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 & Counterclaim-Defendants, v. SIGMAPHARM LABORATORIES, LLC, Defendant & Counterclaim-Plaintiff.	Civil Action No. 18-cv-671-LPS

SIGMAPHARM LABORATORIES, LLC'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT

Defendant Sigmapharm Laboratories, LLC ("Sigmapharm"), by and through the undersigned attorneys, responds by way of Answer, Affirmative Defenses, and Counterclaims to the Complaint of Plaintiffs H. Lundbeck A/S ("Lundbeck"), Takeda Pharmaceutical Company Ltd. ("Takeda Japan"), Takeda Pharmaceuticals U.S.A., Inc. ("Takeda USA"), Takeda Pharmaceuticals International AG ("Takeda International"), and Takeda Pharmaceuticals America, Inc. ("Takeda America") (collectively, "Plaintiffs").

GENERAL DENIAL

Sigmapharm denies all allegations of the Complaint not specifically admitted herein. Unless Sigmapharm explicitly admits a statement of the Complaint, that allegation is denied. Sigmapharm answers herewith stating its specific responses below paragraph by paragraph to the allegations of the Complaint.

SPECIFIC ADMISSIONS AND DENIALS

NATURE OF THE ACTION[1]

1. This paragraph is Plaintiffs' characterization of the action, to which no response is required. To the extent a response is required, however, Sigmapharm denies the allegations of this paragraph, except to admit that Sigmapharm filed Abbreviated New Drug Application ("ANDA") No. 211084 with the Food and Drug Administration ("FDA"), and that ANDA No. 211084 seeks FDA approval to market the ANDA products described therein prior to the dates listed in the FDA Orange Book as the expiration dates of United States Patent No. 7,144,884 ("the '884 Patent"); United States Patent No. 8,476,279 ("the '279 Patent"); 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").

THE PARTIES

2. Sigmapharm lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

3. Sigmapharm lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

4. Sigmapharm lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

5. Sigmapharm lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

[1] To the extent that the headings used in the Complaint purport to make factual allegations to which a response is required, Sigmapharm denies such allegations. The reproduction of such headings herein is done solely for the purposes of readability and convenience, and shall not be construed as an admission.

6. Sigmapharm lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

7. Sigmapharm denies that the subject matter of the patents asserted in the Complaint is "revolutionary." Sigmapharm lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, on that basis, denies them.

8. Admitted.

9. Admitted.

10. Sigmapharm states that ANDA No. 211084 was prepared and filed with the intention of seeking to market the ANDA products described therein upon approval by the FDA. Sigmapharm denies the remaining allegations of this paragraph.

JURISDICTION AND VENUE

11. This paragraph is Plaintiffs' further characterization of the action, to which no response is required. To the extent a response is required, however, and for the purposes of this action only, Sigmapharm admits that the Complaint purports to state claims of alleged patent infringement arising under the patent laws of the United States.

12. For purposes of this action only, Sigmapharm admits that this Court has subject matter jurisdiction.

13. For purposes of this action only, in light of the parties' statutory obligation to cooperate in expediting this action, and without admitting that personal jurisdiction is otherwise proper in this District, Sigmapharm does not contest personal jurisdiction in the above-captioned litigation. Sigmapharm otherwise denies the remaining allegations of this paragraph.

14. Sigmapharm admits that Sigmapharm is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products. Sigmapharm otherwise denies the remaining allegations of this paragraph.

15. Sigmapharm admits that Sigmapharm sells generic and proprietary pharmaceutical products. Sigmapharm otherwise denies the remaining allegations of this paragraph.

16. Sigmapharm admits that Sigmapharm, through counsel, sent a letter dated March 20, 2018, to Takeda Pharmaceuticals U.S.A., Inc. and H. Lundbeck A/S pursuant to 21 U.S.C. § 355(j)(2)(B)(iv). Sigmapharm further admits that ANDA No. 211084 was prepared and filed with the intention of seeking to market the ANDA products described therein upon approval by the FDA. Sigmapharm otherwise denies the remaining allegations of this paragraph, and specifically denies infringing any valid claim of the patents asserted in the Complaint.

17. Sigmapharm admits that Sigmapharm, subject to FDA approval and the successful resolution of this lawsuit, plans to sell the products described in ANDA No. 211084. Sigmapharm otherwise denies the remaining allegations of this paragraph.

18. Denied.

19. For purposes of this action only, in light of the parties' statutory obligation to cooperate in expediting this action, and without admitting that venue and personal jurisdiction are otherwise proper in this District, Sigmapharm does not contest venue or personal jurisdiction in the above-captioned litigation. Sigmapharm admits that Sigmapharm was a defendant named in the civil actions identified in this paragraph, and that Sigmapharm has asserted compulsory counterclaims against non-parties to this action, in other actions in this District. Sigmapharm otherwise denies the remaining allegations of this paragraph.

20. For purposes of this action only, in light of the parties' statutory obligation to cooperate in expediting this action, and without admitting that venue is otherwise proper in this District, Sigmapharm does not contest venue in the above-captioned litigation.

PLAINTIFFS' APPROVED TRINTELLIX® DRUG PRODUCT AND PATENTS

21. Sigmapharm admits that, according to FDA records, Takeda Pharmaceuticals U.S.A., Inc. is the holder of NDA No. 204447 for "Trintellix (vortioxetine hydrobromide)" 5 mg, 10 mg, and 20 mg tablets. Sigmapharm further admits that, according to FDA records, the active ingredient in the product described in NDA No. 204447 is vortioxetine hydrobromide. Sigmapharm further admits that, according to FDA records, NDA No. 204447 was approved on September 30, 2013. Sigmapharm lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, on that basis, denies them.

22. Sigmapharm admits that, according to the current label for Trintellix® as of May 2, 2018, Trintellix® is an oral antidepressant indicated for "the treatment of major depressive disorder (MDD)." Sigmapharm lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, on that basis, denies them.

23. Admitted.

24. Sigmapharm admits that the '884 patent, on its face, states that it issued on December 5, 2006, and that it bears the title "Phenyl-piperazine Derivatives as Serotonin Reuptake Inhibitors." Sigmapharm further admits that Exhibit A to the Complaint appears to be a copy of the '884 patent, but lacks the knowledge or information sufficient to form a belief as to whether Exhibit A is a true and correct copy, and therefore denies the same. Sigmapharm denies that the '884 patent was duly and lawfully issued by the USPTO, and specifically denies that the claims of the '884 patent are valid, enforceable, and/or not expired. Sigmapharm denies any remaining allegations of this paragraph.

