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AstraZeneca UK Limited

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA UK LIMITED, Plaintiffs, v. MACLEODS PHARMACEUTICALS, LTD., MACLEODS PHARMA USA, INC. and AB PHARMACEUTICALS, LLC Defendants.	**Civil Action No. _____**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited (collectively, "AstraZeneca"), for their complaint against Defendants Macleods Pharmaceuticals, Ltd., Macleods Pharma USA, Inc. and AB Pharmaceuticals, LLC (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, W2 6BD, Paddington, London, England.

3. Upon information and belief, Defendant Macleods Pharmaceuticals, Ltd. is a company organized under the laws of India, having its principal place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, India 400059.

4. Upon information and belief, Defendant Macleods Pharma USA, Inc. is a corporation organized under the laws of Delaware, having its principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, NJ 08536.

5. Upon information and belief, Defendant AB Pharmaceuticals, LLC is a company organized under the laws of Missouri, having its principal place of business at 17471 Highland Way Drive, Chesterfield, MO 63005.

6. Upon information and belief, Macleods Pharma USA, Inc. is the U.S. Division of Macleods Pharmaceuticals, Ltd., and the acts of Macleods Pharma USA, Inc. complained of herein were and are aided and abetted by, and done with the cooperation, participation, and assistance of, Macleods Pharmaceuticals, Ltd. Upon information and belief, Macleods Pharma USA, Inc. and Macleods Pharmaceuticals, Ltd. have officers or directors in common.

7. Upon information and belief, AB Pharmaceuticals, LLC is an agent of Macleods Pharmaceuticals, Ltd., and the acts of AB Pharmaceuticals, LLC complained of herein were and are aided and abetted by, and done with the cooperation, participation, and assistance of, Macleods Pharmaceuticals, Ltd.

8. Upon information and belief, Macleods Pharmaceuticals, Ltd., Macleods Pharma USA, Inc. and AB Pharmaceuticals, LLC 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

9. Upon information and belief, Macleods Pharmaceuticals, Ltd., Macleods Pharma USA, Inc. and AB Pharmaceuticals, LLC intend to do business and/or develop, manufacture, sell and/or distribute pharmaceutical products throughout the United States, including in this District.

10. Upon information and belief, Macleods Pharma USA, Inc. is doing business in New Jersey, has continuous and systematic contacts with New Jersey, has engaged in activities related to the subject matter of this action and is subject to personal jurisdiction in this judicial district.

11. 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).

CLAIM FOR RELIEF

Count 1: Direct Infringement by Macleods Pharmaceuticals, Ltd.

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 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), titled "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.

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

16. By a letter dated February 9, 2015 purporting to be a Notice pursuant to 21 U.S.C. § 355 (j)(2)(B) (the "Notice Letter"), Macleods Pharmaceuticals, Ltd. notified AstraZeneca that it had submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 204253 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 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 Letter, Macleods Pharmaceuticals, Ltd. notified AstraZeneca that, as part of ANDA No. 204253, 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.

18. In the Notice Letter, Macleods Pharmaceuticals, Ltd. 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. 204253.

19. Macleods Pharmaceuticals, Ltd. has infringed the ’437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 204253 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.

20. Upon information and belief, the quetiapine fumarate extended release tablets for which Macleods Pharmaceuticals, Ltd. seeks approval under ANDA No. 204253 will infringe one or more claims of the ’437 patent under 35 U.S.C. § 271(a).

21. 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. 204253 will infringe one or more claims of the ’437 patent under 35 U.S.C. § 271(a).

22. 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. 204253 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 Macleods Pharma USA, Inc.

23. AstraZeneca realleges paragraphs 1-22 as if set forth specifically herein.

24. Upon information and belief, Macleods Pharma USA, Inc. has provided financial and/or technical support to Macleods Pharmaceuticals, Ltd. in its preparation and filing of ANDA 204253 and has a present and/or future interest in ANDA 204253 or in the proposed products identified in ANDA 204253.

25. Upon information and belief, Macleods Pharma USA, Inc., through Macleods Pharmaceuticals, Ltd., provides and continues to provide information and materials to the FDA in connection with ANDA No. 204253.

26. Upon information and belief, in the event that the FDA approves ANDA No. 204253, Macleods Pharma USA, 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.

27. Upon information and belief, the quetiapine fumarate extended release tablets for which Macleods Pharma USA, Inc. through Macleods Pharmaceuticals, Ltd., seeks approval under ANDA No. 204253 will infringe one or more claims of the ’437 patent under 35 U.S.C. § 271(a).

28. 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 Macleods Pharma USA, Inc. of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 204253 will infringe the ’437 patent under 35 U.S.C. § 271(a).

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. 204253 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 AB Pharmaceuticals, LLC

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

31. Upon information and belief, AB Pharmaceuticals, LLC has provided financial and/or technical support to Macleods Pharmaceuticals, LLC in its preparation and filing of ANDA 204253 and has a present and/or future interest in ANDA 204253 or in the proposed products identified in ANDA 204253.

32. Upon information and belief, AB Pharmaceuticals, LLC has acted, and continues to act, as the agent of Macleod Pharmaceuticals, Ltd. with regard to ANDA No. 204253 and the quetiapine fumarate extended release tablets described therein.

33. Upon information and belief, AB Pharmaceuticals, LLC provides and continues to provide information and materials to the FDA in connection with ANDA No. 204253.

