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AstraZeneca Pharmaceuticals LP and
AstraZeneca UK Limited

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA UK LIMITED, Plaintiffs, v. PHARMADAX USA, INC., PHARMADAX INC., and PHARMADAX (GUANGZHOU) INC. Defendants.	**Civil Action No._____**

COMPLAINT FOR PATENT INFRINGEMENT

For their complaint which arises at least in part under Title 35 U.S.C., Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited (collectively, "AstraZeneca"), hereby allege against Defendants Pharmadax USA,

Inc., Pharmadax Inc., and Pharmadax (Guangzhou) Inc. (collectively "Defendants"), 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, W2 6BD, Paddington, London, England.

3. Upon information and belief, Defendant Pharmadax USA, Inc. is a corporation organized under the laws of California, having its principal place of business at 15615 Alton Parkway, Suite 450, Pmb 421, Irvine, California 96218.

4. Upon information and belief, Defendant Pharmadax Inc. is a corporation organized under the laws of Taiwan, having its principal place of business at 2F, No. 186, Fuxing N. Rd., Zhongshan Dist., Taipei City 104, Taiwan (R.O.C.).

5. Upon information and belief, Defendant Pharmadax (Guangzhou) Inc., is a corporation organized under the laws of the People's Republic of China, having its principal place of business at Dachong industrial zone, Lishui Town, Nanhai District, Foshan City, 528244 China.

6. Upon information and belief, Pharmadax USA, Inc. and Pharmadax (Guangzhou) Inc. are wholly owned subsidiaries of Pharmadax Inc., and the acts of Pharmadax USA, Inc. and Pharmadax (Guangzhou) Inc. complained of herein were and are aided and abetted by, and done with the cooperation, participation, and assistance of, Pharmadax Inc. Upon information and belief, Pharmadax USA, Inc., Pharmadax (Guangzhou) Inc., and Pharmadax Inc. have officers or directors in common.

7. Upon information and belief, Pharmadax USA, Inc., Pharmadax (Guangzhou) Inc., and Pharmadax Inc. are in the business of, among other things,

manufacturing, marketing and selling generic copies of branded pharmaceutical products throughout the United States.

JURISDICTION AND VENUE

8. Upon information and belief, Pharmadax USA, Inc., Pharmadax (Guangzhou) Inc., and Pharmadax Inc. intend to do business and/or develop, manufacture, sell and/or distribute pharmaceutical products throughout the United States, including in this District.

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(b), 1391(c), 1391(d), and 1400(b). Pharmadax USA, Inc. is subject to personal jurisdiction within this judicial district based on information and belief that Pharmadax USA, Inc.'s principal place of business is within this judicial district and it has regular and systematic business contacts within this judicial district.

10. On October 22, 2014, AstraZeneca filed a complaint against Defendants for patent infringement in the United States District Court for the District of New Jersey ("the New Jersey Pharmadax action"). The New Jersey Pharmadax action is presently pending. That New Jersey complaint alleges the same acts of infringement by Defendants as the present complaint.

11. AstraZeneca previously filed actions for patent infringement against other parties in the District of New Jersey. Those actions, which involve the patent involved in both the New Jersey Pharmadax action and the present action, are AstraZeneca Pharmaceuticals LP et al. v. Anchen Pharmaceuticals, Inc., Civil Action No. 10-CV-1835, AstraZeneca Pharmaceuticals LP et al. v. Osmotica Pharmaceutical Corp., Civil Action Nos. 10-CV-4203 and 11-CV-2484, AstraZeneca Pharmaceuticals LP et al. v. Torrent Pharmaceuticals, Ltd., Civil Action Nos. 10-CV-4205, 10-CV-4971 and in AstraZeneca Pharmaceuticals LP et al. v. Mylan

Pharmaceuticals, Inc., Civil Action Nos. 10-CV-5519 and 11-CV-2483, ("the related Quetiapine actions").

