IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD., and H. LUNDBECK A/S,	)	
Plaintiffs,	)	
v.	)	C.A. No. 19-1955-LPS
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

TEVA PHARMACEUTICALS USA, INC.'S
ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendant Teva Pharmaceuticals USA, Inc., ("Teva") hereby answers and asserts the following defenses to the Complaint brought by Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S (collectively, "Plaintiffs").

ANSWER TO COMPLAINT

Each of the paragraphs below corresponds to the same-numbered paragraphs in Plaintiffs' Complaint. Teva denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or specifications that arguably follow from the admitted facts. Teva denies that Plaintiffs are entitled to the relief requested or any other relief.

With respect to the allegations made in the Complaint, Teva states as follows:

NATURE OF THE ACTION

1. Paragraph 1 contains legal conclusions to which no response is required. To the extent a response is required, Teva admits that the Complaint purports to state an action for 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") arising under the United States patent laws, Title 35, United States Code, § 100 *et seq*., including 35 U.S.C. §§ 271 and 281. Teva further admits that the Complaint purports to relate to Teva's filing of Abbreviated New Drug Application ("ANDA") No. 213692 under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic brexpiprazole tablets, 0.25, 0.5, 1, 2, 3, and 4 mg ("Teva's ANDA Products"). Teva denies any remaining allegations of paragraph 1.

THE PARTIES

2. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

3. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them. This paragraph further contains conclusions of law to which no response is required, and Teva therefore denies them.

4. Teva admits that Plaintiffs are engaged in the business of developing pharmaceutical products. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remainder of Plaintiffs' allegations and therefore denies them.

5. Teva admits that Teva is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054. Teva denies any remaining allegations in paragraph 5.

6. Teva admits that Teva is an indirect, wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. Teva denies any remaining allegations in paragraph 6.

7. No response is required from Teva because the allegations of paragraph 7 are directed solely to Teva Pharmaceuticals Industries Ltd., which has been dismissed from this case.

JURISDICTION AND VENUE

8. Paragraph 8 contains conclusions of law for which no response is required. To the extent that a response is required, and for the purposes of this case only, Teva does not contest subject matter jurisdiction in this matter.

9. Paragraph 9 contains conclusions of law to which no response is required. To the extent that a response is required, Teva admits that it is a Delaware corporation and that it develops, manufactures, imports, markets and/or sells generic drug products in the United States. For purposes of this case only, Teva does not contest personal jurisdiction over it for any claims properly before this Court. Teva denies any remaining allegations in paragraph 9.

10. Teva admits that the cited website speaks for itself. Teva denies any remaining allegations in paragraph 10.

11. Teva admits that that it has active pharmacy wholesale licenses in the state of Delaware with the license numbers A4-0001468, which issued January 31, 2007 and expires September 30, 2020, and A4-0001447, which issued November 14, 2006 and expires September 30, 2020. Teva further admits that it has active controlled substances

distributor/manufacturer licenses in the state of Delaware with the license number DM-0007115, which issued August 31, 2009 and expires June 30, 2021 and DM-0006546, which issued September 15, 2008 and expires June 30, 2021. Teva denies any remaining allegations in paragraph 11.

12. No response is required from Teva because the allegations of paragraph 12 are directed solely to Teva Pharmaceuticals Industries Ltd., which has been dismissed from this case.

13. No response is required from Teva because the allegations of paragraph 13 are directed solely to Teva Pharmaceuticals Industries Ltd., which has been dismissed from this case.

14. Admitted.

15. No response is required from Teva to the extent that the allegations of paragraph 15 are directed solely to Teva Pharmaceuticals Industries Ltd., which has been dismissed from this case. Teva denies any remaining allegations in paragraph 15.

16. No response is required from Teva to the extent that the allegations of paragraph 16 are directed solely to Teva Pharmaceuticals Industries Ltd., which has been dismissed from this case. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them. For purposes of this case only, Teva does not contest personal jurisdiction over it for any claims properly before this Court.