25. Sigmapharm admits that the '279 patent, on its face, states that it issued on July 2, 2013, and that it bears the title "Phenyl-piperazine Derivatives as Serotonin Reuptake Inhibitors." Sigmapharm further admits that Exhibit B to the Complaint appears to be a copy of the '279 patent, but lacks the knowledge or information sufficient to form a belief as to whether Exhibit B is a true and correct copy, and therefore denies the same. Sigmapharm denies that the '279 patent was duly and lawfully issued by the USPTO, and specifically denies that the claims of the '279 patent are valid, enforceable, and/or not expired. Sigmapharm denies any remaining allegations of this paragraph.

26. Sigmapharm admits that the '684 patent, on its face, states that it issued on May 13, 2014, and that it bears the title "1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment." Sigmapharm further admits that Exhibit C to the Complaint appears to be a copy of the '684 patent, but lacks the knowledge or information sufficient to form a belief as to whether Exhibit C is a true and correct copy, and therefore denies the same. Sigmapharm denies that the '684 patent was duly and lawfully issued by the USPTO, and specifically denies that the claims of the '684 patent are valid, enforceable, and/or not expired. Sigmapharm denies any remaining allegations of this paragraph.

27. Sigmapharm admits that the '355 patent, on its face, states that it issued on March 3, 2015, and that it bears the title "1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment." Sigmapharm further admits that Exhibit D to the Complaint appears to be a copy of the '355 patent, but lacks the knowledge or information sufficient to form a belief as to whether Exhibit D is a true and correct copy, and therefore denies the same. Sigmapharm

denies that the ’355 patent was duly and lawfully issued by the USPTO, and specifically denies that the claims of the ’355 patent are valid, enforceable, and/or not expired. Sigmapharm denies any remaining allegations of this paragraph.

28. Sigmapharm admits that the ’946 patent, on its face, states that it issued on January 5, 2016, and that it bears the title “1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment.” Sigmapharm further admits that Exhibit E to the Complaint appears to be a copy of the ’946 patent, but lacks the knowledge or information sufficient to form a belief as to whether Exhibit E is a true and correct copy, and therefore denies the same. Sigmapharm denies that the ’946 patent was duly and lawfully issued by the USPTO, and specifically denies that the claims of the ’946 patent are valid, enforceable, and/or not expired. Sigmapharm denies any remaining allegations of this paragraph.

29. Sigmapharm admits that the ’630 patent, on its face, states that it issued on January 9, 2018, and that it bears the title “1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment.” Sigmapharm further admits that Exhibit F to the Complaint appears to be a copy of the ’630 patent, but lacks the knowledge or information sufficient to form a belief as to whether Exhibit F is a true and correct copy, and therefore denies the same. Sigmapharm denies that the ’630 patent was duly and lawfully issued by the USPTO, and specifically denies that the claims of the ’630 patent are valid, enforceable, and/or not expired. Sigmapharm denies any remaining allegations of this paragraph.

SIGMAPHARM’S ANDA NO. 211084

30. Sigmapharm admits that Sigmapharm submitted ANDA No. 211084 to FDA under 21 U.S.C. § 355(j). Sigmapharm further states that the established name of the drug

product described in ANDA No. 211084 is "Vortioxetine Tablets," that the active ingredient therein is vortioxetine hydrobromide, and that the dosage form for the proposed drug product is tablets. Sigmapharm denies the remaining allegations of this paragraph.

31. Sigmapharm admits that FDA has not yet approved ANDA No. 211084. Sigmapharm denies the remaining allegations of this paragraph.

32. Sigmapharm admits that Sigmapharm, through counsel, sent a notice letter pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B)(iv), and 21 C.F.R. § 314.95 to Takeda Pharmaceuticals U.S.A., Inc. and H. Lundbeck A/S dated March 20, 2018. Sigmapharm further admits the March 20, 2018, notice letter represented that Sigmapharm Laboratories, LLC had submitted to FDA ANDA No. 211084 with Paragraph IV certifications for the '884, '279, '684, '355, '946, and '630 patents. Plaintiffs' reservation of rights requires no response. Sigmapharm denies the remaining allegations of this paragraph.

33. Sigmapharm admits that ANDA No. 211084 was prepared and filed with the intention of seeking to market the ANDA products described therein prior to the expiration dates listed in the Orange Book for the '884, '279, '684, '355, '946, and '630 patents. Sigmapharm otherwise denies the remaining allegations of this paragraph.

34. This paragraph contains Plaintiffs' characterization of, and legal arguments concerning, Sigmapharm's offer of confidential access to certain information from ANDA No. 211084, to which no response is required. To the extent a response is required, however, Sigmapharm states that Sigmapharm's offer of confidential access is fully consistent with 21 U.S.C. § 355(j)(5)(C), and is substantially identical to terms that Plaintiffs' counsel has

considered reasonable and adequate in prior matters. Sigmapharm denies the remaining allegations of this paragraph.

35. This paragraph contains Plaintiffs' characterization of, and legal arguments concerning, Sigmapharm's offer of confidential access to certain information from ANDA No. 211084, to which no response is required. To the extent a response is required, however, Sigmapharm states that Sigmapharm's offer of confidential access is fully consistent with 21 U.S.C. § 355(j)(5)(C), and is substantially identical to terms that Plaintiffs' counsel has considered reasonable and adequate in prior matters. Sigmapharm denies the remaining allegations of this paragraph.

36. This paragraph contains Plaintiffs' characterization of, and legal arguments concerning, Sigmapharm's offer of confidential access to certain information from ANDA No. 211084, to which no response is required. To the extent a response is required, however, Sigmapharm states that Sigmapharm's offer of confidential access is fully consistent with 21 U.S.C. § 355(j)(5)(C), and is substantially identical to terms that Plaintiffs' counsel has considered reasonable and adequate in prior matters. Sigmapharm denies the remaining allegations of this paragraph.

37. This paragraph contains Plaintiffs' purported understanding of certain regulatory requirements, to which no response is required. To the extent a response is required, however, Sigmapharm states that this paragraph accurately quotes portions of the cited regulation. Sigmapharm denies any remaining allegations in this paragraph.

38. This paragraph contains Plaintiffs' characterization of Sigmapharm's March 20, 2018 notice letter, to which no response is required. Sigmapharm's notice letter speaks for itself. To the extent a response is required, however, Sigmapharm states that it has not infringed any

valid claim of the patents asserted in the Complaint, and otherwise denies the allegations of this paragraph.

