

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

OTSUKA PHARMACEUTICAL CO., LTD.,
AND H. LUNDBECK A/S

Plaintiffs,

v.

AJANTA PHARMA LTD.,

Defendant.

C.A. No. 1:19-cv-01939-LPS

**DEFENDANT AJANTA PHARMA LTD.'S
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant Ajanta Pharma Ltd. ("Ajanta" or "Defendant"), by and through its undersigned attorneys, responds to the Complaint for Patent Infringement filed by Plaintiffs Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S (collectively "Plaintiffs") as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Ajanta denies all allegations in Plaintiffs' Complaint, except those expressly admitted below.

NATURE OF THE ACTION

1. Ajanta admits that Plaintiffs brought this action for alleged patent infringement of U.S. Patent Nos. 7,888,362 ("the '362 patent"), 8,349,840 ("the '840 patent"), 8,618,109 ("the '109 patent"), 9,839,637 ("the '637 patent"), and 10,307,419 ("the '419 patent") (collectively, "patents in suit"), arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively. Ajanta

admits that it filed an Abbreviated New Drug Application (“ANDA”) with the Food and Drug Administration (“FDA”). Ajanta denies the remaining allegations in this paragraph.

THE PARTIES

2. On information and belief, Ajanta admits Plaintiff Otsuka’s (“Otsuka”) address. Ajanta is without sufficient information or knowledge to admit or deny the remaining allegations contained in paragraph 2 and, therefore, denies them on this basis.

3. On information and belief, Ajanta admits Plaintiff Lundbeck’s (“Lundbeck”) address. Ajanta is without sufficient information or knowledge to admit or deny the remaining allegations contained in paragraph 3 and, therefore, denies them on this basis.

4. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 4 and, therefore, denies them on this

5. Ajanta admits that it is a corporation organized and existing under the laws of India, with a principal place of business at 98, Ajanta House, Government Industrial Area, Charkop, Kandivali (West), Mumbai, Maharashtra, India, 400067.

JURISDICTION AND VENUE

6. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Ajanta does not contest that subject matter jurisdiction is proper.

7. This paragraph contains legal conclusions to which no answer is required. Ajanta admits it develops, manufactures, markets, and/or sells generic drugs for sale and use throughout the United States.

8. Ajanta states that <http://www.ajantapharma.com/generics.html> speaks for itself, and denies all remaining allegations contained in this paragraph.

9. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Ajanta does not contest that this Court has personal jurisdiction.

10. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Ajanta does not contest that this Court has personal jurisdiction.

11. Ajanta states that ANDA No. 213718 speaks for itself, and denies all remaining allegations in this paragraph.

12. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Ajanta does not contest that venue is proper.

FACTUAL BACKGROUND

The NDA

13. On information and belief, Ajanta admits that Otsuka is the holder of New Drug Application (“NDA”) No. 205422 for REXULTI® (brexpiprazole) Tablets in 0.25, 0.5, 1, 2, 3, and 4 mg dosage forms (“REXULTI® Tablets”).

14. Ajanta admits the FDA approved NDA No. 205422 on July 10, 2015.

15. On information and belief, Ajanta admits that REXULTI® Tablets are prescription drugs approved for the treatment of major depressive disorder and schizophrenia, and that brexpiprazole is the active ingredient in REXULTI® Tablets.

The Patents In Suit

16. Ajanta admits that on its face, the '362 patent has an issue date of February 15, 2011, and is entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." Ajanta admits that a copy of the '362 patent appears to be attached as Exhibit A to the Complaint. Ajanta denies that the '362 patent was duly and legally issued.

17. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 17 and, therefore, denies them on this basis.

18. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 18 and, therefore, denies them on this basis. Ajanta admits that a copy of the terminal disclaimer appears to be attached as Exhibit B to the Complaint.

19. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 19 and, therefore, denies them on this basis. Ajanta admits that a copy of the Submission Pursuant to 37 C.F.R. § 1.765 for Patent Term Extension Application under 35 U.S.C. § 156 and Response to Notice of Final Determination filed by Otsuka appears to be attached as Exhibit C to the Complaint.

20. On information and belief, Ajanta admits that the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") lists the '362 patent in connection with REXULTI® Tablets.

21. Ajanta admits that on its face, the '840 patent has an issue date of January 8, 2013, and is entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental

Disorders.” Ajanta admits that a copy of the ‘840 patent appears to be attached as Exhibit D to the Complaint. Ajanta denies that the ‘840 patent was duly and legally issued.

22. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 22 and, therefore, denies them on this basis.

23. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 23 and, therefore, denies them on this basis.

24. On information and belief, Ajanta admits that the Orange Book lists the ‘840 patent in connection with REXULTI® Tablets.

25. Ajanta admits that on its face, the ‘109 patent has an issue date of December 31, 2013, and is entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders.” Ajanta admits that a copy of the ‘109 patent appears to be attached as Exhibit E to the Complaint. Ajanta denies that the ‘109 patent was duly and legally issued.

26. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 26 and, therefore, denies them on this basis.

27. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 27 and, therefore, denies them on this basis.

28. On information and belief, Ajanta admits that the Orange Book lists the ‘109 patent in connection with REXULTI® Tablets.

29. Ajanta admits that on its face, the ‘637 patent has an issue date of December 12, 2017, and is entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental

Disorders.” Ajanta admits that a copy of the ‘637 patent appears to be attached as Exhibit F to the Complaint. Ajanta denies that the ‘637 patent was duly and legally issued.

30. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 30 and, therefore, denies them on this basis.

31. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 31 and, therefore, denies them on this basis.

32. On information and belief, Ajanta admits that the Orange Book lists the ‘637 patent in connection with REXULTI® Tablets.

33. Ajanta admits that on its face, the ‘419 patent has an issue date of June 4, 2019, and is entitled “Tablet Comprising 7-[4-(4-benzo[b]thiopen-4-yl-piperazine-1-yl)butoxy]-1H-quinolin-2-one or a Salt Thereof.” Ajanta admits that a copy of the ‘419 patent appears to be attached as Exhibit G to the Complaint. Ajanta denies that the ‘419 patent was duly and legally issued.

34. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 34 and, therefore, denies them on this basis.

35. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 35 and, therefore, denies them on this basis.

36. On information and belief, Ajanta admits that the Orange Book lists the ‘419 patent in connection with REXULTI® Tablets.

The ANDA

37. Ajanta admits that it filed ANDA No. 213718 (“Ajanta ANDA”) with the FDA, and that the Ajanta ANDA speaks for itself.

38. Ajanta states that the Ajanta ANDA speaks for itself.

39. Ajanta admits it sent a letter dated August 30, 2019 (the “Notice Letter”) notifying Plaintiffs that it had submitted the Ajanta ANDA to the FDA, and that this Notice Letter speaks for itself.

40. Ajanta admits that this Complaint was filed before the expiration of forty-five days from the date of the Notice Letter.

COUNT I

INFRINGEMENT OF THE '362 PATENT

41. Ajanta incorporates its responses to each preceding paragraph as if fully set forth herein.

42. Ajanta states that the Ajanta ANDA speaks for itself, and denies the allegations contained in paragraph 42 of the Complaint.

43. Ajanta admits that it filed a certification with the FDA that the claims of the '362 patent are invalid, unenforceable and/or not infringed.

44. Ajanta states that the Ajanta ANDA speaks for itself, and denies the allegations contained in paragraph 44 of the Complaint.

45. Ajanta states that the Notice Letter speaks for itself, and denies the allegations contained in paragraph 45 of the Complaint.

46. Ajanta denies the allegations and legal conclusions contained in paragraph 46 of the Complaint.

47. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 47 and, therefore, denies them on this basis.

48. Ajanta denies the allegations and legal conclusions contained in paragraph 48 of the Complaint.

49. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 49 and, therefore, denies them on this basis.

50. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 50 and, therefore, denies them on this basis.

51. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 51 and, therefore, denies them on this basis.

COUNT II

INFRINGEMENT OF THE '840 PATENT

52. Ajanta incorporates its responses to each preceding paragraph as if fully set forth herein.

53. Ajanta states that the Ajanta ANDA speaks for itself, and denies the allegations contained in paragraph 53 of the Complaint.

54. Ajanta admits that it filed a certification with the FDA that the claims of the '840 patent are invalid, unenforceable and/or not infringed.

55. Ajanta states that the Ajanta ANDA speaks for itself, and denies the allegations contained in paragraph 55 of the Complaint.

56. Ajanta states that the Notice Letter speaks for itself, and denies the allegations contained in paragraph 56 of the Complaint.

57. Ajanta denies the allegations and legal conclusions contained in paragraph 57 of the Complaint.

58. Ajanta denies the allegations and legal conclusions contained in paragraph 58 of the Complaint.

59. Ajanta denies the allegations and legal conclusions contained in paragraph 59 of the Complaint.

60. Ajanta denies the allegations and legal conclusions contained in paragraph 60 of the Complaint.

61. Ajanta denies the allegations and legal conclusions contained in paragraph 61 of the Complaint.

62. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 62 and, therefore, denies them on this basis.

63. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 63 and, therefore, denies them on this basis.

64. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 64 and, therefore, denies them on this basis.

65. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 65 and, therefore, denies them on this basis.

COUNT III

INFRINGEMENT OF THE '109 PATENT

66. Ajanta incorporates its responses to each preceding paragraph as if fully set forth herein.

67. Ajanta states that the Ajanta ANDA speaks for itself, and denies the allegations contained in paragraph 67 of the Complaint.

68. Ajanta admits that it filed a certification with the FDA that the claims of the '109 patent are invalid, unenforceable and/or not infringed.

69. Ajanta states that the Ajanta ANDA speaks for itself, and denies the allegations contained in paragraph 69 of the Complaint.

70. Ajanta states that the Notice Letter speaks for itself, and denies the allegations contained in paragraph 70 of the Complaint.

71. Ajanta denies the allegations and legal conclusions contained in paragraph 71 of the Complaint.

72. Ajanta denies the allegations and legal conclusions contained in paragraph 72 of the Complaint.

73. Ajanta denies the allegations and legal conclusions contained in paragraph 73 of the Complaint.

74. Ajanta denies the allegations and legal conclusions contained in paragraph 74 of the Complaint.

75. Ajanta denies the allegations and legal conclusions contained in paragraph 75 of the Complaint.

76. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 76 and, therefore, denies them on this basis.

77. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 77 and, therefore, denies them on this basis.

78. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 78 and, therefore, denies them on this basis.

79. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 79 and, therefore, denies them on this basis.

COUNT IV

INFRINGEMENT OF THE '637 PATENT

80. Ajanta incorporates its responses to each preceding paragraph as if fully set forth herein.

81. Ajanta states that the Ajanta ANDA speaks for itself, and denies the allegations contained in paragraph 81 of the Complaint.

82. Ajanta admits that it filed a certification with the FDA that the claims of the '637 patent are invalid, unenforceable and/or not infringed.

83. Ajanta states that the Ajanta ANDA speaks for itself, and denies the allegations contained in paragraph 83 of the Complaint.

84. Ajanta states that the Notice Letter speaks for itself, and denies the allegations contained in paragraph 84 of the Complaint.

85. Ajanta denies the allegations and legal conclusions contained in paragraph 85 of the Complaint.

86. Ajanta denies the allegations and legal conclusions contained in paragraph 86 of the Complaint.

87. Ajanta denies the allegations and legal conclusions contained in paragraph 87 of the Complaint.

88. Ajanta denies the allegations and legal conclusions contained in paragraph 88 of the Complaint.

89. Ajanta denies the allegations and legal conclusions contained in paragraph 89 of the Complaint.

90. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 90 and, therefore, denies them on this basis.

91. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 91 and, therefore, denies them on this basis.

92. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 92 and, therefore, denies them on this basis.

93. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 93 and, therefore, denies them on this basis.

COUNT V

INFRINGEMENT OF THE '419 PATENT

94. Ajanta incorporates its responses to each preceding paragraph as if fully set forth herein.

95. Ajanta states that the Ajanta ANDA speaks for itself, and denies the allegations contained in paragraph 95 of the Complaint.

96. Ajanta admits that it filed a certification with the FDA that the claims of the '419 patent are invalid, unenforceable and/or not infringed.

97. Ajanta states that the Ajanta ANDA speaks for itself, and denies the allegations contained in paragraph 97 of the Complaint.

98. Ajanta states that the Notice Letter speaks for itself, and denies the allegations contained in paragraph 98 of the Complaint.

99. Ajanta denies the allegations and legal conclusions contained in paragraph 99 of the Complaint.

100. Ajanta denies the allegations and legal conclusions contained in paragraph 100 of the Complaint.

101. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 101 and, therefore, denies them on this basis.

102. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 102 and, therefore, denies them on this basis.

103. Ajanta is without sufficient information or knowledge to admit or deny the allegations contained in paragraph 103 and, therefore, denies them on this basis.

[PLAINTIFFS'] PRAYER FOR RELIEF

Ajanta denies that Plaintiffs are entitled to any of the relief requested in its Prayer for Relief or to any relief whatsoever.

DEFENDANT'S AFFIRMATIVE DEFENSES

Ajanta asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. Ajanta does not assume the burden of proof on any such defenses, except as required by the applicable law with respect to the particular defense asserted. Ajanta reserves the

right to assert other defenses and/or to supplement or amend its Answer and Affirmative Defenses to the Complaint upon discovery of facts or evidence rendering such action appropriate.