17. No response is required from Teva to the extent that the allegations of paragraph 17 are directed solely to Teva Pharmaceuticals Industries Ltd., which has been dismissed from this case. Teva admits that it filed its ANDA No. 213692 with the FDA seeking approval for Teva's ANDA product. This paragraph further contains conclusions of

law to which no response is required, and Teva therefore denies them. For purposes of this case only, Teva does not contest personal jurisdiction over it for any claims properly before this Court.

18. No response is required from Teva to the extent that the allegations of paragraph 18 are directed solely to Teva Pharmaceuticals Industries Ltd., which has been dismissed from this case. Teva admits that it submitted ANDA No. 213692 to FDA. Teva denies the remainder of the allegations in paragraph 18.

19. This paragraph contains conclusions of law to which no response is required, and Teva therefore denies them. For purposes of this case only, Teva does not contest venue in this Court.

20. No response is required from Teva because the allegations of paragraph 20 are directed solely to Teva Pharmaceuticals Industries Ltd., which has been dismissed from this case.

FACTUAL BACKGROUND

The NDA

21. Teva admits that the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") identifies "OTSUKA PHARMACEUTICAL CO LTD" as holding 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"). Except as otherwise expressly admitted, Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

22. Teva admits that the Orange Book indicates that FDA approved NDA No. 205422 on July 10, 2015. Except as otherwise expressly admitted, Teva lacks knowledge or

information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

23. Teva admits that pursuant to the July 10, 2015 FDA approved label for REXULTI® Tablets, "REXULTI is an atypical antipsychotic indicated for: • Use as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) [and] • Treatment of schizophrenia." Teva admits that the Orange Book indicates that brexpiprazole is the active ingredient in REXULTI® Tablets. Except as otherwise expressly admitted, Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

The Patents In Suit

24. Teva admits that the '362 patent is titled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders" and that the face of the patent includes an issue date of February 15, 2011. Teva admits that Exhibit A to the Complaint purports to be a copy of the '362 patent.

25. Teva admits that the file history on record at the United States Patent and Trademark Office ("USPTO") identifies Otsuka as the purported assignee of the '362 patent. Except as otherwise expressly admitted, Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

26. Teva admits that the Orange Book currently lists April 12, 2026 as the expiration date of the '362 patent. Teva admits that what purports to be a copy of a terminal disclaimer concerning the '362 patent is attached to the Complaint as Exhibit B. Teva further states that the document speaks for itself and otherwise denies the remaining allegations.

27. Teva admits that what purports to be a copy of a 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 is attached to the Complaint as Exhibit C. Teva further states that the document speaks for itself and otherwise denies the remaining allegations.

28. Teva admits that the ’362 patent is currently listed in the Orange Book in connection with NDA No. 205422 for REXULTI® Tablets.

29. Teva admits that the ’840 patent is titled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders” and that the face of the patent includes an issue date of January 8, 2013. Teva admits that Exhibit D to the Complaint purports to be a copy of the ’840 patent.

30. Teva admits that the file history on record at the USPTO identifies Otsuka as the purported assignee of the ’840 patent. Except as otherwise expressly admitted, Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs’ allegations and therefore denies them.

31. Teva admits that the Orange Book currently lists April 12, 2026 as the expiration date of the ’840 patent. Except as otherwise expressly admitted, Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs’ allegations and therefore denies them.

32. Teva admits that the ’840 patent is currently listed in the Orange Book in connection with NDA No. 205422 for REXULTI® Tablets.

33. Teva admits that the ’109 patent is titled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders” and that the face of the patent includes

an issue date of December 31, 2013. Teva admits that Exhibit E to the Complaint purports to be a copy of the '109 patent.

34. Teva admits that the file history on record at the USPTO identifies Otsuka as the purported assignee of the '109 patent. Except as otherwise expressly admitted, Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

35. Teva admits that the Orange Book currently lists April 12, 2026 as the expiration date of the '109 patent. Except as otherwise expressly admitted, Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

36. Teva admits that the '109 patent is currently listed in the Orange Book in connection with NDA No. 205422 for REXULTI® Tablets.