39. This paragraph contains Plaintiffs' characterization of Sigmapharm's March 20, 2018, notice letter, to which no response is required. Sigmapharm's notice letter speaks for itself. To the extent a response is required, however, Sigmapharm states that it has not infringed any valid claim of the patents asserted in the Complaint, and otherwise denies the allegations of this paragraph.

40. This paragraph contains Plaintiffs' speculation as to the outcome of future events, to which no response is required. To the extent a response is required, however, Sigmapharm states that the indication set forth in ANDA No. 211084 for the drug product described therein is the treatment of major depressive disorder. Sigmapharm denies the remaining allegations of this paragraph.

41. This paragraph contains Plaintiffs' speculation as to the outcome of future events, to which no response is required. To the extent a response is required, however, Sigmapharm denies the allegations of this paragraph, and specifically denies infringing any valid claim of the patents asserted in the Complaint.

42. Denied.

43. Sigmapharm states that the Notice Letter was dated March 20, 2018. Sigmapharm further states, upon information and belief, that Plaintiffs filed (but did not serve) the Complaint on May 3, 2018. Sigmapharm reserves the right to challenge Plaintiffs' stated entitlement to a stay of FDA approval. Sigmapharm otherwise denies any remaining allegations of this paragraph.

COUNT I
ALLEGED INFRINGEMENT OF THE '884 PATENT

44. Sigmapharm restates, realleges, and incorporates by reference its responses to paragraphs 1-43 as if fully set forth herein.

45. Admitted.

46. Sigmapharm lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

47. Sigmapharm denies infringing any valid claim of the '884 patent. Sigmapharm otherwise denies any remaining allegations of this paragraph.

48. This paragraph contains Plaintiffs' characterization of Sigmapharm's March 20, 2018 notice letter, to which no response is required. Sigmapharm's notice letter speaks for itself. To the extent a response is required, however, Sigmapharm states that it has not infringed any valid claim of the patents asserted in the Complaint, and otherwise denies the allegations of this paragraph.

49. Sigmapharm admits that it submitted ANDA No. 211084 with a Paragraph IV certification, and that, under 35 U.S.C. § 271(e)(2)(A), the mere submission of an application under § 505(j) of the Federal Food, Drug, and Cosmetic Act constitutes an artificial act of infringement for the sole purpose of establishing subject matter jurisdiction for this declaratory judgment action. Sigmapharm denies the remaining allegations of this paragraph, and specifically denies infringing any valid claim of the patents asserted in the Complaint.

50. Denied.

51. Denied.

52. Denied.

53. Denied.

54. Denied.

55. Denied.

COUNT II
ALLEGED INFRINGEMENT OF THE ’279 PATENT

56. Sigmapharm restates, realleges, and incorporates by reference its responses to paragraphs 1-55 as if fully set forth herein.

57. Admitted.

58. Sigmapharm lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

59. Sigmapharm denies infringing any valid claim of the ’279 patent. Sigmapharm otherwise denies any remaining allegations of this paragraph.

60. This paragraph contains Plaintiffs’ speculation as to the outcome of future events, to which no response is required. To the extent a response is required, however, Sigmapharm states that the indication set forth in ANDA No. 211084 for the drug product described therein is the treatment of major depressive disorder. Sigmapharm denies any remaining allegations of this paragraph.

61. This paragraph contains Plaintiffs’ characterization of Sigmapharm’s March 20, 2018, notice letter, to which no response is required. Sigmapharm’s notice letter speaks for itself. To the extent a response is required, however, Sigmapharm states that it has not infringed any valid claim of the patents asserted in the Complaint, and otherwise denies the allegations of this paragraph.

62. Sigmapharm admits that it submitted ANDA No. 211084 with a Paragraph IV certification, and that, under 35 U.S.C. § 271(e)(2)(A), the mere submission of an application under § 505(j) of the Federal Food, Drug, and Cosmetic Act constitutes an artificial act of

infringement for the sole purpose of establishing subject matter jurisdiction for this declaratory judgment action. Sigmapharm denies the remaining allegations of this paragraph, and specifically denies infringing any valid claim of the patents asserted in the Complaint.

63. Denied.

64. Denied.

65. Denied.

66. Denied.

67. Denied.

68. Denied.

COUNT III
ALLEGED INFRINGEMENT OF THE '684 PATENT

69. Sigmapharm restates, realleges, and incorporates by reference its responses to paragraphs 1-68 as if fully set forth herein.

70. Admitted.

71. Sigmapharm lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

72. Sigmapharm denies infringing any valid claim of the '684 patent. Sigmapharm otherwise denies any remaining allegations of this paragraph.

73. This paragraph contains Plaintiffs' characterization of Sigmapharm's March 20, 2018, notice letter, to which no response is required. Sigmapharm's notice letter speaks for itself. To the extent a response is required, however, Sigmapharm states that it has not infringed any valid claim of the patents asserted in the Complaint, and otherwise denies the allegations of this paragraph.

74. Sigmapharm admits that it submitted ANDA No. 211084 with a Paragraph IV certification, and that, under 35 U.S.C. § 271(e)(2)(A), the mere submission of an application under § 505(j) of the Federal Food, Drug, and Cosmetic Act constitutes an artificial act of infringement for the sole purpose of establishing subject matter jurisdiction for this declaratory judgment action. Sigmapharm denies the remaining allegations of this paragraph, and specifically denies infringing any valid claim of the patents asserted in the Complaint.

75. Denied.

76. Denied.

77. Denied.

78. Denied.

79. Denied.

80. Denied.

COUNT IV
ALLEGED INFRINGEMENT OF THE ’355 PATENT

81. Sigmapharm restates, realleges, and incorporates by reference its responses to paragraphs 1-80 as if fully set forth herein.

82. Admitted.

83. Sigmapharm lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

84. Sigmapharm denies infringing any valid claim of the ’355 patent. Sigmapharm otherwise denies any remaining allegations of this paragraph.

85. This paragraph contains Plaintiffs’ speculation as to the outcome of future events, to which no response is required. To the extent a response is required, however, Sigmapharm states that the indication set forth in ANDA No. 211084 for the drug product described therein is

the treatment of major depressive disorder. Sigmapharm denies any remaining allegations of this paragraph.

86. This paragraph contains Plaintiffs' characterization of Sigmapharm's March 20, 2018, notice letter, to which no response is required. Sigmapharm's notice letter speaks for itself. To the extent a response is required, however, Sigmapharm states that it has not infringed any valid claim of the patents asserted in the Complaint, and otherwise denies the allegations of this paragraph.