34. Upon information and belief, AB Pharmaceuticals, LLC 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. 204253.

35. Upon information and belief, in the event that the FDA approves ANDA No. 204253, AB Pharmaceuticals, LLC 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.

36. Upon information and belief, the quetiapine fumarate extended release tablets for which AB Pharmaceuticals, LLC seeks approval under ANDA No. 204253 will infringe one or more claims of the ’437 patent under 35 U.S.C. § 271(a).

37. 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 AB Pharmaceuticals, LLC of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 204253 will infringe the ’437 patent under 35 U.S.C. § 271(a).

38. 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. 204253 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 Macleods Pharmaceuticals, Ltd.

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

40. Macleods Pharmaceuticals, Ltd. has directly infringed the ’437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 204253 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.

41. Upon information and belief, upon FDA approval of ANDA No. 204253, Macleods Pharmaceuticals, Ltd. 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 Macleods Pharma USA, Inc.

42. AstraZeneca realleges paragraphs 1-41 as if set forth specifically herein.

43. Upon information and belief, Macleods Pharmaceuticals, Ltd., Macleods Pharma USA, Inc. and AB Pharmaceuticals, LLC are engaged in a strategic partnership through which Macleods Pharma USA, Inc. has knowingly and intentionally collaborated with Macleods Pharmaceuticals, Ltd., and AB Pharmaceuticals, LLC in order to prepare and file ANDA No. 204253, and to develop, manufacture and distribute the quetiapine fumarate extended release tablets described therein.

44. Macleods Pharmaceuticals, Ltd. has directly infringed the ’437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 204253 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.

45. Upon information and belief, Macleods Pharma USA, Inc. knowingly and intentionally induced and/or aided and abetted Macleods Pharmaceuticals, Ltd. and AB Pharmaceuticals, LLC in the preparation and filing of ANDA No. 204253.

46. Upon information and belief, Macleods Pharma USA, Inc. knowingly and intentionally induced and/or aided and abetted Macleods Pharmaceuticals, Ltd. and AB Pharmaceuticals, LLC in providing information and materials to the FDA in connection with ANDA No. 204253.

47. Upon information and belief, Macleods Pharma USA, Inc. knowingly and intentionally induced and/or aided and abetted Macleods Pharmaceuticals, Ltd. and AB Pharmaceuticals, LLC in the development of the quetiapine fumarate extended release tablets

that are the subject of ANDA No. 204253, and that will infringe the '437 patent under 35 U.S.C. § 271(a).

48. Upon information and belief, Macleods Pharma USA, Inc. has, under 35 U.S.C. § 271(b), induced Macleods Pharmaceuticals, Ltd. and AB Pharmaceuticals, LLC's direct infringement of the '437 patent by knowingly and intentionally inducing and/or aiding and abetting the preparation and filing of ANDA No. 204253.

Count 6: Inducement of Infringement by AB Pharmaceuticals, LLC

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

50. Upon information and belief, Macleods Pharmaceuticals, Ltd., Macleods Pharma USA, Inc. and AB Pharmaceuticals, LLC are engaged in a strategic partnership through which AB Pharmaceuticals, LLC has knowingly and intentionally collaborated with Macleods Pharmaceuticals, Ltd. and Macleods Pharma USA, Inc. in order to prepare and file ANDA No. 204253, and to develop, manufacture and distribute the quetiapine fumarate extended release tablets described therein.

51. Macleods Pharmaceuticals, Ltd. has directly infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 204253 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.

52. Upon information and belief, AB Pharmaceuticals, LLC knowingly and intentionally induced and/or aided and abetted Macleods Pharmaceuticals, Ltd. and Macleods Pharma USA, Inc. in the preparation and filing of ANDA No. 204253.

53. Upon information and belief, AB Pharmaceuticals, LLC knowingly and intentionally induced and/or aided and abetted Macleods Pharmaceuticals, Ltd. and Macleods Pharma USA, Inc. in providing information and materials to the FDA in connection with ANDA No. 204253.

54. Upon information and belief, AB Pharmaceuticals, LLC knowingly and intentionally induced and/or aided and abetted Macleods Pharmaceuticals, Ltd. and Macleods Pharma USA, Inc. in the development of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 204253, and that will infringe the '437 patent under 35 U.S.C. § 271(a).

55. Upon information and belief, AB Pharmaceuticals, LLC has, under 35 U.S.C. § 271(b), induced Macleods Pharmaceuticals, Ltd. and Macleods Pharma 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. 204253.

Count 7: Declaratory Judgment of Future Infringement

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

57. 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. 204253 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

58. 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. 204253 prior to the expiration date of the '437 patent.

Count 8: Exceptional Case

59. AstraZeneca realleges paragraphs 1-59 as if set forth specifically herein.

60. Prior to filing ANDA No. 204253, Defendants were aware of the existence of the '437 patent and, upon information and belief, were aware that the filing of ANDA No. 204253, including a Paragraph IV certification with respect to the '437 patent, infringed the patent.

61. Upon information and belief, prior to sending the Notice Letter, Defendants were aware that the '437 patent was challenged in at least 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 quetiapine actions"). The defendants in these actions failed in their allegations that the '437 patent was invalid.

62. 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 quetiapine actions.

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

64. 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. 204253 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 27, 2015

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.

Dated: February 27, 2015

Respectfully submitted,

By: s/ John E. Flaherty

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