**FIRST AFFIRMATIVE DEFENSE
(No direct infringement)**

Ajanta does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '362, '840, '109, '637, and '419 patents and if the products that are the subject of ANDA No. 213718 were marketed, Ajanta would not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '362, '840, '109, '637, and '419 patents.

**SECOND AFFIRMATIVE DEFENSE
(No indirect infringement)**

Ajanta has not induced or contributed to, and does not and will not induce or contribute to, the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable claims of the '362, '840, '109, '637, and '419 patents and if the products that are the subject of ANDA No. 213718 were marketed, Ajanta would not induce or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable claims of the '362, '840, '109, '637, and '419 patents.

**THIRD AFFIRMATIVE DEFENSE
(Invalidity)**

The claims of the '362, '840, '109, '637, and '419 patents are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions

of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**FOURTH AFFIRMATIVE DEFENSE
(Prosecution history estoppel)**

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent application leading to the '362, '840, '109, '637, and '419 patents, Plaintiffs are estopped from maintaining that any valid or enforceable claims of the '362, '840, '109, '637, and '419 patents are infringed by the product that is the subject of Ajanta's ANDA No. 213718.

**FIFTH AFFIRMATIVE DEFENSE
(Failure to state a claim)**

Plaintiffs have failed to state a claim upon which relief can be granted.

DEFENDANT'S COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Ajanta Pharma Ltd. ("Ajanta"), for its Counterclaims against Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S (collectively "Otsuka"), allege as follows:

1. Ajanta repeats and incorporates by reference each of the foregoing paragraphs of Ajanta's Answer and Affirmative Defenses to the Complaint.

THE PARTIES

2. Ajanta Pharma Ltd. is a corporation organized and existing under the laws of India, with a principal place of business at 98, Ajanta House, Government Industrial Area, Charkop, Kandivali (West), Mumbai, Maharashtra, India, 400067.

3. Upon information and belief, Otsuka Pharmaceutical Co., Ltd. (“Otsuka”) is a corporation organized and existing under the laws of Japan, with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

4. Upon information and belief, H. Lundbeck A/S (“Lundbeck”) is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark.

5. Upon information and belief, Lundbeck is the exclusive licensee of the ‘362, ‘840, ‘109, ‘637, and ‘419 patents.

6. Otsuka and Lundbeck are collectively referred to hereinafter as “Otsuka.”

JURISDICTION and VENUE

7. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 35 U.S.C. § 271(3)(5); 28 U.S.C. §§ 1331, 1337(a), 1338, 2201, 2202; and/or 21 U.S.C. § 355(j), based on an actual controversy between Ajanta and Otsuka arising under the Patent Laws of the United States, 35 U.S.C. § 100 et seq.

8. This Court has personal jurisdiction over Otsuka based, *inter alia*, on the filing by Otsuka of this lawsuit in this jurisdiction.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and 1400(b), and 21 U.S.C. § 355(j)(5)(c)(i)(II).

PATENTS AT ISSUE

U.S. Patent No. 7,888,362

10. This is a counterclaim for declaratory judgment of non-infringement, unenforceability, and/or invalidity of one or more claims of United States Patent No.

7,888,362 (“the ‘362 patent”) under 35 U.S.C. § 271(e)(5), 28 U.S.C. §§ 2201 and 2202, 12 U.S.C. § 355(j), and 21 U.S.C. § 355(J)(5)(c).

11. On information and belief, on February 15, 2011, the Patent and Trademark Office (“PTO”) issued the ‘362 patent entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders.” The ‘362 patent lists, on its face, Yamashita, Ito Hiroshi, Miyamura Nobuaki, Oshima Shin, Matsubara Kunio, Kuroda Jun, Takahashi Hideaki, Shimizu Haruka, Tanaka Satoshi, and Tatsuyoshi as inventors. On information and belief, Otsuka Pharmaceutical Co., Ltd. is the assignee of the ‘362 patent.

12. According to the Food and Drug Administration (“FDA”) publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (known as “the Orange Book”), the ‘362 patent will expire on April 12, 2026.

U.S. Patent No. 8,349,840

13. This is also a counterclaim for declaratory judgment of non-infringement, unenforceability, and/or invalidity of one or more claims of United States Patent No. 8,349,840 (“the ‘840 patent”) under 35 U.S.C. § 271(e)(5), 28 U.S.C. §§ 2201 and 2202, 12 U.S.C. § 355(j), and 21 U.S.C. § 355(J)(5)(c).