37. Teva admits that the '637 patent is titled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders" and that the face of the patent includes an issue date of December 12, 2017. Teva admits that Exhibit F to the Complaint purports to be a copy of the '637 patent.

38. Teva admits that the file history on record at the USPTO identifies Otsuka as the purported assignee of the '637 patent. Except as otherwise expressly admitted, Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

39. Teva admits that the Orange Book currently lists April 12, 2026 as the expiration date of the '637 patent. Except as otherwise expressly admitted, Teva lacks

knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

40. Teva admits that the '637 patent is currently listed in the Orange Book in connection with NDA No. 205422 for REXULTI® Tablets.

41. Teva admits that the '419 patent is titled "Table Comprising 7-[4-(4-benzo[b]thiopen-4-yl-piperazin-1-yl)butoxy]- 1H-quinoline-2-one or a Salt Thereof" and that the face of the patent includes an issue date of June 4, 2019. Teva admits that Exhibit G to the Complaint purports to be a copy of the '419 patent.

42. Teva admits that the file history on record at the USPTO identifies Otsuka as the purported assignee of the '419 patent. Except as otherwise expressly admitted, Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

43. Teva admits that the Orange Book currently lists October 12, 2032 as the expiration date of the '419 patent. Except as otherwise expressly admitted, Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

44. Teva admits that the '419 patent is currently listed in the Orange Book in connection with NDA No. 205422 for REXULTI® Tablets.

The ANDA

45. Teva admits that it filed ANDA No. 213692 with FDA pursuant to 21 U.S.C. § 355(j) seeking approval of Teva's ANDA Products. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

46. Teva admits that ANDA No. 213692 includes certifications pursuant to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification") that the claims of the patents-in-suit are invalid, unenforceable and/or would not be infringed by Teva's ANDA Products.

47. Teva admits that it sent a letter, dated September 6, 2019, to Otsuka providing a "Notice of Paragraph IV Certification" for ANDA No. 213692 ("Teva's Sept. 6 Notice Letter") pursuant to § 505(j)(2)(B) of the FDCA and 21 C.F.R. § 314.95. Teva states that its Sept. 6 Notice Letter speaks for itself. Upon information and belief, and as Plaintiffs allege in their Complaint, Otsuka received Teva's Sept. 6 Notice Letter. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

48. Teva admits that it sent a second letter, dated September 17, 2019, to Otsuka providing a "Notice of Paragraph IV Certification" for ANDA No. 213692 ("Teva's Sept. 17 Notice Letter") pursuant to § 505(j)(2)(B) of the FDCA and 21 C.F.R. § 314.95. Teva states that its Sept. 17 Notice Letter speaks for itself. Upon information and belief, and as Plaintiffs allege in their Complaint, Otsuka received Teva's Sept. 17 Notice Letter. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

49. Teva admits that Plaintiffs filed this action on October 15, 2019. Except as otherwise expressly admitted, Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

COUNT I

(Infringement of the '362 Patent)

50. Teva realleges and incorporates by reference fully herein, each preceding paragraph.

51. Teva admits that it filed ANDA No. 213692 seeking approval to market Teva's ANDA Products in the United States. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

52. Teva admits that ANDA No. 213692 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) stating that the claims of the '362 patent are invalid, unenforceable and/or not infringed.

53. Teva admits that it submitted ANDA No. 213692 to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of Teva's ANDA Products. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

54. Paragraph 54 contains legal conclusions to which no response is required. Teva states that its Sept. 6 Notice Letter and Sept. 17 Notice Letter speak for themselves. To the extent an answer is required, denied.

55. Paragraph 55 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

56. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

57. Paragraph 57 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

58. Teva admits that it filed ANDA No. 213692 seeking approval for Teva's ANDA Products. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

59. Paragraph 59 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

60. Paragraph 60 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

COUNT II

(Infringement of the '840 Patent)

61. Teva realleges and incorporates by reference fully herein, each preceding paragraph.

62. Teva admits that it filed ANDA No. 213692 seeking approval to market Teva's ANDA Products in the United States. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

63. Teva admits that ANDA No. 213692 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) stating that the claims of the '840 patent are invalid, unenforceable and/or not infringed.

