IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, TAKEDA PHARMACEUTICAL COMPANY LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS INTERNATIONAL AG and TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs,	)	
v.	)	C.A. No. 18-113 (LPS)
ALEMBIC PHARMACEUTICALS LIMITED. ALEMBIC GLOBAL HOLDING S/A, and ALEMBIC PHARMACEUTICALS, INC., Defendants.	)	

DEFENDANTS' ANSWER AND DEFENSES TO PLAINTIFFS' FIRST AMENDED COMPLAINT AND COUNTERCLAIMS OF ALEMBIC PHARMACEUTICALS LIMITED AND ALEMBIC PHARMACEUTICALS, INC.

Defendants Alembic Pharmaceuticals Limited ("APL"), Alembic Pharmaceuticals, Inc. ("Alembic Inc.") (collectively "Alembic") and Alembic Global Holdings S/A ("Alembic Global"), hereby answer the First Amended Complaint of Plaintiffs H. Lundbeck A/S ("Lundbeck"), Takeda Pharmaceutical Company LTD. ("Takeda LTD"), Takeda Pharmaceuticals U.S.A., Inc. ("Takeda USA"), Takeda Pharmaceuticals International AG ("Takeda International") and Takeda Pharmaceuticals America, Inc. ("Takeda America") (collectively "Plaintiffs") as follows:

GENERAL DENIAL

Unless expressly admitted below, Alembic and Alembic Global deny each and every allegation Plaintiffs have made in their First Amended Complaint. Any factual allegation admitted below is admitted only as to the specific admitted facts, and not as to any purported

conclusions, characterizations, or implications that may allegedly follow from the admitted facts.

NATURE OF THE ACTION

1. Paragraph 1 contains legal conclusions to which no response is required. To the extent that an answer is required, Alembic admits that APL filed Abbreviated New Drug Application ("ANDA") No. 211066 seeking approval from the United States Food and Drug Administration ("FDA") for a generic vortioxetine hydrobromide tablet product prior to the expiration of U.S. Patent No. 8,722,684 (the "'684 patent"), U.S. Patent No. 8,969,355 ("the '355 patent"), U.S. Patent No. 9,227,946 ("the '946 patent"), and U.S. Patent No. 9,861,630 ("the '630 patent"). Alembic admits that the First Amended Complaint purports to bring an action by Plaintiffs for infringement of the '684 patent, the '355 patent, the '946 patent, and the '630 patent against Alembic. Alembic and Alembic Global deny the remaining allegations of Paragraph 1.

THE PARTIES

2. Alembic and Alembic Global are without sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 2, and therefore deny those allegations.

3. Alembic and Alembic Global are without sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 3, and therefore deny those allegations.

4. Alembic and Alembic Global are without sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 4, and therefore deny those allegations.

5. Alembic and Alembic Global are without sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 5, and therefore deny those

allegations.

6. Alembic and Alembic Global are without sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 6, and therefore deny those allegations.

7. Alembic and Alembic Global are without sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 7, and therefore deny those allegations.

8. APL admits that it is a corporation organized and existing under the laws of India, having a principal place of business at Alembic Road, Vadodara, 390 003, Gujarat, India.

9. Alembic Global admits that it is a corporation organized and existing under the laws of Switzerland, with a principal place of business at Rue Fritz-Courvoisier 40, 2300 La Chaux-de-Fonds, Switzerland.

10. Alembic Global admits that it is a wholly own subsidiary of APL.

11. Alembic Global admits that it maintains a website, http://alembicglobal.ch, which states:

> Alembic Global Holding SA is the 100 % subsidiary of the flagship company Alembic Pharmaceuticals Limited, India, located in Switzerland. The basic objective of forming a wholly owned overseas subsidiary is to expand business globally aiming at purchase, sale, packaging, manufacturing, research and development of pharmaceutical products, intermediates and raw materials as well as acquisition and management of Intellectual property. Alembic Global Holding SA is the headquarter for all the overseas business in countries like USA, Europe, UAE, Australia and other developed markets. Company has wholly owned subsidiaries in these countries. Alembic Global Holding SA has also set up a branch in Dubai, UAE to cater to its distribution network in the rest of the world markets.

12. Alembic Inc. admits that it is a company organized and existing under the laws of Delaware, having its principal place of business at 750 Route 202, Bridgewater, New Jersey 08807.

13. Alembic Inc. admits that it is a wholly owned subsidiary of APL and Alembic Global.

14. Alembic admits that Alembic Inc. and Alembic Global are each directed under the control of APL. Alembic and Alembic Global deny the remaining allegations in Paragraph 14.

15. Paragraph 15 contains legal conclusions to which no response is required. To the extent that an answer is required, Alembic and Alembic Global deny the allegations in Paragraph 15.

16. Alembic admits that APL provided input or review of ANDA No. 211066. Alembic and Alembic Global deny the remaining allegations in Paragraph 16.

17. Alembic admits that APL caused ANDA No. 211066 to be submitted to the FDA and seeks FDA approval of ANDA No. 211066. Alembic and Alembic Global deny the remaining allegations in Paragraph 17.