14. On information and belief, on January 8, 2013, the PTO issued the ‘840 patent entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders.” The ‘840 patent lists, on its face, Yamashita, Ito Hiroshi, Miyamura Nobuaki, Oshima Shin, Matsubara Kunio, Kuroda Jun, Takahashi Hideaki, Shimizu Haruka, Tanaka Satoshi, and Tatsuyoshi as inventors. On information and belief, Otsuka Pharmaceutical Co., Ltd. is the assignee of the ‘840 patent.

15. According to the FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (known as “the Orange Book”), the ‘840 patent will expire on April 12, 2026.

U.S. Patent No. 8,618,109

16. This is also a counterclaim for declaratory judgment of non-infringement, unenforceability, and/or invalidity of one or more claims of United States Patent No. 8,618,109 (“the ‘109 patent”) under 35 U.S.C. § 271(e)(5), 28 U.S.C. §§ 2201 and 2202, 12 U.S.C. § 355(j), and 21 U.S.C. § 355(J)(5)(c).

17. On information and belief, on December 31, 2013, the PTO issued the ‘109 patent entitled “Piperazine-substituted Benzothiophenes for Treatment of Mental Disorders.” The ‘109 patent lists, on its face, Yamashita, Ito Hiroshi, Miyamura Nobuaki, Oshima Shin, Matsubara Kunio, Kuroda Jun, Takahashi Hideaki, Shimizu Haruka, Tanaka Satoshi, and Tatsuyoshi as inventors. On information and belief, Otsuka Pharmaceutical Co., Ltd. is the assignee of the ‘109 patent.

18. According to the FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (known as “the Orange Book”), the ‘109 patent will expire on April 12, 2026.

U.S. Patent No. 9,839,637

19. This is also a counterclaim for declaratory judgment of non-infringement, unenforceability, and/or invalidity of one or more claims of United States Patent No. 9,839,637 (“the ‘637 patent”) under 35 U.S.C. § 271(e)(5), 28 U.S.C. §§ 2201 and 2202, 12 U.S.C. § 355(j), and 21 U.S.C. § 355(J)(5)(c).

20. On information and belief, on December 12, 2017, the PTO issued the '637 patent entitled "Piperazine-substituted Benzothiophenes for Treatment of Mental Disorders." The '637 patent lists, on its face, Yamashita, Ito Hiroshi, Miyamura Nobuaki, Oshima Shin, Matsubara Kunio, Kuroda Jun, Takahashi Hideaki, Shimizu Haruka, Tanaka Satoshi, and Tatsuyoshi as inventors. On information and belief, Otsuka Pharmaceutical Co., Ltd. is the assignee of the '637 patent.

21. According to the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as "the Orange Book"), the '637 patent will expire on April 12, 2026.

U.S. Patent No. 10,307,419

22. This is also a counterclaim for declaratory judgment of non-infringement, unenforceability, and/or invalidity of one or more claims of United States Patent No. 10,307,419 ("the '419 patent") under 35 U.S.C. § 271(e)(5), 28 U.S.C. §§ 2201 and 2202, 12 U.S.C. § 355(j), and 21 U.S.C. § 355(J)(5)(c).

23. On information and belief, on June 4, 2019, the PTO issued the '419 patent entitled "Tablet Comprising 7-[4-(4-benzo[b]thiopen-4-yl-piperazine-1-yl)butoxy]-1H-quinolin-2-one or a Salt Thereof." The '419 patent lists, on its face, Inoue and Yoshiharu as inventors. On information and belief, Otsuka Pharmaceutical Co., Ltd. is the assignee of the '419 patent.

24. According to the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as "the Orange Book"), the '419 patent will expire on October 12, 2032.

THE APPLICATIONS AT ISSUE

The NDA

25. On information and belief, Otsuka is the current holder of NDA No. 205422 for 0.25 mg, 0.5 mg, 1.0 mg, 2.0 mg, 3.0 mg, and 4.0 mg brexpiprazole tablets, which Otsuka markets and sells, directly or indirectly, under the trade name REXULTI® in the United States, including this judicial district.

26. On information and belief, the FDA approved NDA No. 205422 on July 10, 2015, which permitted Otsuka to market and sell its brexpiprazole tablets in this judicial district and throughout the United States.