87. Sigmapharm admits that it submitted ANDA No. 211084 with a Paragraph IV certification, and that, under 35 U.S.C. § 271(e)(2)(A), the mere submission of an application under § 505(j) of the Federal Food, Drug, and Cosmetic Act constitutes an artificial act of infringement for the sole purpose of establishing subject matter jurisdiction for this declaratory judgment action. Sigmapharm denies the remaining allegations of this paragraph, and specifically denies infringing any valid claim of the patents asserted in the Complaint.

88. Denied.

89. Denied.

90. Denied.

91. Denied.

92. Denied.

93. Denied.

COUNT V
ALLEGED INFRINGEMENT OF THE '946 PATENT

94. Sigmapharm restates, realleges, and incorporates by reference its responses to paragraphs 1-93 as if fully set forth herein.

95. Admitted.

96. Sigmapharm lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

97. Sigmapharm denies infringing any valid claim of the '946 patent. Sigmapharm otherwise denies any remaining allegations of this paragraph.

98. This paragraph contains Plaintiffs' speculation as to the outcome of future events, to which no response is required. To the extent a response is required, however, Plaintiff states that the indication set forth in ANDA No. 211084 for the drug product described therein is the treatment of major depressive disorder. Sigmapharm denies any remaining allegations of this paragraph.

99. This paragraph contains Plaintiffs' characterization of Sigmapharm's March 20, 2018, notice letter, to which no response is required. Sigmapharm's notice letter speaks for itself. To the extent a response is required, however, Sigmapharm states that it has not infringed any valid claim of the patents asserted in the Complaint, and otherwise denies the allegations of this paragraph.

100. Sigmapharm admits that it submitted ANDA No. 211084 with a Paragraph IV certification, and that, under 35 U.S.C. § 271(e)(2)(A), the mere submission of an application under § 505(j) of the Federal Food, Drug, and Cosmetic Act constitutes an artificial act of infringement for the sole purpose of establishing subject matter jurisdiction for this declaratory judgment action. Sigmapharm denies the remaining allegations of this paragraph, and specifically denies infringing any valid claim of the patents asserted in the Complaint.

101. Denied.

102. Denied.

103. Denied.

104. Denied.

105. Denied.

106. Denied.

COUNT VI
ALLEGED INFRINGEMENT OF THE '630 PATENT

107. Sigmapharm restates, realleges, and incorporates by reference its responses to paragraphs 1-106 as if fully set forth herein.

108. Admitted.

109. Sigmapharm lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

110. Sigmapharm denies infringing any valid claim of the '630 patent. Sigmapharm otherwise denies any remaining allegations of this paragraph.

111. This paragraph contains Plaintiffs' speculation as to the outcome of future events, to which no response is required. To the extent a response is required, however, Sigmapharm states that the indication set forth in ANDA No. 211084 for the drug product described therein is the treatment of major depressive disorder. Sigmapharm denies any remaining allegations of this paragraph.

112. This paragraph contains Plaintiffs' characterization of Sigmapharm's March 20, 2018, notice letter, to which no response is required. Sigmapharm's notice letter speaks for itself. To the extent a response is required, however, Sigmapharm states that it has not infringed any valid claim of the patents asserted in the Complaint, and otherwise denies the allegations of this paragraph.

113. Sigmapharm admits that it submitted ANDA No. 211084 with a Paragraph IV certification, and that, under 35 U.S.C. § 271(e)(2)(A), the mere submission of an application

under § 505(j) of the Federal Food, Drug, and Cosmetic Act constitutes an artificial act of infringement for the sole purpose of establishing subject matter jurisdiction for this declaratory judgment action. Sigmapharm denies the remaining allegations of this paragraph, and specifically denies infringing any valid claim of the patents asserted in the Complaint.

114. Denied.

115. Denied.

116. Denied.

117. Denied.

118. Denied.

119. Denied.

REQUEST FOR RELIEF

Wherefore, Sigmapharm:

1. Denies that Plaintiffs are entitled to any relief;

2. Denies that Plaintiffs are entitled to the relief stated in Plaintiffs' prayer for relief;

3. Prays for an entry of judgment in favor of Sigmapharm and against Plaintiffs, and for dismissal with prejudice of this action; and

4. Prays for any such other and further relief as to which the Court concludes Sigmapharm is entitled, including relief under 35 U.S.C. § 285.

AFFIRMATIVE DEFENSES

Further answering the Complaint, Sigmapharm asserts the following defenses in response to the allegations of the Complaint, undertaking the burden of proof only as to those defenses required by law, regardless of how such defenses are denominated below. Sigmapharm reserves the right to amend this Answer with additional defenses as further information is obtained.

FIRST AFFIRMATIVE DEFENSE

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

To the extent that Plaintiffs allege that submission of Sigmapharm's ANDA makes this case an exceptional case under 35 U.S.C. § 285, the Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

The claims of the '884, '279, '684, '355, '946, and '630 patents are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 135, 256, and 287, or other judicially-created bases for invalidation and unenforceability including, at least, non-statutory double patenting.

FOURTH AFFIRMATIVE DEFENSE

The manufacture, use, sale, offer for sale, or importation of Sigmapharm's proposed ANDA products that are the subject of ANDA No. 211084 will not infringe, directly or indirectly, any valid and/or enforceable claims of the '884, '279, '684, '355, '946, and '630 patents, either literally or under the doctrine of equivalents.

FIFTH AFFIRMATIVE DEFENSE

Any claim of infringement of the patents-in-suit under the doctrine of equivalents would be precluded by prosecution history estoppel.

SIXTH AFFIRMATIVE DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

SEVENTH AFFIRMATIVE DEFENSE

Sigmapharm has not infringed, and is not infringing, directly or indirectly, any valid claim of the patents-in-suit, and all activities Sigmapharm has performed or is performing in relation to Sigmapharm's ANDA products have solely been for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

RESERVATION OF RIGHTS

Sigmapharm reserves the right to assert or plead any additional affirmative defenses, the availability of which may arise or become known throughout the course of this legal action.

COUNTERCLAIMS

Sigmapharm Laboratories, LLC ("Sigmapharm" or "Counterclaim-Plaintiff"), by way of counterclaim against H. Lundbeck A/S ("Lundbeck"), Takeda Pharmaceutical Company Ltd. ("Takeda Japan"), Takeda Pharmaceuticals U.S.A., Inc. ("Takeda USA"), Takeda Pharmaceuticals International AG ("Takeda International"), and Takeda Pharmaceuticals America, Inc. ("Takeda America") (collectively, "Counterclaim-Defendants"), alleges as follows:

THE PARTIES

1. Sigmapharm is a corporation organized and existing under the laws of Pennsylvania. Sigmapharm has its principal place of business at 3375 Progress Drive, Bensalem, Pennsylvania 19020.