18. Alembic admits that it intends to commercially manufacture, market, offer for sale, and sell vortioxetine hydrobromide tablets as described in ANDA No. 211066 ("the ANDA Products") throughout the United States and in the State of Delaware in the event the FDA approves ANDA No. 211066. Alembic and Alembic Global deny the remaining allegations in Paragraph 18.

19. Alembic admits that it intends to commercially manufacture, market, distribute, offer for sale, and/or sell the ANDA Products in the event the FDA approves ANDA No. 211066. Alembic and Alembic Global deny the remaining allegations in Paragraph 19.

JURISDICTION AND VENUE

20. This paragraph contains conclusions of law to which no response is required. To the extent an answer is required, Alembic and Alembic Global admit that the First Amended Complaint purports to bring an action by Plaintiffs for infringement of the '684 patent, the '355 patent, the '946 patent, and the '630 patent against Alembic and Alembic Global.

21. This paragraph contains conclusions of law to which no response is required. To the extent an answer is required, for the sole purpose of this litigation and to conserve judicial resources, Alembic and Alembic Global are not challenging jurisdiction, without prejudice to their rights to challenge the Court's jurisdiction in any future matter. All other allegations of this paragraph are denied.

22. This paragraph contains conclusions of law to which no response is required. To the extent an answer is required, for the sole purpose of this litigation and to conserve judicial resources, Alembic is not challenging personal jurisdiction as to Alembic, without prejudice to its rights to challenge the Court's jurisdiction over it in any future matter.

23. Alembic Inc. admits that it is a corporation organized and existing under the laws of the State of Delaware.

24. Alembic admits that it manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drug products, either directly or through subsidiaries or agents, within the United States and in this judicial district. All other allegations of this paragraph are denied.

25. Alembic admits that it maintains a website, http:www.alembicusa.com, which states:

> Alembic is a vertically integrated organization, with expertise spanning the entire pharmaceuticals value chain: Research &

> Development (R&D), Manufacturing and Marketing of finished dosage formulations, as well as active pharmaceutical ingredients and intermediates.

and

> Alembic has identified the United States as the key market for expansion and development. Alembic has experienced tremendous growth since its first launch in October 2015. The company now sells more than 35 products in the United States, representing more than 150+ SKUs under its own label. Alembic intends to launch 8 to 10 products each year over the next 3 years.

26. Alembic admits that it is licensed to sell generic and proprietary pharmaceutical products in the State of Delaware. All other allegations of this paragraph are denied.

27. Alembic admits that ANDA No. 211066 was prepared and filed with the intention of seeking to market the ANDA Products nationwide, including within this judicial district. Alembic and Alembic Global deny the remaining allegations in Paragraph 27.

28. Alembic admits that it intends to sell the ANDA Products in the State of Delaware in the event the FDA approves ANDA No. 211066. Alembic and Alembic Global are without sufficient knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 28, and therefore deny those allegations.

29. Alembic admits that it intends to sell the ANDA Products in the State of Delaware in the event the FDA approves ANDA No. 211066. Alembic and Alembic Global are without sufficient knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 29, and therefore deny those allegations.

30. This paragraph contains conclusions of law to which no response is required. To the extent an answer is required, Alembic admits that certain Alembic entities have been named as a Defendant in *Wyeth LLC et al v. Alembic Pharmaceuticals, Ltd. et al*, 16-cv-01305, D.I. 24

(D. Del. April 4, 2017); *Bayer Pharma AG et al v. Alembic Pharmaceuticals Limited et al*, 15-cv-00832, D.I. 12 (D. Del. Oct. 29, 2015), and *Forest Laboratories, LLC et al v. Alembic Pharmaceuticals Limited et al*, 15-cv-00273, D.I. (D. Del. June 5, 2015). Alembic and Alembic Global deny the remaining allegations in Paragraph 30.

31. This paragraph contains conclusions of law to which no response is required. To the extent an answer is required, for the sole purpose of this litigation and to conserve judicial resources, APL is not challenging venue or jurisdiction, without prejudice to its rights to challenge venue or jurisdiction in any future matter.

32. This paragraph contains conclusions of law to which no response is required. To the extent an answer is required, for the sole purpose of this litigation and to conserve judicial resources, Alembic Global is not challenging venue or jurisdiction, without prejudice to its rights to challenge venue or jurisdiction in any future matter.

33. This paragraph contains conclusions of law to which no response is required. To the extent an answer is required, for the sole purpose of this litigation and to conserve judicial resources, Alembic Inc. is not challenging venue or jurisdiction, without prejudice to its rights to challenge venue or jurisdiction in any future matter.

PLAINTIFFS' APPROVED TRINTELLIX® DRUG PRODUCT AND PATENTS

34. Alembic and Alembic Global admit that Takeda USA is the purported holder of New Drug Application ("NDA") No. 204447 for vortioxetine hydrobromide tablets in 5 mg, 10 mg, 15 mg, and 20 mg dosage strengths. Alembic and Alembic Global admit that the FDA approved NDA No. 204447 on September 30, 2013. Alembic and Alembic Global are without sufficient information to form a belief as to the remaining allegations in Paragraph 34, and therefore deny those allegations.