27. The Federal Food, Drug, and Cosmetic Act (“the Act”) authorizes a pharmaceutical company to file an Abbreviated New Drug Application (“ANDA”), which the FDA will approve if the pharmaceutical company shows that its product has the same active ingredient as, and is bioequivalent to, a product that the FDA has already approved. Typically, the ANDA applicant submits data showing that its product is bioequivalent to a product that has been the subject of an approved NDA.

28. The Act requires NDA holders to submit to the FDA the patent number and expiration date of any patent(s) for which the NDA holder believes “a claim of patent infringement could reasonably be asserted if a person not licensed by the [NDA] owner engaged in the manufacture, use or sale of the drug.” 21 U.S.C. § 355(b)(1). The FDA — with no substantive review of the patents — lists the patent number(s) and expiration date(s) in the Orange Book.

29. If an ANDA applicant seeks approval to market its generic product before a patent listed in the Orange Book expires, the applicant must include in its ANDA a certification that its proposed product would not infringe that patent, and/or that the patent is invalid and/or unenforceable. The ANDA applicant must then send notice to the NDA holder and patent owner(s), which includes a detailed statement of the factual and legal bases of the ANDA applicant's opinion that the patent is invalid, unenforceable, and/or would not be infringed.

30. Upon information and belief, Otsuka, as the NDA holder for REXULTI® (NDA No. 205422), filed requests with the FDA pursuant to 21 U.S.C. § 355(b)(1) to list the '362 patent in the Orange Book for REXULTI®.

31. Upon information and belief, Otsuka, as the NDA holder for REXULTI® (NDA No. 205422), filed requests with the FDA pursuant to 21 U.S.C. § 355(b)(1) to list the '840 patent in the Orange Book for REXULTI®.

32. Upon information and belief, Otsuka, as the NDA holder for REXULTI® (NDA No. 205422), filed requests with the FDA pursuant to 21 U.S.C. § 355(b)(1) to list the '109 patent in the Orange Book for REXULTI®.

33. Upon information and belief, Otsuka, as the NDA holder for REXULTI® (NDA No. 205422), filed requests with the FDA pursuant to 21 U.S.C. § 355(b)(1) to list the '637 patent in the Orange Book for REXULTI®.

34. Upon information and belief, Otsuka, as the NDA holder for REXULTI® (NDA No. 205422), filed requests with the FDA pursuant to 21 U.S.C. § 355(b)(1) to list the '419 patent in the Orange Book for REXULTI®.

35. Otsuka's maintenance of the '362, '840, '109, '637 and '419 patents in the Orange Book means that it believes each of these patents "claims the drug for which the application was submitted [i.e., REXULTI®] and with respect to which a claim or patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." See 21 U.S.C. § 355(b)(1).

ANDA NO. 213718

36. Ajanta has filed an ANDA with the FDA seeking approval to market Brexpiprazole Tablets, 0.25 mg, 0.5 mg, 1.0 mg, 2.0 mg, 3.0 mg, and 4.0 mg ("ANDA Products"). As part of the application, Ajanta certified that its ANDA Products described in ANDA No. 213718 did not infringe the '362, '840, '109, '637 and '419 patents, and/or that the '362, '840, '109, '637 and '419 patents is/are invalid and/or unenforceable.

37. Ajanta provided notice of its certification with respect to the '362, '840, '109, '637 and '419 patents to Otsuka, received by Otsuka on or about August 30, 2019. The notice provided the factual and legal bases as to why, in Ajanta's opinion, the '362, '840, '109, '637 and '419 patents were invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the ANDA Products before the expiration of the '362, '840, '109, '637 and '419 patents. Ajanta also enclosed an Offer of Confidential Access to Ajanta's ANDA in accordance with 21 U.S.C. § 505(j)(5)(C)(i)(III).

38. On October 11, 2019, Otsuka sued Ajanta alleging infringement of the '362, '840, '109, '637 and '419 patents in the above-captioned action in the District of Delaware.

39. Otsuka's conduct impairs Ajanta's ability to market Ajanta's ANDA Products. Ajanta thus seeks a declaratory judgment that its ANDA Products do not

infringe the '362, '840, '109, '637 and '419 patents and/or that these patents are invalid and/or unenforceable.

THE PRESENCE OF A CASE OF ACTUAL CONTROVERSY

40. By maintaining the Orange Book listing of the '362, '840, '109, '637 and '419 patents in connection with REXULTI®, Otsuka continues to represent that the '362, '840, '109, '637 and '419 patents could reasonably be asserted against anyone making, using, or selling a generic brexpiprazole product without a license from Otsuka.

41. Ajanta's Paragraph IV certification states that the '362, '840, '109, '637 and '419 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, and/or offer for sale of the ANDA Products.