2. Sigmapharm filed ANDA No. 211084 with FDA pursuant to 21 U.S.C. § 355(j) to obtain approval to market 5 mg, 10 mg, and 20 mg tablets containing vortioxetine hydrobromide. ("Sigmapharm's ANDA Products").

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

4. Upon information and belief, Takeda Pharmaceutical Company 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.

5. Upon information and belief, Takeda Pharmaceuticals International AG is a corporation organized and existing under the laws of Switzerland, with a place of business at Thurgauerstrasse 130, 8152 Glattpark-Opfikon, Zurich, Switzerland.

6. Upon information and belief, Takeda Pharmaceuticals U.S.A., Inc. 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.

7. In this lawsuit, Counterclaim-Defendants have alleged in their Complaint that they own all rights, title, and interest in and to United States Patent No. 7,144,884 ("the '884 patent"); United States Patent No. 8,476,279 ("the '279 patent"); 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").

8. In this lawsuit, Counterclaim-Defendants have alleged that the products described in Sigmapharm's ANDA No. 211084 would, if marketed, infringe one of more claims of the '884, '279, '684, '355, '946, and '630 patents.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that the counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, as well as 28 U.S.C. §§ 2201 and 2202.

10. This Court may declare the rights and other legal relations of the parties involved pursuant to 28 U.S.C. §§ 2201 and 2202 because this action is based on a case of actual controversy within the Court's jurisdiction seeking a declaratory judgment that the manufacture, use, offer for sale, sale, and/or importation of the products described in Sigmapharm's ANDA No. 211084 would not infringe the claims of the '884, '279, '684, '355, '946, or '630 patents.

11. This Court has personal jurisdiction over Counterclaim-Defendants at least by virtue of Counterclaim-Defendants having filed this lawsuit in this District.

12. Pursuant to the parties' agreement and solely for the purposes of this action, venue for these counterclaims is proper within this district.

FACTUAL BACKGROUND

A. FDA Approval of New Brand Name Drugs.

13. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

14. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355.

15. An NDA must include, among other things, the number of any patent that allegedly claims the "drug" or "a method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b)(1), -(c)(2).

16. Upon approval of an NDA, FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 C.F.R. § 314.53(e).

17. FDA's duties with respect to Orange Book listings are purely ministerial. If the NDA holder submits a patent to FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(l); 21 C.F.R. § 314.53(e)-(f). FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

B. FDA Approval of New Generic Drugs.

18. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

19. Under the Hatch-Waxman Amendments, a generic manufacturer submits to FDA what is called an Abbreviated New Drug Application ("ANDA").

20. Among other things, an ANDA must also contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j))(2)(A)(vii); 21 C.F.R. §314.94(a)(12).

21. A "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to the patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

22. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of each of its paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

23. Upon receiving notice of the paragraph IV certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

24. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the paragraph IV certifications, because doing so, regardless of merit, prevents FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions requiring court action. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

25. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, FDA will not approve the ANDA until the patent expires. *Id.* If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

C. Sigmapharm's ANDA and Counterclaim-Defendants' Complaint.

26. Sigmapharm filed ANDA No. 211084 seeking FDA approval for Sigmapharm's ANDA Products.

27. Counterclaim-Defendant Takeda USA alleges that it is the holder of NDA No. 204447 for TRINTELLIX® tablets (5 mg, 10 mg, and 20 mg dosage strengths).

28. Counterclaim-Defendants allege that they are the owners of the '884, '279, '684, '355, '946, and '630 patents, which are listed in the Orange Book in connection with NDA No. 204447.

29. Sigmapharm's ANDA No. 211084 includes paragraph IV certifications to the '884, '279, '684, '355, '946, and '630 patents.

30. On March 20, 2018, Sigmapharm sent to Counterclaim-Defendants a statutorily-required notice letter of its paragraph IV certifications, which contained a detailed factual and legal statement as to why the '884, '279, '684, '355, '946, and '630 patents are invalid, unenforceable, and/or not infringed by Sigmapharm's ANDA Products.

31. In their Complaint, Counterclaim-Defendants have alleged that Sigmapharm has infringed the '884, '279, '684, '355, '946, and '630 patents by filing ANDA No. 211084 with FDA, and will infringe the '884, '279, '684, '355, '946, and '630 patents by manufacturing, using, offering for sale, selling or importing the products described in that ANDA.

32. As a consequence of the foregoing, there is an actual and justiciable controversy between Sigmapharm and Counterclaim-Defendants as to whether the claims of the '884, '279, '684, '355, '946, and '630 patents are invalid and/or unenforceable, and whether those claims are being infringed by Sigmapharm's ANDA No. 211084, or will be infringed by the manufacture, use, sale, offer for sale, and/or importation of the products described therein.

FIRST COUNT
(Declaration of Non-Infringement of the '884 Patent)

33. Sigmapharm re-alleges and incorporates by reference the allegations in Paragraphs 1 through 32 of these Counterclaims, and Paragraphs 1 through 119 of this Answer.

34. The manufacture, use, offer for sale and/or importation into the United States of the products covered by Sigmapharm's ANDA No. 211084 would not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '884 patent, either literally or under the doctrine of equivalents.

SECOND COUNT
(Declaration of Invalidity of the '884 Patent)

35. Sigmapharm re-alleges and incorporates by reference the allegations in Paragraphs 1 through 34 of these Counterclaims, and Paragraphs 1 through 119 of this Answer.

36. The claims of the '884 patent are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 135, 256, and 287, or other judicially-created bases for invalidation and unenforceability including, at least, non-statutory double patenting.

37. By way of example, the claims of the '884 patent are invalid for failing to comply with the conditions for patentability under 35 U.S.C. §§ 102 and/or 103 in view of one or more of the following prior art references, alone or in combination with other prior art: European Patent App. Pub. No. EP 0 301 549; V.J. Nickolson & J.H. Wieringa, "Presynaptic α-block and inhibition of noradrenaline and 5-hydroxytryptamine reuptake by a series of compounds related to mianserin," *Journal of Pharmacy and Pharmacology* 33, no. 1 (1981): 760- 766; S.H. Wong, et al., "Liquid-chromatographic determination of two antidepressants, trazodone and mianserin, in plasma," *Clinical Chemistry* 30, no. 2 (1984): 230- 233; and/or International App. Pub. No. WO 00/76984 A2 (Dec. 21, 2000).