35. Alembic and Alembic Global are without sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 35, and therefore deny those allegations.

36. Alembic and Alembic Global admit that the ’684, ’355, ’946, and ’630 patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the “Orange Book”) for TRINTELLIX®.

37. Alembic and Alembic Global admit that the ’684 patent was issued by the USPTO on May 13, 2014.

38. Alembic and Alembic Global admit that the ’355 patent was issued by the USPTO on March 3, 2015.

39. Alembic and Alembic Global admit that the ’946 patent was issued by the USPTO on January 5, 2016.

40. Alembic and Alembic Global admit that the ’630 patent was issued by the USPTO on January 9, 2018.

DEFENDANTS’ ANDA NO. 211066

41. This paragraph contains conclusions of law to which no response is required. To the extent an answer is required, Alembic admits that it caused ANDA No. 211066 to be submitted to the FDA because it seeks approval to commercially manufacture, market, offer for sale, and sell the ANDA Products prior to the expiration of the ’684, ’355, ’946, and ’630 patents. Alembic and Alembic Global deny the remaining allegations in Paragraph 41.

42. Alembic admits that, as of the time of this Answer, Alembic has not been informed and does not believe that the FDA has approved ANDA No. 211066. Alembic Global denies the remaining allegations in Paragraph 42.

43. APL admits that it sent Lundbeck and Takeda USA a First Notice Letter dated December 8, 2017 representing that APL submitted ANDA 211066 to the FDA with a Paragraph IV certification for the ’684, ’355, and ’946, patents. Alembic and Alembic Global deny the remaining allegations in Paragraph 43.

44. APL admits that it sent Lundbeck and Takeda USA a Second Notice Letter dated February 9, 2018 representing that APL submitted to the FDA a Paragraph IV certification for the ’630 patent. Alembic and Alembic Global deny the remaining allegations in Paragraph 44.

45. This paragraph contains conclusions of law to which no response is required. To the extent an answer is required, Alembic admits that it caused ANDA No. 211066 to be submitted to the FDA because it seeks approval to commercially manufacture, market, offer for sale, and sell the ANDA Products prior to the expiration of the ’684, ’355, ’946, and ’630 patents. Alembic and Alembic Global deny the remaining allegations in Paragraph 45.

46. This paragraph contains conclusions of law to which no response is required. To the extent an answer is required, Alembic admits that, as described in the First Notice Letter, Alembic offered confidential access to portions of ANDA No. 211066 to Lundbeck and Takeda in consideration of Lundbeck’s and Takeda’s agreement to abide by certain restrictions as indicated in the First Notice Letter. Alembic and Alembic Global deny the remaining allegations in Paragraph 46.

47. Alembic admits that outside counsel for Plaintiffs corresponded with outside counsel for Alembic to request a modification to the terms under which Alembic would grant Plaintiffs confidential access to ANDA No. 211066. Alembic admits that no agreement was reached. Alembic and Alembic Global deny the remaining allegations in Paragraph 47.

48. This paragraph contains conclusions of law to which no response is required. To

the extent an answer is required, Alembic admits that it sent the Second Notice Letter to Lundbeck and Takeda after Plaintiffs filed their original Complaint in this case. Alembic admits that, as described in the Second Notice Letter, Alembic offered confidential access to portions of ANDA No. 211066 to Lundbeck and Takeda in consideration of Lundbeck's and Takeda's agreement to abide by certain restrictions as indicated in the First Notice Letter. Alembic and Alembic Global deny the remaining allegations in Paragraph 48.

49. Alembic admits that outside counsel for Plaintiffs corresponded with outside counsel for Alembic to requesting a modification to the terms under which Alembic would grant Plaintiffs confidential access to ANDA No. 211066. Alembic admits that no agreement was reached. Alembic and Alembic Global deny the remaining allegations in Paragraph 49.

50. This paragraph contains conclusions of law to which no response is required.

51. Alembic admits that Alembic's First Notice Letter and Second Notice Letter do not allege that claims 1, 2, 4, 5, or 7 of the '355 Patent are invalid or unenforceable or that claims 1, 2, 4 or 5 of the '946 Patent are invalid or unenforceable.

52. Alembic admits that the indication set forth in the proposed labeling submitted in ANDA No. 211066 for the ANDA Products is the treatment of major depressive disorder (MDD). Alembic and Alembic Global are without sufficient knowledge to form a belief as to the truth of the remaining allegations in Paragraph 52, and therefore deny those allegations.

53. This paragraph contains conclusions of law to which no response is required. To the extent an answer is required, Alembic admits that, if the FDA approves ANDA No. 211066, Alembic intends to manufacture, market, import, offer for sale, and/or sell the ANDA Products in the United States prior to the expiration of the '684, '355, '946, and '630 patents. Alembic and Alembic Global deny the remaining allegations in Paragraph 53.

54. Alembic and Alembic Global deny the allegations in Paragraph 54.

55. This paragraph contains conclusions of law to which no response is required. To the extent an answer is required, Alembic admits that Plaintiffs brought this action within forty-five days of Plaintiffs' receipt of the First Notice Letter. Alembic and Alembic Global deny the remaining allegations in Paragraph 55.