42. Otsuka's Complaint gives rise to an actual controversy with respect to the '362, '840, '109, '637 and '419 patents with respect to ANDA No. 213718.

43. Ajanta has made, and will continue to make, substantial preparations in connection with its request for FDA approval of its ANDA Products.

44. To avoid legal uncertainty and to protect Ajanta's substantial investment (and anticipated future investment) in Ajanta's ANDA Products, Ajanta seeks declaratory relief with respect to the '362, '840, '109, '637 and '419 patents.

45. Ajanta has not stipulated to or otherwise consented to the validity, infringement, or enforceability of the '362, '840, '109, '637 and '419 patents.

46. Upon FDA approval of Ajanta's ANDA, Ajanta will be able to market and sell its ANDA Products in the United States.

47. A judgment declaring that the '362, '840, '109, '637 and '419 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, and/or offer for sale of Ajanta's ANDA Products will remove any independent barriers to competition that may exist by virtue of Otsuka's maintenance of the listing of the '362, '840, '109, '637 and '419 patents in the Orange Book in connection with NDA No. 205422.

48. The totality of circumstances support that a case or controversy exists with respect to the infringement, invalidity, and/or unenforceability of the '362, '840, '109, '637 and '419 patents.

FIRST COUNT

(Declaratory Judgment of Non-Infringement of the '362 Patent)

49. Ajanta repeats and incorporates by reference each of the foregoing paragraphs of Ajanta's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

50. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Otsuka and Ajanta concerning the infringement of the '362 patent.

51. Ajanta's manufacture, use, offer for sale, sale, and/or importation into the United States of Ajanta's ANDA Products pursuant to ANDA No. 213718 does not infringe any valid and enforceable claim of the '362 patent.

52. Thus, Ajanta is entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation into the United States of Ajanta's ANDA Products do not infringe any valid and enforceable claim of the '362 patent.

SECOND COUNT

(Declaratory Judgment of Invalidity of the '362 Patent)

53. Ajanta repeats and incorporates by reference each of the foregoing paragraphs of Ajanta's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

54. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Otsuka and Ajanta concerning the invalidity of claims of the '362 patent.

55. The claims of the '362 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 et seq., including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation.

56. Thus, Ajanta is entitled to a declaration that the claims of the '362 patent are invalid.

THIRD COUNT

(Declaratory Judgment of Non-Infringement of the '840 Patent)

57. Ajanta repeats and incorporates by reference each of the foregoing paragraphs of Ajanta's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

58. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Otsuka and Ajanta concerning the infringement of the '840 patent.

59. Ajanta's manufacture, use, offer for sale, sale, and/or importation into the United States of Ajanta's ANDA Products pursuant to ANDA No. 213718 does not infringe any valid and enforceable claim of the '840 patent.

60. Thus, Ajanta is entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation into the United States of Ajanta's ANDA Products do not infringe any valid and enforceable claim of the '840 patent.

FOURTH COUNT

(Declaratory Judgment of Invalidity of the '840 Patent)

61. Ajanta repeats and incorporates by reference each of the foregoing paragraphs of Ajanta's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

62. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of

sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Otsuka and Ajanta concerning the invalidity of claims of the '840 patent.

63. The claims of the '840 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 et seq., including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation.

64. Thus, Ajanta is entitled to a declaration that the claims of the '840 patent are invalid.

FIFTH COUNT

(Declaratory Judgment of Non-Infringement of the '109 Patent)

65. Ajanta repeats and incorporates by reference each of the foregoing paragraphs of Ajanta's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

66. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Otsuka and Ajanta concerning the infringement of the '109 patent.

67. Ajanta's manufacture, use, offer for sale, sale, and/or importation into the United States of Ajanta's ANDA Products pursuant to ANDA No. 213718 does not infringe any valid and enforceable claim of the '109 patent.

68. Thus, Ajanta is entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation into the United States of Ajanta's ANDA Products do not infringe any valid and enforceable claim of the '109 patent.

SIXTH COUNT

(Declaratory Judgment of Invalidity of the '109 Patent)

69. Ajanta repeats and incorporates by reference each of the foregoing paragraphs of Ajanta's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

70. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Otsuka and Ajanta concerning the invalidity of claims of the '109 patent.

71. The claims of the '109 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 et seq., including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation.