38. Additionally or in the alternative, and by way of example, the claims of the '884 patent are further invalid under 35 U.S.C. § 112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and/or (3) failing to comply with the "definiteness" requirement. To the extent that the '884 patent claims could be construed as covering Sigmapharm's ANDA Product, the claims: (1) do not satisfy the written description requirement because the specification fails to describe what is claimed in sufficient detail that those skilled in the art could conclude that the inventors were in possession of the claimed invention as of the filing date; (2) do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation; and/or (3) do not satisfy the definiteness requirement because the claims, viewed in light of the specification and prosecution history, do not inform those skilled in the art about the scope of the invention with reasonable certainty.

39. Sigmapharm reserves the right to provide additional bases for invalidity of the '884 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

40. Sigmapharm is entitled to a declaration that each claim of the '884 patent is invalid.

THIRD COUNT
(Declaration of Non-Infringement of the '279 Patent)

41. Sigmapharm re-alleges and incorporates by reference the allegations in Paragraphs 1 through 40 of these Counterclaims, and Paragraphs 1 through 119 of this Answer.

42. The manufacture, use, offer for sale and/or importation into the United States of the products covered by Sigmapharm's ANDA No. 211084 would not directly infringe,

indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the ’279 patent, either literally or under the doctrine of equivalents.

FOURTH COUNT
(Declaration of Invalidity of the ’279 Patent)

43. Sigmapharm re-alleges and incorporates by reference the allegations in Paragraphs 1 through 42 of these Counterclaims, and Paragraphs 1 through 119 of this Answer.

44. The claims of the ’279 patent are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 135, 256, and 287, or other judicially-created bases for invalidation and unenforceability including, at least, non-statutory double patenting.

45. By way of example, the claims of the ’279 patent are invalid for failing to comply with the conditions for patentability under 35 U.S.C. §§ 102 and/or 103 in view of one or more of the following prior art references, alone or in combination with other prior art: European Patent App. Pub. No. EP 0 301 549; V.J. Nickolson & J.H. Wieringa, “Presynaptic α-block and inhibition of noradrenaline and 5-hydroxytryptamine reuptake by a series of compounds related to mianserin,” *Journal of Pharmacy and Pharmacology* 33, no. 1 (1981): 760- 766; S.H. Wong, et al., “Liquid-chromatographic determination of two antidepressants, trazodone and mianserin, in plasma,” *Clinical Chemistry* 30, no. 2 (1984): 230- 233; and/or International App. Pub. No. WO 00/76984 A2 (Dec. 21, 2000).

46. Additionally or in the alternative, and by way of example, the claims of the ’279 patent are further invalid under 35 U.S.C. § 112 for (1) failing to comply with the “written description” requirement, (2) failing to comply with the “enablement” requirement, and/or (3) failing to comply with the “definiteness” requirement. To the extent that the ’279 patent claims could be construed as covering Sigmapharm’s ANDA Product, the claims: (1) do not satisfy the

written description requirement because the specification fails to describe what is claimed in sufficient detail that those skilled in the art could conclude that the inventors were in possession of the claimed invention as of the filing date; (2) do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation; and/or (3) do not satisfy the definiteness requirement because the claims, viewed in light of the specification and prosecution history, do not inform those skilled in the art about the scope of the invention with reasonable certainty.

47. Sigmapharm reserves the right to provide additional bases for invalidity of the ’279 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

48. Sigmapharm is entitled to a declaration that each claim of the ’279 patent is invalid.

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

49. Sigmapharm re-alleges and incorporates by reference the allegations in Paragraphs 1 through 48 of these Counterclaims, and Paragraphs 1 through 119 of this Answer.

50. The manufacture, use, offer for sale and/or importation into the United States of the products covered by Sigmapharm’s ANDA No. 211084 would not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the ’684 patent, either literally or under the doctrine of equivalents.

SIXTH COUNT
(Declaration of Invalidity of the ’684 Patent)

51. Sigmapharm re-alleges and incorporates by reference the allegations in Paragraphs 1 through 50 of these Counterclaims, and Paragraphs 1 through 119 of this Answer.

52. The claims of the ’684 patent are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 135, 256, and 287, or other judicially-created bases for invalidation and unenforceability including, at least, non-statutory double patenting.

53. By way of example, the claims of the ’684 patent are invalid for failing to comply with the conditions for patentability under 35 U.S.C. §§ 102 and/or 103 in view of one or more of the following prior art references, alone or in combination with other prior art: International Patent Application Publication No. WO 03/029232; Brittain, POLYMORPHISM PHARMACEUTICAL SOLIDS (1999); Berge et al., *Pharmaceutical Salts*, J. PHARM. SCI. 66(1):1–19 (Jan. 1977); Stahl, *Preparation of Water-Soluble Compounds Through Salt Formation*, THE PRACTICE OF MEDICINAL CHEMISTRY (2d ed., 2003), pp. 601-15; Gould, *Salt Selection for Basic Drugs*, INT. J. PHARM. 33:201-17 (1986); Mullin, CRYSTALLIZATION (Elsevier, 4th ed.) (2001); Raw et al., *Regulatory Considerations of Pharmaceutical Solid Polymorphism in Abbreviated New Drug Applications*, ADV. DRUG DELIV. REV. 56:397-414 (2004); Morrisette et al., *High throughput Crystallization: Polymorphs, Salts, Co-crystals and Solvates of Pharmaceutical Solids*, ADV. DRUG DELIV. REV. 56:277 (2004); FEDERAL DRUG ADMINISTRATION, DRAFT GUIDANCE FOR INDUSTRY, ANDAS: PHARMACEUTICAL SOLID POLYMORPHISM (Dec. 2004); Hilfiker, POLYMORPHISM IN THE PHARMACEUTICAL INDUSTRY (May 2006); Hilfiker et al., *Polymorphism – Integrated Approach From High-Throughput Screening to Crystallization Optimization*, J THERM ANAL CAL. 73:429-40 (2003); U.S. Patent Application Publication No. 2003/0116497; Wade and Weller, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS,

72 (2d ed. 1994); and/or Ansel et al., PHARMACEUTICAL DOSAGE FORMS AND DRUG DELIVERY SYSTEMS 60-61, 224 (1999).