56. Alembic admits that Alembic sent Plaintiffs the Second Notice Letter after Plaintiffs filed the original Complaint and that Plaintiffs filed their First Amended Complaint after receiving Alembic's Second Notice Letter relating to the '630 patent.

COUNT I
(Infringement of the '684 Patent)

57. Alembic and Alembic Global incorporate by reference each of their responses to Paragraphs 1-56 as though fully set forth herein.

58. Alembic admits that it caused the submission of ANDA No. 211066 to the FDA and seeks FDA approval of ANDA No. 211066. All other allegations of this paragraph are denied.

59. Alembic and Alembic Global are without sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 59, and therefore deny those allegations

60. Alembic and Alembic Global deny the allegations in Paragraph 60.

61. Alembic and Alembic Global deny the allegations in Paragraph 61.

62. Alembic and Alembic Global deny the allegations in Paragraph 62.

63. Alembic and Alembic Global deny the allegations in Paragraph 63.

64. Alembic and Alembic Global deny the allegations in Paragraph 64.

65. Alembic and Alembic Global deny the allegations in Paragraph 65.

66. Alembic and Alembic Global deny the allegations in Paragraph 66.

67. Alembic and Alembic Global deny the allegations in Paragraph 67.

COUNT II
(Infringement of the '355 Patent)

68. Alembic and Alembic Global incorporate by reference each of their responses to Paragraphs 1-67 as though fully set forth herein.

69. Alembic admits that it caused the submission of ANDA No. 211066 to the FDA and seeks FDA approval of ANDA No. 211066. All other allegations of this paragraph are denied.

70. Alembic and Alembic Global are without sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 70, and therefore deny those allegations

71. Alembic and Alembic Global deny the allegations in Paragraph 71.

72. Alembic admits that its First Notice Letter and Second Notice Letter do not allege that claims 1, 2, 4, 5, or 7 of the '355 Patent are invalid or unenforceable. Alembic and Alembic Global deny the remaining allegations of Paragraph 72.

73. Alembic admits that the ANDA Products will be indicated for the treatment of major depressive disorder.

74. Alembic and Alembic Global deny the allegations in Paragraph 74.

75. Alembic and Alembic Global deny the allegations in Paragraph 75.

76. Alembic and Alembic Global deny the allegations in Paragraph 76.

77. Alembic and Alembic Global deny the allegations in Paragraph 77.

78. Alembic and Alembic Global deny the allegations in Paragraph 78.

79. Alembic and Alembic Global deny the allegations in Paragraph 79.

80. Alembic and Alembic Global deny the allegations in Paragraph 80.

COUNT III
(Infringement of the '946 Patent)

81. Alembic and Alembic Global incorporate by reference each of their responses to Paragraphs 1-80 as though fully set forth herein.

82. Alembic admits that it caused the submission of ANDA No. 211066 to the FDA and seeks FDA approval of ANDA No. 211066. All other allegations of this paragraph are denied.

83. Alembic and Alembic Global are without sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 83, and therefore deny those allegations

84. Alembic and Alembic Global deny the allegations in Paragraph 84.

85. Alembic admits that its First Notice Letter and Second Notice Letter do not allege that claims 1, 2, 4, or 5 of the '946 Patent are invalid or unenforceable. Alembic and Alembic Global deny the remaining allegations of Paragraph 85.

86. Alembic admits that the ANDA Products will be indicated for the treatment of major depressive disorder.

87. Alembic and Alembic Global deny the allegations in Paragraph 87.

88. Alembic and Alembic Global deny the allegations in Paragraph 88.

89. Alembic and Alembic Global deny the allegations in Paragraph 89.

90. Alembic and Alembic Global deny the allegations in Paragraph 90.

91. Alembic and Alembic Global deny the allegations in Paragraph 91.

92. Alembic and Alembic Global deny the allegations in Paragraph 92.

93. Alembic and Alembic Global deny the allegations in Paragraph 93.

COUNT II
(Infringement of the '630 Patent)

94. Alembic and Alembic Global incorporate by reference each of their responses to Paragraphs 1-93 as though fully set forth herein.

95. Alembic admits that it caused the submission of ANDA No. 211066 to the FDA and seeks FDA approval of ANDA No. 211066. All other allegations of this paragraph are denied.

96. Alembic and Alembic Global are without sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 96, and therefore deny those allegations

97. Alembic and Alembic Global deny the allegations in Paragraph 97.

98. Alembic admits that the ANDA Products will be indicated for the treatment of major depressive disorder.

99. Alembic and Alembic Global deny the allegations in Paragraph 99.

100. Alembic and Alembic Global deny the allegations in Paragraph 100.

101. Alembic and Alembic Global deny the allegations in Paragraph 101.

102. Alembic and Alembic Global deny the allegations in Paragraph 102.

103. Alembic and Alembic Global deny the allegations in Paragraph 103.

104. Alembic and Alembic Global deny the allegations in Paragraph 104.

105. Alembic and Alembic Global deny the allegations in Paragraph 105.

PRAYER FOR RELIEF

A. Alembic and Alembic Global deny that Plaintiffs are entitled to the relief requested in Paragraph A.

B. Alembic and Alembic Global deny that Plaintiffs are entitled to the relief

requested in Paragraph B.