64. Teva admits that it submitted ANDA No. 213692 to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of Teva's ANDA Products. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

65. Paragraph 65 contains legal conclusions to which no response is required. Teva states that its Sept. 6 Notice Letter and Sept. 17 Notice Letter speak for themselves. To the extent an answer is required, denied.

66. Paragraph 66 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

67. Paragraph 67 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

68. Denied.

69. Denied.

70. Denied.

71. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations in Paragraph 71 and therefore denies them.

72. Teva admits that it filed ANDA No. 213692 seeking approval of Teva's ANDA Products. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

73. Paragraph 73 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

74. Paragraph 74 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

COUNT III

(Infringement of the '109 Patent)

75. Teva realleges and incorporates by reference fully herein, each preceding paragraph.

76. Teva admits that it filed ANDA No. 213692 seeking approval to market Teva's ANDA Products in the United States. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

77. Teva admits that ANDA No. 213692 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) stating that the claims of the '109 patent are invalid, unenforceable and/or not infringed. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

78. Teva admits that it submitted ANDA No. 213692 to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of Teva's ANDA Products. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

79. Paragraph 79 contains legal conclusions to which no response is required. Teva states that its Sept. 6 Notice Letter and Sept. 17 Notice Letter speak for themselves. To the extent an answer is required, denied.

80. Paragraph 80 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

81. Paragraph 81 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

82. Denied.

83. Denied.

84. Denied.

85. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations in Paragraph 85 and therefore denies them.

86. Teva admits that it filed ANDA No. 213692 seeking approval of Teva's ANDA Products. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

87. Paragraph 87 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

88. Paragraph 88 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

COUNT IV

(Infringement of the '637 Patent)

89. Teva realleges and incorporates by reference fully herein, each preceding paragraph.

90. Teva admits that it filed ANDA No. 213692 seeking approval to market Teva's ANDA Products in the United States. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

91. Teva admits that ANDA No. 213692 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) stating that the claims of the '637 patent are invalid, unenforceable and/or not infringed. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

92. Teva admits that it submitted ANDA No. 213692 to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of Teva's ANDA Products. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

93. Paragraph 93 contains legal conclusions to which no response is required. Teva states that its Sept. 6 Notice Letter and Sept. 17 Notice Letter speak for themselves. To the extent an answer is required, denied.

94. Paragraph 94 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

95. Paragraph 95 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

96. Denied.

97. Denied.

98. Denied.

99. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations in Paragraph 85 and therefore denies them.

100. Teva admits that it filed ANDA No. 213692 seeking approval of Teva's ANDA Products. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

101. Paragraph 101 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

102. Paragraph 102 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

COUNT V

(Infringement of the '419 Patent)

103. Teva realleges and incorporates by reference fully herein, each preceding paragraph.

104. Teva admits that it filed ANDA No. 213692 seeking approval to market Teva's ANDA Products in the United States. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

105. Teva admits that ANDA No. 213692 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) stating that the claims of the '419 patent are invalid, unenforceable and/or not infringed. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

106. Teva admits that it submitted ANDA No. 213692 to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of Teva's ANDA Products. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

107. Paragraph 107 contains legal conclusions to which no response is required. Teva states that its Sept. 6 Notice Letter and Sept. 17 Notice Letter speak for themselves. To the extent an answer is required, denied.

108. Paragraph 108 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

109. Paragraph 109 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

110. Teva admits that it filed ANDA No. 213692 seeking approval for Teva's ANDA Products. Except as otherwise expressly admitted, Teva denies the remaining allegations in this paragraph.