12. Upon information and belief, Pharmadax USA, Inc., Pharmadax (Guangzhou) Inc., and Pharmadax Inc. are amenable to suit in the District of New Jersey; however, one or more of the Defendants may assert in the New Jersey Pharmadax action that they are not subject to personal jurisdiction in the District of New Jersey.

13. AstraZeneca is therefore filing the instant complaint, which has identical infringement claims against Pharmadax USA, Inc., Pharmadax (Guangzhou) Inc., and Pharmadax Inc. as the New Jersey Pharmadax action, as a so-called Hatch-Waxman "protective suit" to preserve its rights for a 30-month stay under 21 U.S.C. § 355(j)(5)(B)(iii). If Pharmadax USA, Inc., Pharmadax (Guangzhou) Inc., or Pharmadax Inc. challenges personal jurisdiction in the New Jersey Pharmadax action, AstraZeneca intends to move this Court to stay or transfer the instant action pending resolution of any jurisdictional challenge in the New Jersey Pharmadax action.

INTRADISTRICT ASSIGNMENT

14. Plaintiffs are filing this Complaint in the Southern Division because Pharmadax USA, Inc.'s principal place of business is located in the County of Orange.

CLAIM FOR RELIEF

Count 1: Direct Infringement by Pharmadax USA, Inc.

15. AstraZeneca realleges paragraphs 1-14 above as if set forth specifically herein.

16. 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 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.

17. 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 A), 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.

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

19. By a letter dated September 11, 2014 purporting to be a Notice pursuant to 21 U.S.C. § 355 (j)(2)(B) (the "Notice Letter"), Pharmadax notified AstraZeneca that it had submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 206260 seeking the approval of the FDA to commercially manufacture, use and sell, prior to the expiration of the '437 patent, 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.

20. In the Notice Letter, Pharmadax USA, Inc. notified AstraZeneca that, as part of ANDA No. 206260, 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.

21. In the Notice Letter, Pharmadax USA, Inc. alleged that 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. 206260.

22. Pharmadax USA, Inc. also alleged in the Notice Letter that the '437 patent is invalid and unenforceable.

23. Pharmadax USA, Inc. has infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 206260 seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '437 patent, the process of preparing the drug that is claimed in the '437 patent, or the use of which is claimed in the '437 patent, prior to the expiration of the patent.

24. Upon information and belief, the quetiapine fumarate extended release tablets for which Pharmadax USA, Inc. seeks approval under ANDA No. 206260 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

25. 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. 206260 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

26. 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. 206260 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 Pharmadax (Guangzhou) Inc.

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

28. Upon information and belief, Pharmadax (Guangzhou) Inc. has developed, and will manufacture, supply and/or distribute, the quetiapine fumarate extended release tablets that are the subject of ANDA No. 206260 and that will infringe the '437 patent under 35 U.S.C. § 271.

29. Upon information and belief, Pharmadax (Guangzhou) Inc. has provided technical support to Pharmadax USA, Inc. in its preparation and filing of ANDA 206260 and has a present and/or future interest in ANDA 206260 or in the proposed products identified in ANDA 206260.

30. Upon information and belief, Pharmadax (Guangzhou) Inc., through Pharmadax USA, Inc., provides and continues to provide information and materials to the FDA in connection with ANDA No. 206260.

31. Upon information and belief, Pharmadax (Guangzhou) 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. 206260.

32. Upon information and belief, in the event that the FDA approves ANDA No. 206260, Pharmadax (Guangzhou) 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.

33. Upon information and belief, the quetiapine fumarate extended release tablets for which Pharmadax (Guangzhou) Inc. through Pharmadax USA Inc. seeks approval under ANDA No. 206260 will infringe one or more claims of the ’437 patent under 35 U.S.C. § 271(a).

34. 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 Pharmadax (Guangzhou) Inc. of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 206260 will infringe the ’437 patent under 35 U.S.C. § 271(a).

35. 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. 206260 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: Direct Infringement by Pharmadax Inc.