54. Additionally or in the alternative, and by way of example, the claims of the '684 patent are further invalid under 35 U.S.C. § 112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and/or (3) failing to comply with the "definiteness" requirement. To the extent that the '684 patent claims could be construed as covering Sigmapharm's ANDA Product, the claims: (1) do not satisfy the written description requirement because the specification fails to describe what is claimed in sufficient detail that those skilled in the art could conclude that the inventors were in possession of the claimed invention as of the filing date; (2) do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation; and/or (3) do not satisfy the definiteness requirement because the claims, viewed in light of the specification and prosecution history, do not inform those skilled in the art about the scope of the invention with reasonable certainty.

55. Sigmapharm reserves the right to provide additional bases for invalidity of the '684 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

56. Sigmapharm is entitled to a declaration that each claim of the '684 patent is invalid.

SEVENTH COUNT
(Declaration of Non-Infringement of the '355 Patent)

57. Sigmapharm re-alleges and incorporates by reference the allegations in Paragraphs 1 through 56 of these Counterclaims, and Paragraphs 1 through 119 of this Answer.

58. The manufacture, use, offer for sale and/or importation into the United States of the products covered by Sigmapharm's ANDA No. 211084 would not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '355 patent, either literally or under the doctrine of equivalents.

EIGHTH COUNT
(Declaration of Invalidity of the '355 Patent)

59. Sigmapharm re-alleges and incorporates by reference the allegations in Paragraphs 1 through 58 of these Counterclaims, and Paragraphs 1 through 119 of this Answer.

60. The claims of the '355 patent are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 135, 256, and 287, or other judicially-created bases for invalidation and unenforceability including, at least, non-statutory double patenting.

61. By way of example, the claims of the '355 patent are invalid for failing to comply with the conditions for patentability under 35 U.S.C. §§ 102 and/or 103 in view of one or more of the following prior art references, alone or in combination with other prior art: International Patent Application Publication No. WO 03/029232; Brittain, POLYMORPHISM PHARMACEUTICAL SOLIDS (1999); Berge et al., *Pharmaceutical Salts*, J. PHARM. SCI. 66(1):1–19 (Jan. 1977); Stahl, *Preparation of Water-Soluble Compounds Through Salt Formation*, THE PRACTICE OF MEDICINAL CHEMISTRY (2d ed., 2003), pp. 601-15; Gould, *Salt Selection for Basic Drugs*, INT. J. PHARM. 33:201-17 (1986); Mullin, CRYSTALLIZATION (Elsevier, 4th ed.) (2001); Raw et al., *Regulatory Considerations of Pharmaceutical Solid Polymorphism in Abbreviated New Drug Applications*, ADV. DRUG DELIV. REV. 56:397-414 (2004); Morrisette et al., *High throughput Crystallization: Polymorphs, Salts, Co-crystals and Solvates of Pharmaceutical Solids*, ADV. DRUG DELIV.

REV. 56:277 (2004); FEDERAL DRUG ADMINISTRATION, DRAFT GUIDANCE FOR INDUSTRY, ANDAS: PHARMACEUTICAL SOLID POLYMORPHISM (Dec. 2004); Hilfiker, POLYMORPHISM IN THE PHARMACEUTICAL INDUSTRY (May 2006); Hilfiker et al., *Polymorphism – Integrated Approach From High-Throughput Screening to Crystallization Optimization*, J THERM ANAL CAL. 73:429-40 (2003); U.S. Patent Application Publication No. 2003/0116497; Wade and Weller, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS, 72 (2d ed. 1994); and/or Ansel et al., PHARMACEUTICAL DOSAGE FORMS AND DRUG DELIVERY SYSTEMS 60-61, 224 (1999).

62. Additionally or in the alternative, and by way of example, the claims of the ’355 patent are further invalid under 35 U.S.C. § 112 for (1) failing to comply with the “written description” requirement, (2) failing to comply with the “enablement” requirement, and/or (3) failing to comply with the “definiteness” requirement. To the extent that the ’355 patent claims could be construed as covering Sigmapharm’s ANDA Product, the claims: (1) do not satisfy the written description requirement because the specification fails to describe what is claimed in sufficient detail that those skilled in the art could conclude that the inventors were in possession of the claimed invention as of the filing date; (2) do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation; and/or (3) do not satisfy the definiteness requirement because the claims, viewed in light of the specification and prosecution history, do not inform those skilled in the art about the scope of the invention with reasonable certainty.

63. Sigmapharm reserves the right to provide additional bases for invalidity of the ’355 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

64. Sigmapharm is entitled to a declaration that each claim of the ’355 patent is invalid.

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

65. Sigmapharm re-alleges and incorporates by reference the allegations in Paragraphs 1 through 64 of these Counterclaims, and Paragraphs 1 through 119 of this Answer.

66. The manufacture, use, offer for sale and/or importation into the United States of the products covered by Sigmapharm’s ANDA No. 211084 would not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the ’946 patent, either literally or under the doctrine of equivalents.

TENTH COUNT
(Declaration of Invalidity of the ’946 Patent)

67. Sigmapharm re-alleges and incorporates by reference the allegations in Paragraphs 1 through 66 of these Counterclaims, and Paragraphs 1 through 119 of this Answer.

68. The claims of the ’946 patent are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 135, 256, and 287, or other judicially-created bases for invalidation and unenforceability including, at least, non-statutory double patenting.

69. By way of example, the claims of the ’946 patent are invalid for failing to comply with the conditions for patentability under 35 U.S.C. §§ 102 and/or 103 in view of one or more of the following prior art references, alone or in combination with other prior art: International Patent Application Publication No. WO 03/029232; Brittain, POLYMORPHISM

PHARMACEUTICAL SOLIDS (1999); Berge et al., *Pharmaceutical Salts*, J. PHARM. SCI. 66(1):1–19 (Jan. 1977); Stahl, *Preparation of Water-Soluble Compounds Through Salt Formation*, THE PRACTICE OF MEDICINAL CHEMISTRY (2d ed., 2003), pp. 601-15; Gould, *Salt Selection for Basic Drugs*, INT. J. PHARM. 33:201-17 (1986); Mullin, CRYSTALLIZATION (Elsevier, 4th ed.) (2001); Raw et al., *Regulatory Considerations of Pharmaceutical Solid Polymorphism in Abbreviated New Drug Applications*, ADV. DRUG DELIV. REV. 56:397-414 (2004); Morrisette et al., *High throughput Crystallization: Polymorphs, Salts, Co-crystals and Solvates of Pharmaceutical Solids*, ADV. DRUG DELIV. REV. 56:277 (2004); FEDERAL DRUG ADMINISTRATION, DRAFT GUIDANCE FOR INDUSTRY, ANDAS: PHARMACEUTICAL SOLID POLYMORPHISM (Dec. 2004); Hilfiker, POLYMORPHISM IN THE PHARMACEUTICAL INDUSTRY (May 2006); Hilfiker et al., *Polymorphism – Integrated Approach From High-Throughput Screening to Crystallization Optimization*, J THERM ANAL CAL. 73:429-40 (2003); U.S. Patent Application Publication No. 2003/0116497; Wade and Weller, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS, 72 (2d ed. 1994); and/or Ansel et al., PHARMACEUTICAL DOSAGE FORMS AND DRUG DELIVERY SYSTEMS 60-61, 224 (1999).