111. Paragraph 111 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

112. Paragraph 112 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

RESPONSE TO REQUEST FOR RELIEF

Teva denies all allegations not specifically admitted herein, and further denies that Plaintiffs are entitled to the judgement and relief requested in Paragraphs A-H of their Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

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

SECOND AFFIRMATIVE DEFENSE
(Non-infringement)

The manufacture, use, sale, offer for sale, and/or importation of Teva's ANDA Products that are the subject of ANDA No. 213692 has not and will not infringe directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner any valid and enforceable claim 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 satisfy one or more of the conditions for patentability under the patent laws of the United States, including without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting.

FOURTH AFFIRMATIVE DEFENSE
(No Injunctive Relief)

Plaintiffs may not seek injunctive relief under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 against Teva because Plaintiff's alleged damages are not irreparable and Plaintiffs have an adequate remedy at law.

FIFTH AFFIRMATIVE DEFENSE
(No Costs)

Plaintiffs are barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

SIXTH AFFIRMATIVE DEFENSE
(No Exceptional Case)

Teva's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

SEVENTH AFFIRMATIVE DEFENSE
(Additional Defenses)

Teva reserves the right to add or amend this list of Affirmative Defenses with additional defenses that discovery may yield, including unenforceability.

COUNTERCLAIMS

In further response to the Complaint, Defendant/Counterclaim-Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva"), without admitting any of the allegations of Plaintiffs other than those expressly admitted herein, and without prejudice of the rights of Teva to plead additional Counterclaims as the facts of the matter warrant, alleges as follows:

THE PARTIES

1. Teva is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

2. On information and belief, Counterclaim Defendant 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.

3. Upon information and believe, Counterclaim Defendant 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.

JURISDICTION AND VENUE

4. This is a declaratory judgment action arising under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has personal jurisdiction over Otsuka and Lundbeck (collectively, "Counterclaim Defendants") because, among other reasons, they subjected themselves to the jurisdiction of this Court by filing their Complaint here.

6. Venue is proper in this District pursuant to §§ 1391 and 1400(b).

7. There is an actual and justiciable controversy between the parties as to the infringement and validity 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").

FACTUAL BACKGROUND

8. According to the United States Food & Drug Administration ("FDA") publication titled Approved Drug Products and Therapeutic Equivalence Evaluations (the "Orange Book"), Otsuka is the holder of approved New Drug Application ("NDA") No. 205422, under which the FDA granted approval for brexpiprazole tablets in 0.25, 0.5, 1, 2, 3 and 4 mg dosage forms marketed in the United States under the trade name REXULTI® ("REXULTI® Tablets").

9. NDA holders are required to disclose to the FDA the patent numbers of patents claiming the drug or the method of using such drug for which the NDA is submitted. The FDA lists these patents in the Orange Book.

10. The Orange Book lists the '362 patent, the '840 patent, the '109 patent, the '637 patent, and the '419 patent in association with NDA No. 205422, for REXULTI® Tablets.

11. Upon information and belief, the '362 patent was issued on or about February 15, 2011, and states on its face that it was assigned to Otsuka.

12. Upon information and belief, the '840 patent was issued on or about January 8, 2013, and states on its face that it was assigned to Otsuka.

13. Upon information and belief, the '109 patent was issued on or about December 31, 2013, and states on its face that it was assigned to Otsuka.

14. Upon information and belief, the '637 patent was issued on or about December 12, 2017, and states on its face that it was assigned to Otsuka.

15. Upon information and belief, the ’419 patent was issued on or about June 4, 2019, and states on its face that it was assigned to Otsuka.

16. Upon information and belief, Otsuka caused ’362 patent, the ’840 patent, the ’109 patent, the ’637 patent, and the ’419 patent to be listed in the Orange Book in connection with NDA No. 205422.

17. Teva filed ANDA No. 213692 (“Teva’s ANDA”) with the FDA seeking approval for brexpiprazole tablets 0.25, 0.5, 1, 2, 3, and 4 mg (“Teva’s ANDA Products”).

