at 39465 Paseo Padre Parkway, Suite 2600, Fremont, California 94538 and a place of business at 30209 Aragon Place, Union City, California 94587.

4. Upon information and belief, Handa does not intend to manufacture or distribute the products identified in its Abbreviated New Drug Application ("ANDA") No. 90-482.

5. Upon information and belief, Handa intends to partner with one or more different entities (referred to herein as "John Doe Entity") to manufacture and distribute the products identified in its ANDA No. 90-482.

6. Upon information and belief, Defendant John Doe Entity is one or more corporations or other legal entities, the name and address of residence of which are presently unknown.

7. Upon information and belief, the acts of Handa complained of herein were done under the direction and control of, with the authorization of, with the cooperation, participation, assistance of, and for the benefit of, John Doe Entity.

JURISDICTION AND VENUE

8. Upon information and belief, Handa does business throughout the United States, including in this District.

9. Upon information and belief, John Doe Entity does business and/or develops, manufactures, sells and/or distributes pharmaceutical products throughout the United States, including in this District.

10. 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).

11. In its answer to an earlier complaint filed in this Court by AstraZeneca against Handa and John Doe entity involving the same ANDA (Civil Action No. 3:08-cv-03773 (JAP)(TJB)), Handa for purposes of that lawsuit, waived its objections to venue and personal jurisdiction in this District.

CLAIMS FOR RELIEF

Count 1: Direct Infringement By Handa

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 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.

14. 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.

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

16. 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.

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

18. By letters dated July 10, 2008 ("First Notice Letter"), July 23, 2008 ("Second Notice Letter") and October 16, 2008 ("Third Notice Letter") purporting to be Notices pursuant to 21 U.S.C. § 355 (j)(2)(B), Handa notified AstraZeneca that it had submitted to the FDA ANDA No. 90-482 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 50, 200, 300 and 400 mg strengths as generic versions of AstraZeneca's SEROQUEL® XR 50, 200, 300 and 400 mg extended release tablets. On July 28, 2008, AstraZeneca filed a complaint against Defendants in this Court for patent infringement based on the ANDA filing described in the First and Second Notice Letters. That suit, Civil Action Nos. 3:08-cv-03773 (JAP)(TJB)("the first action"), is assigned to the Honorable Joel A. Pisano and Magistrate Judge Tonianne J. Bongiovanni. On October 28, 2008, AstraZeneca filed another complaint against Defendants in this Court for patent infringement based on the ANDA filing described in the Third Notice Letter. That suit, Civil Action No. 3:08-cv-05328 (JAP)(JJH)("the second action"), is assigned to the Honorable Joel A. Pisano and Magistrate Judge John J. Hughes. The parties, in an effort to coordinate the first and second actions, have sent a letter to Chief Judge Garrett E. Brown requesting that the second action be reassigned to Magistrate Judge Bongiovanni. The present action should be consolidated with the first and second actions.

19. By a letter dated November 14, 2008, purporting to be a notice pursuant to 21 U.S.C. §355(j)(2)(B) (the "Fourth Notice Letter"), Handa 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. The First, Second, Third, and Fourth Notice Letters are referred to collectively as "the Notice Letters".

20. In the Fourth Notice Letter, Handa 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 '288 and '437 patents.

21. In the Fourth Notice Letter, Handa alleged that claims 4 and 8 of the '288 patent and claims 1-15 of the '437 patent will not be infringed by the quetiapine fumarate extended release tablets that are the subject of ANDA No. 90-482. Handa did not allege in the Notice Letters that the quetiapine fumarate extended release tablets that are the subject of ANDA No. 90-482 will not infringe claims 1-3 and 5-7 of the '288 patent.

22. Handa also alleged in the Fourth Notice Letter that the '288 patent is invalid and unenforceable, and that the '437 patent is invalid.

23. Handa has infringed the '288 patent and the '437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-482 seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '288 and '437 patents, or the use of which is claimed in the '288 and '437 patents, prior to the expiration of those patents.

24. The quetiapine fumarate extended release tablets for which Handa seeks approval under ANDA No. 90-482 will infringe one or more claims of the '288 patent under 35 U.S.C. § 271(a).

25. Upon information and belief, the quetiapine fumarate extended release tablets for which Handa seeks approval under ANDA No. 90-482 will infringe one or more claims of the '437 patent under 35 U.S.C. §271(a).

26. 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. 90-482 will infringe one or more claims of the '288 patent under 35 U.S.C. § 271(a).

27. Upon information and belief, 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. 90-482 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

28. 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 September 26, 2011, the expiration date of the '288 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled.

29. 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 John Doe Entity

30. AstraZeneca realleges paragraphs 1-29 as if set forth specifically herein.

31. Upon information and belief, John Doe Entity has developed, and will manufacture, supply and/or distribute, the quetiapine fumarate extended release tablets that are the subject of ANDA No. 90-482 and that will infringe the '288 and '437 patents under 35 U.S.C. § 271(a).

32. Upon information and belief, John Doe Entity has provided financial and/or technical support to Handa in its preparation and filing of ANDA 90-482 and has a present and/or future interest in ANDA 90-482 or in the proposed products identified in ANDA 90-482.

33. Upon information and belief, John Doe Entity initiates, directs and controls the activities of Handa with regard to ANDA No. 90-482 and the quetiapine fumarate extended release tablets described therein.

34. Upon information and belief, Handa has acted, and continues to act, as the agent of John Doe Entity with regard to ANDA No. 90-482 and the quetiapine fumarate extended release tablets described therein.