C. Alembic and Alembic Global deny that Plaintiffs are entitled to the relief requested in Paragraph C.

D. Alembic and Alembic Global deny that Plaintiffs are entitled to the relief requested in Paragraph D.

E. Alembic and Alembic Global deny that Plaintiffs are entitled to the relief requested in Paragraph E.

F. Alembic and Alembic Global deny that Plaintiffs are entitled to the relief requested in Paragraph F.

G. Alembic and Alembic Global deny that Plaintiffs are entitled to the relief requested in Paragraph G.

H. Alembic and Alembic Global deny that Plaintiffs are entitled to the relief requested in Paragraph H.

I. Alembic and Alembic Global deny that Plaintiffs are entitled to the relief requested in Paragraph I.

PRAYER FOR RELIEF

Alembic demands a trial by jury as to all issues so triable.

DEFENSES

Without prejudice to the denials set forth in the Answer to the First Amended Complaint, without admitting any allegation in the First Amended Complaint not otherwise expressly admitted, and without undertaking any of the burdens of proof imposed by law on Plaintiffs, Alembic and Alembic Global assert the following defenses set forth below.

FIRST DEFENSE
(Non-Infringement of the ’684 Patent)

The manufacture, use, sale, offer for sale, or importation of the products described in Alembic Pharmaceuticals, Ltd. ANDA No. 211066 has not infringed, does not infringe, and would not – if made, used, offered for sale, imported, or marketed – infringe directly and/or indirectly any valid and enforceable claim of the ’684 patent, either literally or under the doctrine of equivalents.

SECOND DEFENSE
(Non-Infringement of the ’355 Patent)

The manufacture, use, sale, offer for sale, or importation of the products described in Alembic Pharmaceuticals, Ltd. ANDA No. 211066 has not infringed, does not infringe, and would not – if made, used, offered for sale, imported, or marketed – infringe directly and/or indirectly any valid and enforceable claim of the ’355 patent, either literally or under the doctrine of equivalents.

THIRD DEFENSE
(Non-Infringement of the ’946 Patent)

The manufacture, use, sale, offer for sale, or importation of the products described in Alembic Pharmaceuticals, Ltd. ANDA No. 211066 has not infringed, does not infringe, and would not – if made, used, offered for sale, imported, or marketed – infringe directly and/or indirectly any valid and enforceable claim of the ’946 patent, either literally or under the doctrine of equivalents.

FOURTH DEFENSE
(Non-Infringement of the ’630 Patent)

The manufacture, use, sale, offer for sale, or importation of the products described in Alembic Pharmaceuticals, Ltd. ANDA No. 211066 has not infringed, does not infringe, and

would not – if made, used, offered for sale, imported, or marketed – infringe directly and/or indirectly any valid and enforceable claim of the ’630 patent, either literally or under the doctrine of equivalents.

FIFTH DEFENSE
(Invalidity of the ’684 Patent)

The claims of the ’684 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112.

SIXTH DEFENSE
(Invalidity of the ’355 Patent)

The claims of the ’355 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112.

SEVENTH DEFENSE
(Invalidity of the ’946 Patent)

The claims of the ’946 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112.

EIGHTH DEFENSE
(Invalidity of the ’630 Patent)

The claims of the ’630 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112.

NINTH DEFENSE
(Double Patenting)

The claims of the ’684 patent are invalid under the doctrine of obviousness-type double

patenting.

TENTH DEFENSE
(Failure to State a Claim)

Plaintiffs' Amended Complaint, in whole or in part, fails to state a claim, or any facts to support any claim, upon which relief can be granted.

ELEVENTH DEFENSE
(No Recovery of Costs)

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

TWELFTH DEFENSE
(No Attorney's Fees)

Plaintiffs are not entitled to attorney's fees against Alembic or Alembic Global because Plaintiffs have not sufficiently alleged, and cannot prove, that this is an exceptional case under 35 U.S.C. § 285.

THIRTEENTH DEFENSE
(Improper Party)

Alembic Global did not participate in the filing of the ANDA and will not market the ANDA products. Therefore, it is not a proper party to this case and should be dismissed.

RESERVATION OF RIGHTS

Alembic and Alembic Global reserve their rights to assert any additional defenses or counterclaims, at law or equity that may exist.

COUNTERCLAIMS OF DEFENDANTS/COUNTER-CLAIMANTS ALEMBIC PHARMACEUTICALS LIMITED. AND ALEMBIC PHARMACEUTICALS INC.