18. Teva’s ANDA includes a Paragraph IV certification under 21 U.S.C. § 355(b)(2)(A)(iv) (“Paragraph IV certification”) that the ’362 patent, the ’840 patent, the ’109 patent, the ’637 patent, and the ’419 patent are invalid, unenforceable, or not infringed by Teva’s ANDA Products.

19. Teva sent notice of the Paragraph IV certification regarding the ’362 patent, the ’840 patent, the ’109 patent, the ’637 patent, and the ’419 patent on September 6, 2019 and September 17, 2019 (“Teva’s Notice Letters”), which provided a detailed statement of the factual and legal bases, for its opinion that the claims of ’362 patent, the ’840 patent, the ’109 patent, the ’637 patent, and the ’419 patent are invalid or not infringed, directly or indirectly, either literally or under the doctrine of equivalents, by commercial manufacture, use, offer for sale, and/or sale of Teva’s ANDA Products.

20. Counterclaim Defendants initiated the present litigation by filing a complaint against Teva on October 15, 2019.

21. Counterclaim Defendants have alleged in the present action that Teva has infringed and will infringe the ’362 patent, the ’840 patent, the ’109 patent, the ’637 patent, and

the ’419 patent by filing Teva’s ANDA with the FDA and/or by manufacturing, using, or selling the product described in Teva’s ANDA.

22. As a consequence of the foregoing, there is an actual and justiciable controversy between Teva and Counterclaim Defendants as to whether the claims of the ’362 patent, the ’840 patent, the ’109 patent, the ’637 patent, and the ’419 patent are invalid, and whether those claims are being infringed or will be infringed by Teva’s ANDA or by the manufacture, use, or sale of Teva’s ANDA Products.

COUNT I

Declaratory Judgment of Non-Infringement of the ’362 Patent

23. Teva realleges and incorporates by reference the allegations of paragraphs 1-22 as though fully set forth herein.

24. A present, genuine, and justiciable controversy exists between Teva and Counterclaim Defendants regarding, inter alia, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of Teva’s ANDA Products would infringe any valid or enforceable claim of the ’362 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

25. The manufacture, use, offer for sale, sale, importation, and/or marketing of Teva’s ANDA Products would not infringe any valid or enforceable claim of the ’362 patent, either directly or indirectly.

26. Teva is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the ’362 patent.

COUNT II

Declaratory Judgment of Invalidity of the ’362 Patent

27. Teva realleges and incorporates by reference the allegations of paragraphs 1-26 as though fully set forth herein.

28. A present, genuine, and justiciable controversy exists between Teva and Counterclaim Defendants regarding, inter alia, the invalidity of the ’362 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

29. In accordance with 21 U.S.C. § 355(j)(2)(B), Teva’s Notice Letters included a detailed statement of factual and legal bases for why one or more claims of the ’362 patent are invalid.

30. Upon information and belief, the claims of the ’362 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or judicially created doctrines of invalidity or unenforceability.

31. By way of non-limiting examples, one or more claims of the ’362 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior art to the ’362 patent. Non-limiting examples of such art include ABILIFY® Label 2003, Oshiro et al., “Novel Antipsychotic Agents With Dopamine Autoreceptor Agonist Properties: Synthesis and Pharmacology of 7-[4-(4-Phenyl-1-Piperazinyl)Butoxy]-3,4-Dihydro-2(1H)-Quinolinone Derivatives,” 41 J. Med. Chem. 658-667 (1998), and U.S. Publication No. 2005/0043309 to Clark et al., in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

32. Teva is entitled to a judicial declaration that the claims of the ’362 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

COUNT III

Declaratory Judgment of Non-Infringement of the ’840 Patent

33. Teva realleges and incorporates by reference the allegations of paragraphs 1-32 as though fully set forth herein.

34. A present, genuine, and justiciable controversy exists between Teva and Counterclaim Defendants regarding, inter alia, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of Teva’s ANDA Products would infringe any valid or enforceable claim of the ’840 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

35. The manufacture, use, offer for sale, sale, importation, and/or marketing of Teva’s ANDA Products would not infringe any valid or enforceable claim of the ’840 patent, either directly or indirectly.