35. Upon information and belief, John Doe Entity, through Handa as its agent, initiated, directed and controlled the preparation and filing of ANDA No. 90-482 with the FDA.

36. Upon information and belief, John Doe Entity, through Handa as its agent, provides and continues to provide information and materials to the FDA in connection with ANDA No. 90-482.

37. Upon information and belief, John Doe Entity has infringed the '288 and '437 patents under 35 U.S.C. § 271(e)(2)(A) by initiating, directing and controlling the preparation and filing of ANDA No. 90-482.

38. Upon information and belief, in the event that the FDA approves ANDA No. 90-482, John Doe Entity 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.

39. The quetiapine fumarate extended release tablets for which John Doe Entity seeks approval under ANDA No. 90-482 will infringe one or more claims of the '288 patent under 35 U.S.C. § 271(a).

40. Upon information and belief, the quetiapine fumarate extended release tablets for which John Doe Entity seeks approval under ANDA No. 90-482 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

41. 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. 90-482 will infringe one or more claims of the '288 patent under 35 U.S.C. § 271(a).

42. Upon information and belief, the commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, by John Doe Entity of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 90-482 will infringe the '437 patent under 35 U.S.C. § 271(a).

43. 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 September 26, 2011, the expiration date of the '288 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled.

44. 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 John Doe Entity

45. AstraZeneca realleges paragraphs 1-44 as if set forth specifically herein.

46. Upon information and belief, John Doe Entity and Handa are engaged in a strategic partnership through which John Doe Entity has knowingly and intentionally collaborated with Handa in order to prepare and file ANDA No. 90-482, and to develop, manufacture and distribute the quetiapine fumarate extended release tablets described therein.

47. Handa has directly infringed the '288 patent and the '437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-482 seeking approval from the FDA to engage in

the commercial manufacture, use or sale of a drug claimed in the '288 and '437 patents, or the use of which is claimed in the '288 and '437 patents, prior to the expiration of those patents.

48. Upon information and belief, John Doe Entity knowingly and intentionally induced and/or aided and abetted Handa in the preparation and filing of ANDA No. 90-482.

49. Upon information and belief, John Doe Entity knowingly and intentionally induced and/or aided and abetted Handa in providing information and materials to the FDA in connection with ANDA No. 90-482.

50. Upon information and belief, John Doe Entity knowingly and intentionally induced and/or aided and abetted Handa in the development of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 90-482, and that will infringe the '288 and '437 patents under 35 U.S.C. § 271(a).

51. Upon information and belief, John Doe Entity has, under 35 U.S.C. § 271(b), induced Handa's direct infringement of the '288 and '437 patents by knowingly and intentionally inducing and/or aiding and abetting the preparation and filing of ANDA No. 90-482.

Count 4: Declaratory Judgment Of Future Infringement

52. AstraZeneca realleges paragraphs 1-51 as if set forth specifically herein.

53. The commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, by Defendants of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 90-482 will infringe one or more claims of the '288 patent under 35 U.S.C. § 271(a).

54. Upon information and belief, the commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, by Defendants

of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 90-482 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

55. AstraZeneca is entitled to a declaration of infringement against Defendants, and an order of this Court enjoining Defendants from engaging in 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. 90-482 prior to the expiration dates of the '288 and '437 patents.

Count 5: Exceptional Case

56. AstraZeneca realleges paragraphs 1-55 as if set forth specifically herein.

57. Prior to filing ANDA No. 90-482, Defendants were aware of the existence of the '288 and '437 patents, and, upon information and belief, were aware that the filing of ANDA No. 90-482, including a Paragraph IV certification with respect to the '288 and '437 patents, infringed those patents.

58. Prior to sending the Notice Letters, Defendants were aware that, in AstraZeneca Pharmaceuticals LP et al. v. Teva Pharmaceuticals USA, Inc., Civil Action Nos. 05-CV-5333, 06-CV-1528 and 07-CV-3001 ("Teva Actions") and in AstraZeneca Pharmaceuticals LP et al. v. Sandoz, Inc., Civil Action No. 07-CV-1632 ("Sandoz Action"), both Teva and Sandoz had (a) alleged that the '288 patent was invalid for obviousness under 35 U.S.C. §103 based on Schmutz et al. U.S. Patent No. 3,539,573 ("Schmutz") and Horrom U.S. Patent No. 4,097,597 ("Horrom"), the only patents on which Defendants base their Paragraph IV certification of invalidity, and (b) abandoned those obviousness defenses.

59. On information and belief, prior to sending the Notice Letters, Defendants were aware of the arguments of unenforceability of the '288 patent asserted by Teva and Sandoz in the Teva and Sandoz actions.

60. The opinions set forth in the Notice Letters that the '288 and '437 patents are invalid, unenforceable and/or not infringed are devoid of an objective, good faith basis in either the facts or the law.

61. 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 '288 and '437 patents remain valid and enforceable, and that these patents have 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 that is not earlier than the later of September 26, 2011, the expiration date of the '288 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled.

(c) 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;

(d) A permanent injunction against any infringement of the ‘288 and ‘437 patents by Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them;

(e) 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;

(f) To the extent that Defendants have committed any acts with respect to the subject matter claimed in the ‘288 patent or 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;

(g) Costs and expenses in this action; and

(h) Such other relief as this Court may deem proper.

Respectfully submitted,

Dated: December 8, 2008

By: s/ Andrew T. Berry

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