72. Thus, Ajanta is entitled to a declaration that the claims of the '109 patent are invalid.

SEVENTH COUNT

(Declaratory Judgment of Non-Infringement of the '637 Patent)

73. Ajanta repeats and incorporates by reference each of the foregoing paragraphs of Ajanta's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

74. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Otsuka and Ajanta concerning the infringement of the '637 patent.

75. Ajanta's manufacture, use, offer for sale, sale, and/or importation into the United States of Ajanta's ANDA Products pursuant to ANDA No. 213718 does not infringe any valid and enforceable claim of the '637 patent.

76. Thus, Ajanta is entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation into the United States of Ajanta's ANDA Products do not infringe any valid and enforceable claim of the '637 patent.

EIGHTH COUNT

(Declaratory Judgment of Invalidity of the '637 Patent)

77. Ajanta repeats and incorporates by reference each of the foregoing paragraphs of Ajanta's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

78. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of

sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Otsuka and Ajanta concerning the invalidity of claims of the '637 patent.

79. The claims of the '637 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 et seq., including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation.

80. Thus, Ajanta is entitled to a declaration that the claims of the '637 patent are invalid.

NINTH COUNT

(Declaratory Judgment of Non-Infringement of the '419 Patent)

81. Ajanta repeats and incorporates by reference each of the foregoing paragraphs of Ajanta's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

82. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Otsuka and Ajanta concerning the infringement of the '419 patent.

83. Ajanta's manufacture, use, offer for sale, sale, and/or importation into the United States of Ajanta's ANDA Products pursuant to ANDA No. 213718 does not infringe any valid and enforceable claim of the '419 patent.

84. Thus, Ajanta is entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation into the United States of Ajanta's ANDA Products do not infringe any valid and enforceable claim of the '419 patent.

TENTH COUNT

(Declaratory Judgment of Invalidity of the '419 Patent)

85. Ajanta repeats and incorporates by reference each of the foregoing paragraphs of Ajanta's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

86. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Otsuka and Ajanta concerning the invalidity of claims of the '419 patent.

87. The claims of the '419 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 et seq., including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation.

88. Thus, Ajanta is entitled to a declaration that the claims of the '419 patent are invalid.

EXCEPTIONAL CASE

89. This case is an exceptional one, and Ajanta is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

PRAYERS FOR RELIEF

WHEREFORE, Defendant Ajanta Pharma Ltd. pray that the Court enter judgment in its favor and against Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S as follows:

- A. Declaring that the making, using, selling, offering for sale, marketing, or importation of Ajanta's ANDA Products described in ANDA No. 213718 do not infringe any valid or enforceable claim of the '362 patent;
- B. Declaring that the '362 patent and all of its claims are invalid;
- C. Declaring that the making, using, selling, offering for sale, marketing, or importation of Ajanta's ANDA Products described in ANDA No. 213718 do not infringe any valid or enforceable claim of the '840 patent;
- D. Declaring that the '840 patent and all of its claims are invalid;
- E. Declaring that the making, using, selling, offering for sale, marketing, or importation of Ajanta's ANDA Products described in ANDA No. 213718 do not infringe any valid or enforceable claim of the '109 patent;
- F. Declaring that the '109 patent and all of its claims are invalid;
- G. Declaring that the making, using, selling, offering for sale, marketing, or importation of Ajanta's ANDA Products described in ANDA No. 213718 do not infringe any valid or enforceable claim of the '637 patent;
- H. Declaring that the '637 patent and all of its claims are invalid;

- I. Declaring that the making, using, selling, offering for sale, marketing, or importation of Ajanta's ANDA Products described in ANDA No. 213718 do not infringe any valid or enforceable claim of the '419 patent;
- J. Declaring that the '419 patent and all of its claims are invalid;
- K. Enjoining Otsuka and its agents, representatives, attorneys, and those persons in active concert or participation with it who receive actual notice hereof, from threatening or initiating infringement litigation against Ajanta or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Ajanta, or charging it either orally or in writing with infringement of any patent asserted herein against Ajanta;
- L. Enjoining Otsuka and its agents, representatives, attorneys, and those persons in active concert or participation with it who receive actual notice hereof, from interfering with FDA's approval of ANDA No. 213718;
- M. Granting Ajanta judgment in its favor on Otsuka's claims;
- N. Denying Otsuka's claims with prejudice;
- O. Finding this case to be exceptional under 35 U.S.C. § 285 and awarding Ajanta its costs and reasonable attorneys' fees; and
- P. Awarding any other such relief as is just and proper.

Dated: February 12, 2020

Respectfully submitted,

STAMOULIS & WEINBLATT, LLC

/s/ Stamatios Stamoulis

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