36. Teva is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the ’840 patent.

COUNT IV

Declaratory Judgment of Invalidity of the ’840 Patent

37. Teva realleges and incorporates by reference the allegations of paragraphs 1-36 as though fully set forth herein.

38. A present, genuine, and justiciable controversy exists between Teva and Counterclaim Defendants regarding, inter alia, the invalidity of the ’840 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

39. In accordance with 21 U.S.C. § 355(j)(2)(B), Teva’s Notice Letters included a detailed statement of factual and legal bases for why one or more claims of the ’840 patent are invalid.

40. Upon information and belief, the claims of the ’840 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or judicially created doctrines of invalidity or unenforceability.

41. By way of non-limiting examples, one or more claims of the ’840 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior art to the ’840 patent. Non-limiting examples of such art include ABILIFY® Label 2003; Oshiro et al., “Novel Antipsychotic Agents With Dopamine Autoreceptor Agonist Properties: Synthesis and Pharmacology of 7-[4-(4-Phenyl-1-Piperazinyl)Butoxy]-3,4-Dihydro-2(1H)-Quinolinone Derivatives,” 41 J. Med. Chem. 658-667 (1998), and U.S. Publication No. 2005/0043309 to Clark et al., in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

42. Teva is entitled to a judicial declaration that the claims of the ’840 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

COUNT V

Declaratory Judgment of Non-Infringement of the ’109 Patent

43. Teva realleges and incorporates by reference the allegations of paragraphs 1-42 as though fully set forth herein.

44. A present, genuine, and justiciable controversy exists between Teva and Counterclaim Defendants regarding, inter alia, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of Teva’s ANDA Products would infringe any valid or enforceable claim of the ’109 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

45. The manufacture, use, offer for sale, sale, importation, and/or marketing of Teva’s ANDA Products would not infringe any valid or enforceable claim of the ’109 patent, either directly or indirectly.

46. Teva is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the ’109 patent.

COUNT VI

Declaratory Judgment of Invalidity of the ’109 Patent

47. Teva realleges and incorporates by reference the allegations of paragraphs 1-46 as though fully set forth herein.

48. A present, genuine, and justiciable controversy exists between Teva and Counterclaim Defendants regarding, inter alia, the invalidity of the ’109 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

49. In accordance with 21 U.S.C. § 355(j)(2)(B), Teva's Notice Letters included a detailed statement of factual and legal bases for why one or more claims of the '109 patent are invalid.

50. Upon information and belief, the claims of the '109 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or judicially created doctrines of invalidity or unenforceability.

51. By way of non-limiting examples, one or more claims of the '109 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior art to the '109 patent Non-limiting examples of such art include ABILIFY® Label 2003, Oshiro et al., "Novel Antipsychotic Agents With Dopamine Autoreceptor Agonist Properties: Synthesis and Pharmacology of 7-[4-(4-Phenyl-1-Piperazinyl)Butoxy]-3,4-Dihydro-2(1H)-Quinolinone Derivatives," 41 J. Med. Chem. 658-667 (1998), U.S. Publication No. 2005/0043309 to Clark et al., in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

52. Teva is entitled to a judicial declaration that the claims of the '109 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

COUNT VII

Declaratory Judgment of Non-Infringement of the '637 Patent

53. Teva realleges and incorporates by reference the allegations of paragraphs 1-52 as though fully set forth herein.

54. A present, genuine, and justiciable controversy exists between Teva and Counterclaim Defendants regarding, inter alia, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of Teva's ANDA Products would infringe any valid or enforceable claim of the '637 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

55. The manufacture, use, offer for sale, sale, importation, and/or marketing of Teva's ANDA Products would not infringe any valid or enforceable claim of the '637 patent, either directly or indirectly.