Defendants/Counter-Claimants Alembic Pharmaceuticals Limited ("APL") and Alembic Pharmaceuticals, Inc. ("Alembic Inc.") (collectively "Alembic"), bring the following

Counterclaims against Plaintiffs/Counterclaim-Defendants H. Lundbeck A/S ("Lundbeck"), Takeda Pharmaceutical Company LTD. ("Takeda LTD"), Takeda Pharmaceuticals U.S.A., Inc. ("Takeda USA"), Takeda Pharmaceuticals International AG ("Takeda International") and Takeda Pharmaceuticals America, Inc. ("Takeda America") (collectively "Plaintiffs/Counterclaim-Defendants") and state as follows:

1. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. § 2201 & 2202, and the patent laws of the United States, 35 U.S.C. § 100, et seq., based on an actual controversy between the parties to declare that APL is free to continue to seeks approval of its Abbreviated New Drug Application ("ANDA") No. 211066, and, Alembic, upon approval by the United States Food and Drug Administration ("FDA"), can engage in the manufacture, use, market, offer for sale, and/or sale of the products described in ANDA No. 211066.

PARTIES

2. APL is a corporation organized and existing under the laws of India and having a principal place of business at Alembic Road, Vadodara, Gujarat - 390003, India.

3. Alembic, Inc. is a company organized and existing under the laws of Delaware, having its principal place of business at 750 Route 202, Bridgewater, New Jersey 08807.

4. Upon information and belief, Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Upon information and belief, Lundbeck is the assignee and owner of United States Patent No. 8,722,684 ("the '684 Patent"); United States Patent No. 8,969,355 ("the '355 Patent"); United States Patent No. 9,227,946 ("the '946 Patent"); and United States Patent No. 9,861,630 ("the '630 Patent").

5. Upon information and belief, Takeda Ltd. is a corporation organized and existing under the laws of Japan, with a place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka

540-8645, Japan. Under information and belief, and based on Plaintiffs' allegations, Lundbeck has granted Takeda Ltd. an exclusive license to the '684, '355, '946, and '630 Patents in connection with the use, importation, distribution, marketing, promotion, and sale of TRINTELLIX® in the United States.

6. Upon information and belief, Takeda International is a corporation organized and existing under the laws of Switzerland, with a place of business at Thurgauerstrasse 130, 8152 Glattpark-Opfikon, Zurich, Switzerland. Upon information and belief, and based on Plaintiffs' allegations, Takeda International is an indirect wholly owned subsidiary of Takeda Japan. Upon information and belief, and based on Plaintiffs' allegations, Takeda International has an exclusive sublicense to the '684, '355, '946, and '630 Patents from Takeda Japan in connection with the commercialization of TRINTELLIX® in the United States.

7. Upon information and belief, Takeda USA is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at One Takeda Parkway, Deerfield, IL 60015. Upon information and belief, Takeda International and Takeda Japan own Takeda USA. Upon information and belief, Takeda USA holds the New Drug Application ("NDA") No. 204447 for TRINTELLIX® and has an exclusive sublicense to the '684, '355, '946, and '630 Patents from Takeda International, which grants it the right to import, distribute, and sell TRINTELLIX® in the United States on behalf of Takeda.

8. Upon information and belief, Takeda America is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at One Takeda Parkway, Deerfield, IL 60015. Upon information and belief, and based on Plaintiffs' allegations, Takeda America is a wholly owned subsidiary of Takeda USA. Upon information and belief, and based on Plaintiffs' allegations, Takeda America distributes and markets

TRINTELLIX® in the United States on behalf of Takeda USA.

JURISDICTION AND VENUE

9. These counterclaims arise under patent laws of the United States, 35 U.S.C. § 100 et seq., 21 U.S.C. § 355(c)(3)(D)(ii), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

10. On December 4, 2017, Plaintiffs/Counterclaim-Defendants filed an Amended Complaint in this Court seeking, among other things, a judgment that Alembic infringed one or more claims of the ’684, ’355, ’946, and ’630 Patents by virtue of Alembic’s filing of a Paragraph IV Certification associated with ANDA No. 211066 with respect to the ’684, ’355, and ’946 Patents, and subsequent Paragraph IV Certification of the ’630 Patent. An immediate and justiciable controversy exists between the parties regarding whether the products described in ANDA No. 211066 infringe any valid and enforceable claim of the ’684, ’355, ’946, and ’630 Patents.

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b), and because, inter alia, Plaintiffs/Counterclaim-Defendants have consented to venue in this Court by filing the instant action in this jurisdiction.

13. Personal jurisdiction is proper in this Court as to Plaintiffs/Counterclaim-Defendants, because, *inter alia*, they have subjected themselves to the jurisdiction of this Court by virtue of filing their Amended Complaint.

BACKGROUND

14. Alembic hereby incorporates each response to each of the foregoing paragraphs in the First Amended Complaint, and realleges and incorporates by reference the foregoing

Paragraphs 1-14 of the Counterclaims as if fully stated herein.

15. Plaintiffs/Counterclaim-Defendants have alleged in this action that Lundbeck is the owner of the ’684, ’355, ’946, and ’630 Patents.

16. Plaintiffs/Counterclaim-Defendants have also alleged in this action that Takeda USA holds NDA No. 204447 for TRINTELLIX® tablets, containing vortioxetine hydrobromide in 5 mg, 10 mg, 15 mg, and 20 mg dosage strengths. Upon information and belief, Takeda USA holds an exclusive sublicense to the ’684, ’355, ’946, and ’630 Patents.