36. AstraZeneca realleges paragraphs 1-35 as if set forth specifically herein.

37. Upon information and belief, Pharmadax Inc. has developed, and will manufacture, supply and/or distribute, the quetiapine fumarate extended release tablets that are the subject of ANDA No. 206260 and that will infringe the '437 patent under 35 U.S.C. § 271.

38. Upon information and belief, Pharmadax Inc. has provided financial and/or technical support to Pharmadax USA, Inc. and Pharmadax (Guangzhou) Inc. in their preparation and filing of ANDA 206260 and has a present and/or future interest in ANDA 206260 or in the proposed products identified in ANDA 206260.

39. Upon information and belief, Pharmadax Inc. initiates, directs and controls the activities of Pharmadax USA, Inc. and Pharmadax (Guangzhou) Inc. with regard to ANDA No. 206260 and the quetiapine fumarate extended release tablets described therein.

40. Upon information and belief, Pharmadax USA, Inc. has acted, and continues to act, as the agent of Pharmadax Inc. with regard to ANDA No. 206260 and the quetiapine fumarate extended release tablets described therein.

41. Upon information and belief, Pharmadax Inc., through Pharmadax USA, Inc. as its agent, initiated, directed and controlled the preparation and filing of ANDA No. 206260 with the FDA.

42. Upon information and belief, Pharmadax Inc., through Pharmadax USA, Inc. as its agent, provides and continues to provide information and materials to the FDA in connection with ANDA No. 206260.

43. Upon information and belief, Pharmadax 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. 206260.

44. Upon information and belief, in the event that the FDA approves ANDA No. 206260, Pharmadax 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.

45. Upon information and belief, the quetiapine fumarate extended release tablets for which Pharmadax Inc. seeks approval under ANDA No. 206260 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

46. 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 Pharmadax Inc. of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 206260 will infringe the '437 patent under 35 U.S.C. § 271(a).

47. 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. 206260 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 4: Inducement of Infringement by Pharmadax USA, Inc.

48. AstraZeneca realleges paragraphs 1-47 as if set forth specifically herein.

49. Pharmadax USA, Inc. has directly infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 206260 seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '437 patent, the process for preparing the drug that is claimed in the '437 patent, or the use of which is claimed in the '437 patent, prior to the expiration of the patent.

50. Upon information and belief, upon FDA approval of ANDA No. 206260, Pharmadax USA, Inc. will, under 35 U.S.C. § 271(b), induce direct

infringement of the ’437 patent by knowingly and intentionally inducing others to practice and perform the claims of the ’437 patent.

Count 5: Inducement of Infringement by Pharmadax (Guangzhou) Inc.

51. AstraZeneca realleges paragraphs 1-50 as if set forth specifically herein.

52. Upon information and belief, Pharmadax USA, Inc., Pharmadax (Guangzhou) Inc., and Pharmadax Inc. are engaged in a strategic partnership through which Pharmadax (Guangzhou) Inc. has knowingly and intentionally collaborated with Pharmadax USA, Inc., and Pharmadax Inc. in order to prepare and file ANDA No. 206260, and to develop, manufacture and distribute the quetiapine fumarate extended release tablets described therein.

53. Pharmadax USA, Inc. has directly infringed the ’437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 206260 seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the ’437 patent, the process for preparing the drug that is claimed in the ’437 patent, or the use of which is claimed in the ’437 patent, prior to the expiration of the patent.

54. Upon information and belief, Pharmadax (Guangzhou) Inc. knowingly and intentionally induced and/or aided and abetted Pharmadax USA, Inc. and Pharmadax Inc. in the preparation and filing of ANDA No. 206260.

55. Upon information and belief, Pharmadax (Guangzhou) Inc. knowingly and intentionally induced and/or aided and abetted Pharmadax USA, Inc. and Pharmadax Inc. in providing information and materials to the FDA in connection with ANDA No. 206260.