56. Teva is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the '637 patent.

COUNT VIII

Declaratory Judgment of Invalidity of the '637 Patent

57. Teva realleges and incorporates by reference the allegations of paragraphs 1-56 as though fully set forth herein.

58. A present, genuine, and justiciable controversy exists between Teva and Counterclaim Defendants regarding, inter alia, the invalidity of the '637 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

59. In accordance with 21 U.S.C. § 355(j)(2)(B), Teva's Notice Letters included a detailed statement of factual and legal bases for why one or more claims of the '637 patent are invalid.

60. Upon information and belief, the claims of the '637 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to,

§§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or judicially created doctrines of invalidity or unenforceability.

61. By way of non-limiting examples, one or more claims of the ’637 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior art to the ’637 patent. Non-limiting examples of such art include ABILIFY® Label 2003, Oshiro et al., “Novel Antipsychotic Agents With Dopamine Autoreceptor Agonist Properties: Synthesis and Pharmacology of 7-[4-(4-Phenyl-1-Piperazinyl)Butoxy]-3,4-Dihydro-2(1H)-Quinolinone Derivatives,” 41 J. Med. Chem. 658-667 (1998), and U.S. Publication No. 2005/0043309 to Clark et al., in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

62. Teva is entitled to a judicial declaration that the ’637 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

COUNT IX

Declaratory Judgment of Non-Infringement of the ’419 Patent

63. Teva realleges and incorporates by reference the allegations of paragraphs 1-62 as though fully set forth herein.

64. A present, genuine, and justiciable controversy exists between Teva and Counterclaim Defendants regarding, inter alia, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of Teva’s ANDA Products would infringe any valid or enforceable claim of the ’419 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

65. The manufacture, use, offer for sale, sale, importation, and/or marketing of Teva's ANDA Products would not infringe any valid or enforceable claim of the '419 patent, either directly or indirectly.

66. Teva is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the '419 patent.

COUNT X

Declaratory Judgment of Invalidity of the '419 Patent

67. Teva realleges and incorporates by reference the allegations of paragraphs 1-66 as though fully set forth herein.

68. A present, genuine, and justiciable controversy exists between Teva and Counterclaim Defendants regarding, inter alia, the invalidity of the '419 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

69. In accordance with 21 U.S.C. § 355(j)(2)(B), Teva's Notice Letters included a detailed statement of factual and legal bases for why one or more claims of the '419 patent are invalid.

70. Upon information and belief, the claims of the '419 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or judicially created doctrines of invalidity or unenforceability.

71. By way of non-limiting examples, one or more claims of the '419 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior art to the '419 patent. Non-limiting examples of such art include U.S. Patent Publication

No. 2010/0179322A1 to Yamashita et al. and U.S. Patent Publication No. 2007/0154544A1 to Hrakovsky et al., in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

72. Teva is entitled to a judicial declaration that the ’419 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully prays for judgment in its favor and against Counterclaim Defendants:

(a) Declaring that the filing of Teva’s ANDA did not infringe one or more valid and enforceable claims of ’362 patent, the ’840 patent, the ’109 patent, the ’637 patent, and the ’419 patent;

(b) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of Teva’s ANDA Products described in Teva’s ANDA has not infringed, does not infringe, and would not – if made used, sold, offered for sale, imported, or marketed – infringe, either directly or indirectly, any valid and/or enforceable claim of ’362 patent, the ’840 patent, the ’109 patent, the ’637 patent, and the ’419 patent, either literally or under the doctrine of equivalents;

(c) Declaring that the claims of the ’362 patent, the ’840 patent, the ’109 patent, the ’637 patent, and the ’419 patent are invalid;

(d) Ordering that the Complaint be dismissed with prejudice and judgment entered in favor of Teva;

(e) Denying Plaintiffs/Counterclaim Defendants any of the relief they request in the Complaint;

(f) Declaring this case exceptional in favor of Teva pursuant to 35 U.S.C. § 285;

(g) Awarding costs and attorneys' fees to Teva; and

(h) Awarding Teva such other and further relief as the Court may deem just and proper.

/s/ Karen E. Keller

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