70. Additionally or in the alternative, and by way of example, the claims of the ’946 patent are further invalid under 35 U.S.C. § 112 for (1) failing to comply with the “written description” requirement, (2) failing to comply with the “enablement” requirement, and/or (3) failing to comply with the “definiteness” requirement. To the extent that the ’946 patent claims could be construed as covering Sigmapharm’s ANDA Product, the claims: (1) do not satisfy the written description requirement because the specification fails to describe what is claimed in sufficient detail that those skilled in the art could conclude that the inventors were in possession

of the claimed invention as of the filing date; (2) do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation; and/or (3) do not satisfy the definiteness requirement because the claims, viewed in light of the specification and prosecution history, do not inform those skilled in the art about the scope of the invention with reasonable certainty.

71. Sigmapharm reserves the right to provide additional bases for invalidity of the ’946 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

72. Sigmapharm is entitled to a declaration that each claim of the ’946 patent is invalid.

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

73. Sigmapharm re-alleges and incorporates by reference the allegations in Paragraphs 1 through 72 of these Counterclaims, and Paragraphs 1 through 119 of this Answer.

74. The manufacture, use, offer for sale and/or importation into the United States of the products covered by Sigmapharm’s ANDA No. 211084 would not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the ’630 patent, either literally or under the doctrine of equivalents.

TWELFTH COUNT
(Declaration of Invalidity of the ’630 Patent)

75. Sigmapharm re-alleges and incorporates by reference the allegations in Paragraphs 1 through 74 of these Counterclaims, and Paragraphs 1 through 119 of this Answer.

76. The claims of the ’630 patent are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of

§§ 101, 102, 103, 111, 112, 116, 135, 256, and 287, or other judicially-created bases for invalidation and unenforceability including, at least, non-statutory double patenting.

77. By way of example, the claims of the ’630 patent are invalid for failing to comply with the conditions for patentability under 35 U.S.C. §§ 102 and/or 103 in view of one or more of the following prior art references, alone or in combination with other prior art: International Patent Application Publication No. WO 03/029232; Brittain, POLYMORPHISM PHARMACEUTICAL SOLIDS (1999); Berge et al., *Pharmaceutical Salts*, J. PHARM. SCI. 66(1):1–19 (Jan. 1977); Stahl, *Preparation of Water-Soluble Compounds Through Salt Formation*, THE PRACTICE OF MEDICINAL CHEMISTRY (2d ed., 2003), pp. 601-15; Gould, *Salt Selection for Basic Drugs*, INT. J. PHARM. 33:201-17 (1986); Mullin, CRYSTALLIZATION (Elsevier, 4th ed.) (2001); Raw et al., *Regulatory Considerations of Pharmaceutical Solid Polymorphism in Abbreviated New Drug Applications*, ADV. DRUG DELIV. REV. 56:397-414 (2004); Morrisette et al., *High throughput Crystallization: Polymorphs, Salts, Co-crystals and Solvates of Pharmaceutical Solids*, ADV. DRUG DELIV. REV. 56:277 (2004); FEDERAL DRUG ADMINISTRATION, DRAFT GUIDANCE FOR INDUSTRY, ANDAS: PHARMACEUTICAL SOLID POLYMORPHISM (Dec. 2004); Hilfiker, POLYMORPHISM IN THE PHARMACEUTICAL INDUSTRY (May 2006); Hilfiker et al., *Polymorphism – Integrated Approach From High-Throughput Screening to Crystallization Optimization*, J THERM ANAL CAL. 73:429-40 (2003); U.S. Patent Application Publication No. 2003/0116497; Wade and Weller, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS, 72 (2d ed. 1994); and/or Ansel et al., PHARMACEUTICAL DOSAGE FORMS AND DRUG DELIVERY SYSTEMS 60-61, 224 (1999).

78. Additionally or in the alternative, and by way of example, the claims of the '630 patent are further invalid under 35 U.S.C. § 112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and/or (3) failing to comply with the "definiteness" requirement. To the extent that the '630 patent claims could be construed as covering Sigmapharm's ANDA Product, the claims: (1) do not satisfy the written description requirement because the specification fails to describe what is claimed in sufficient detail that those skilled in the art could conclude that the inventors were in possession of the claimed invention as of the filing date; (2) do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation; and/or (3) do not satisfy the definiteness requirement because the claims, viewed in light of the specification and prosecution history, do not inform those skilled in the art about the scope of the invention with reasonable certainty.

79. Sigmapharm reserves the right to provide additional bases for invalidity of the '630 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

80. Sigmapharm is entitled to a declaration that each claim of the '630 patent is invalid.

PRAYER FOR RELIEF

WHEREFORE, Defendant and Counterclaim-Plaintiff Sigmapharm Laboratories, LLC respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs and Counterclaim-Defendants as follows:

A. Dismissing the Complaint, and each and every paragraph within Counterclaim-Defendants' Prayer for Relief, with prejudice;

B. Declaring that Sigmapharm has not infringed and will not infringe any valid claim of the ’884, ’279, ’684, ’355, ’946, and ’630 patents;

C. Declaring that the claims of the ’884, ’279, ’684, ’355, ’946, and ’630 patents are invalid for failure to meet one or more of the requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, 112 and/or other judicially-created bases for invalidation and unenforceability;

D. Declaring that Counterclaim-Defendants and their respective officers, employees, agents, representatives, attorneys, and others acting on Counterclaim-Defendants’ behalf, from representing to anyone, either directly or indirectly, that Sigmapharm’s ANDA Products have infringed, are infringing, or will infringe any claims of the ’884, ’279, ’684, ’355, ’946, and ’630 patents.

E. Finding that this case is exceptional under 35 U.S.C. § 285 and awarding Sigmapharm Laboratories, LLC its costs, expenses, and attorneys’ fees in this action; and

F. Awarding Sigmapharm Laboratories, LLC any further and additional relief as the Court deems just and proper.

Dated: May 23, 2018

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