17. Alembic submitted ANDA No. 211066 seeking approval from the FDA to engage in the manufacture, use, market, offer for sale, and/or sale of the products described in ANDA No. 211066, namely vortioxetine hydrobromide tablets. ANDA No. 211066 contained a certification under 21 C.F.R. § 314.94(a)(12)(i)(A)(4) and 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV”) of the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”) as to the ’684, ’355, ’946, and ’630 Patents.

18. In a First Notice Letter dated December 8, 2017, Alembic timely notified Plaintiffs/Counterclaim Defendants that Alembic had submitted a Paragraph IV Certification with the FDA with respect to the ’684, ’355, and ’946 Patents, and that the ’684, ’355, and ’946 Patents are invalid, unenforceable, and/or not infringed by the products described in Alembic's ANDA No. 211066. Alembic’s First Notice Letter contained an Offer of Confidential Access (“OCA”) that offered to provide Plaintiffs/Counterclaim Defendants with confidential access to certain information from Alembic's ANDA No. 211066 for the sole and exclusive purpose of Plaintiffs/Counterclaim Defendants determining whether an infringement action could be brought.

19. In a Second Notice Letter dated February 9, 2018, Alembic timely notified

Plaintiffs/Counterclaim Defendants that Alembic had submitted a Paragraph IV Certification with the FDA with respect to the ’630 Patent, and that the ’630 Patent is invalid, unenforceable, and/or not infringed by the products described in Alembic's ANDA No. 211066. Alembic’s Second Notice Letter contained a second OCA that offered to provide Plaintiffs/Counterclaim Defendants with confidential access to certain information from Alembic's ANDA No. 211066 for the sole and exclusive purpose of Plaintiffs/Counterclaim Defendants determining whether an infringement action could be brought.

20. Plaintiffs/Counterclaim Defendants filed their Complaint and First Amended Complaint against Defendants/Counterclaimants before agreeing to the terms of the OCA.

21. On January 19, 2018, Plaintiffs/Counterclaim-Defendants filed a Complaint, alleging infringement of the ’684, ’355, and ’946 Patents.by Alembic.

22. On February 23, 2018, Plaintiffs/Counterclaim-Defendants filed their Amended Complaint, alleging infringement of the ’684, ’355, ’946, and ’630 Patents by Alembic.

FIRST COUNTERCLAIM

(Declaration of Non-Infringement of the ’684 Patent)

23. Alembic realleges and incorporates by reference the foregoing Paragraphs 1-22 of the Counterclaims as if fully stated herein.

24. This is a counterclaim for declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 for the purpose of determining an actual and justiciable controversy between the parties.

25. The products described in ANDA No. 211066 have not infringed and do not and would not, if manufactured, used, offered for sale, or sold, infringe, or induce or contribute to the infringement of, any valid and enforceable claim of the ’684 patent.

26. Because Plaintiffs/Counterclaim-Defendants maintain that the commercial

manufacture, use, offer for sale, or sale of products described in ANDA No. 211066 would directly and/or indirectly infringe the ’684 patent, a declaration of rights between the parties is appropriate and necessary to establish that commercial manufacture, use, offer for sale, or sale of the products described in ANDA No. 211066 within the United States would not directly and/or indirectly infringe the ’684 patent.

27. Alembic is entitled to a declaration that the manufacture, use, offer for sale, or sale of the products described in ANDA No. 211066 would not infringe the claims of the ’684 patent.

SECOND COUNTERCLAIM

(Declaration of Invalidity of the ’684 Patent)

28. Alembic realleges and incorporates by reference the foregoing Paragraphs 1-27 of the Counterclaims as if fully stated herein.

29. This is a counterclaim for declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 for the purpose of determining an actual and justiciable controversy between the parties.

30. Because Plaintiffs/Counterclaim-Defendants maintain and Alembic denies that the ’684 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the ’684 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112, and/or obviousness–type double patenting.

31. Alembic is entitled to a declaration that the claims of the ’684 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112.

THIRD COUNTERCLAIM

(Declaration of Non-Infringement of the ’355 Patent)

32. Alembic realleges and incorporates by reference the foregoing Paragraphs 1-31 of the Counterclaims as if fully stated herein.

33. This is a counterclaim for declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 for the purpose of determining an actual and justiciable controversy between the parties.

34. The products described in ANDA No. 211066 have not infringed and do not and would not, if manufactured, used, offered for sale, or sold, infringe, or induce or contribute to the infringement of, any valid and enforceable claim of the ’355 patent.

35. Because Plaintiffs/Counterclaim-Defendants maintain that the commercial manufacture, use, offer for sale, or sale of products described in ANDA No. 211066 would directly and/or indirectly infringe the ’355 patent, a declaration of rights between the parties is appropriate and necessary to establish that commercial manufacture, use, offer for sale, or sale of the products described in ANDA No. 211066 within the United States would not directly and/or indirectly infringe the ’355 patent.

36. Alembic is entitled to a declaration that the manufacture, use, offer for sale, or sale of the products described in ANDA No. 211066 would not infringe the claims of the ’355 patent.