56. Upon information and belief, Pharmadax(Guangzhou) Inc. knowingly and intentionally induced and/or aided and abetted Pharmadax USA, Inc. and Pharmadax Inc. in the development of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 206260, and that will infringe the ’437 patent under 35 U.S.C. § 271(a).

57. Upon information and belief, Pharmadax(Guangzhou) Inc. has, under 35 U.S.C. § 271(b), induced Pharmadax USA, Inc.'s and Pharmadax Inc.'s direct infringement of the '437 patent by knowingly and intentionally inducing and/or aiding and abetting the preparation and filing of ANDA No. 206260.

Count 6: Inducement of Infringement by Pharmadax Inc.

58. AstraZeneca realleges paragraphs 1-57 as if set forth specifically herein.

59. Upon information and belief, Pharmadax Inc., Pharmadax (Guangzhou) Inc., and Pharmadax USA, Inc. are engaged in a strategic partnership through which Pharmadax Inc. has knowingly and intentionally collaborated with Pharmadax (Guangzhou) Inc. and Pharmadax USA, Inc. in order to prepare and file ANDA No. 206260, and to develop, manufacture and distribute the quetiapine fumarate extended release tablets described therein.

60. Pharmadax USA, Inc. has directly infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 206260 seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '437 patent, the process for preparing the drug that is claimed in the '437 patent, or the use of which is claimed in the '437 patent, prior to the expiration of those patents.

61. Upon information and belief, Pharmadax Inc. knowingly and intentionally induced and/or aided and abetted Pharmadax (Guangzhou) Inc. and Pharmadax USA, Inc. in the preparation and filing of ANDA No. 206260.

62. Upon information and belief, Pharmadax Inc. knowingly and intentionally induced and/or aided and abetted Pharmadax (Guangzhou) Inc. and Pharmadax USA, Inc. in providing information and materials to the FDA in connection with ANDA No. 206260.

63. Upon information and belief, Pharmadax Inc. knowingly and intentionally induced and/or aided and abetted Pharmadax (Guangzhou) Inc. and Pharmadax USA, Inc. in the development of the quetiapine fumarate extended release

tablets that are the subject of ANDA No. 206260, and that will infringe the ’437 patent under 35 U.S.C. § 271(a).

64. Upon information and belief, Pharmadax Inc. has, under 35 U.S.C. § 271(b), induced Pharmadax (Guangzhou) Inc.’s and Pharmadax USA, Inc.’s direct infringement of the ’437 patent by knowingly and intentionally inducing and/or aiding and abetting the preparation and filing of ANDA No. 206260.

Count 7: Declaratory Judgment of Future Infringement

65. AstraZeneca realleges paragraphs 1-64 as if set forth specifically herein.

66. 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. 206260 will infringe one or more claims of the ’437 patent under 35 U.S.C. § 271(a).

67. 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. 206260 prior to the expiration dates of the ’437 patent.

Count 8: Exceptional Case

68. AstraZeneca realleges paragraphs 1-67 as if set forth specifically herein.

69. Prior to filing ANDA No. 206260, Defendants were aware of the existence of the ’437 patent, and, upon information and belief, were aware that the filing of ANDA No. 206260, including a Paragraph IV certification with respect to the ’437 patent, infringed the patent.

70. Upon information and belief, prior to sending the Notice Letter, Defendants were aware that the ’437 patent was challenged in the related Quetiapine actions. The defendants in these actions failed in their allegations that the ’437 patent was invalid.

71. On information and belief, prior to sending the Notice Letter, Defendants were aware of the invalidity arguments of the ’437 patent asserted by the defendants in the related Quetiapine actions.

72. The opinions set forth in the Notice Letter, to the effect that the ’437 patent is invalid, unenforceable and/or not infringed, cause this case to stand out from others in that those opinions lack merit in either the facts or the law.

73. 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 the patent has been infringed by Defendants;

(b) A judgment declaring that the effective date of any approval of ANDA No. 206260 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: October 23, 2014

By: /s/ Michael K. O'Neill

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