FOURTH COUNTERCLAIM

(Declaration of Invalidity of the ’355 Patent)

37. Alembic realleges and incorporates by reference the foregoing Paragraphs 1-36 of the Counterclaims as if fully stated herein.

38. This is a counterclaim for declaratory judgment pursuant to 28 U.S.C. §§ 2201

and 2202 for the purpose of determining an actual and justiciable controversy between the parties.

39. Because Plaintiffs/Counterclaim-Defendants maintain and Alembic denies that the ’355 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the ’355 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112, and/or obviousness–type double patenting.

40. Alembic is entitled to a declaration that the claims of the ’355 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112.

FIFTH COUNTERCLAIM

(Declaration of Non-Infringement of the ’946 Patent)

41. Alembic realleges and incorporates by reference the foregoing Paragraphs 1-40 of the Counterclaims as if fully stated herein.

42. This is a counterclaim for declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 for the purpose of determining an actual and justiciable controversy between the parties.

43. The products described in ANDA No. 211066 have not infringed and do not and would not, if manufactured, used, offered for sale, or sold, infringe, or induce or contribute to the infringement of, any valid and enforceable claim of the ’946 patent.

44. Because Plaintiffs/Counterclaim-Defendants maintain that the commercial manufacture, use, offer for sale, or sale of products described in ANDA No. 211066 would directly and/or indirectly infringe the ’946 patent, a declaration of rights between the parties is

appropriate and necessary to establish that commercial manufacture, use, offer for sale, or sale of the products described in ANDA No. 211066 within the United States would not directly and/or indirectly infringe the ’946 patent.

45. Alembic is entitled to a declaration that the manufacture, use, offer for sale, or sale of the products described in ANDA No. 211066 would not infringe the claims of the ’946 patent.

SIXTH COUNTERCLAIM

(Declaration of Invalidity of the ’946 Patent)

46. Alembic realleges and incorporates by reference the foregoing Paragraphs 1-45 of the Counterclaims as if fully stated herein.

47. This is a counterclaim for declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 for the purpose of determining an actual and justiciable controversy between the parties.

48. Because Plaintiffs/Counterclaim-Defendants maintain and Alembic denies that the ’946 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the ’946 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112, and/or obviousness–type double patenting.

49. Alembic is entitled to a declaration that the claims of the ’946 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112.

SEVENTH COUNTERCLAIM

(Declaration of Non-Infringement of the ’630 Patent)

50. Alembic realleges and incorporates by reference the foregoing Paragraphs 1-49 of the Counterclaims as if fully stated herein.

51. This is a counterclaim for declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 for the purpose of determining an actual and justiciable controversy between the parties.

52. The products described in ANDA No. 211066 have not infringed and do not and would not, if manufactured, used, offered for sale, or sold, infringe, or induce or contribute to the infringement of, any valid and enforceable claim of the ’630 patent.

53. Because Plaintiffs/Counterclaim-Defendants maintain that the commercial manufacture, use, offer for sale, or sale of products described in ANDA No. 211066 would directly and/or indirectly infringe the ’630 patent, a declaration of rights between the parties is appropriate and necessary to establish that commercial manufacture, use, offer for sale, or sale of the products described in ANDA No. 211066 within the United States would not directly and/or indirectly infringe the ’630 patent.

54. Alembic is entitled to a declaration that the manufacture, use, offer for sale, or sale of the products described in ANDA No. 211066 would not infringe the claims of the ’630 patent.

EIGHTH COUNTERCLAIM

(Declaration of Invalidity of the ’630 Patent)

55. Alembic realleges and incorporates by reference the foregoing Paragraphs 1-54 of the Counterclaims as if fully stated herein.

56. This is a counterclaim for declaratory judgment pursuant to 28 U.S.C. §§ 2201

and 2202 for the purpose of determining an actual and justiciable controversy between the parties.

57. Because Plaintiffs/Counterclaim-Defendants maintain and Alembic denies that the ’630 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the ’630 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112, and/or obviousness–type double patenting.

58. Alembic is entitled to a declaration that the claims of the ’630 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Counterclaimants respectfully request that this Court enter a Judgement and Order:

A. dismissing the Amended Complaint, and the claims for relief contained therein, with prejudice;

B. declaring that Alembic and the products described in ANDA No. 211066 have not infringed, are not infringing and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid and enforceable claim of the ’684, ’355, ’946, and ’630 Patents;

C. declaring the claims of the ’684, ’355, ’946, and ’630 Patents invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112, and/or

obviousness–type double patenting;

D. permanently enjoining Plaintiffs/Counterclaim-Defendants, their assigns, successors, officers, employees, agents, representatives, attorneys, and others acting on its behalf, from threatening or initiating infringement litigation over products subject of ANDA No. 211066 against Alembic, or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Alembic or charging them either orally or in writing with infringement of the'684, '355, '946, and '630 Patents;

E. declaring this an exceptional case under 35 U.S.C. § 285 and awarding Alembic its attorneys' fees, costs, and expenses; and

F. granting Alembic such other and further relief as this Court deems just and proper.

Dated: April 13, 2018

RICHARDS LAYTON & FINGER, PA

/s/ Kelly E. Farnan

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