IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, *et al.*, Plaintiffs, v. APICORE US LLC, Defendant.	C.A. No. 1:18-cv-01034-LPS

ANSWER AND COUNTERCLAIMS OF
DEFENDANTS APICORE US LLC

Defendant Apicore US LLC ("Apicore"), by and through its undersigned attorneys, answer the averments made in the numbered paragraphs of the Complaint, dated July 12, 2018, ("Complaint") filed by 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, "Lundbeck and Takeda" or "Plaintiffs") as follows:

NATURE OF THE ACTION

1. Paragraph 1 contains conclusions of law to which no response is required. To the extent an answer is required, Apicore admits that the Complaint purports to state a cause of action under the United States patent laws, Title 35 of the United States Code.

THE PARTIES

2. Apicore is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 and therefore denies the same.

3. Apicore is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 and therefore denies the same.

4. Apicore is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4 and therefore denies the same.

5. Apicore is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5 and therefore denies the same.

6. Apicore is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 6 and therefore denies the same.

7. Apicore is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 7, and therefore denies the same.

8. Apicore admits the allegations of Paragraph 8.

9. Apicore admits that it submitted ANDA No. 210982 to the FDA. Apicore denies any remaining allegations in Paragraph 9.

10. Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, Apicore denies the allegations of Paragraph 10.

11. Apicore admits that it submitted Drug Master File ("DMF") 31759 to the FDA.

JURISDICTION AND VENUE

12. Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, Apicore admits that this action purports to state a cause of action under 35 U.S.C. § 271(e)(2)(A).

13. Paragraph 13 contains legal conclusions to which no response is required. To the extent a response is required, Apicore admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338.

14. Paragraph 14 contains legal conclusions to which no response is required. To the extent a response is required, Apicore does not contest personal jurisdiction solely for the purposes of this action. Apicore denies the remaining allegations in Paragraph 14 of the Complaint.

15. Apicore admits the allegations in paragraph 15.

16. Paragraph 16 contains legal conclusions to which no response is required. To the extent a response is required, Apicore denies the allegations in Paragraph 16.

17. Paragraph 17 contains legal conclusions to which no response is required. To the extent a response is required, Apicore denies the allegations in Paragraph 17.

18. Apicore admits that Apicore sent a Notice Letter pursuant to 21 U.S.C. § 355(j)(2)(B) to Lundbeck and Takeda USA. Apicore denies the remaining allegations in Paragraph 18.

19. Paragraph 19 contains legal conclusions to which no response is required. To the extent a response is required, Apicore denies the allegations in Paragraph 19.

20. Paragraph 20 contains legal conclusions to which no response is required. To the extent a response is required, Apicore denies the allegations in Paragraph 20.

21. Paragraph 21 contains legal conclusions to which no response is required. To the extent a response is required, Apicore does not contest venue in this judicial district for the purposes of this litigation only. Apicore denies the remaining allegations in Paragraph 21 of the Complaint.

PLAINTIFFS' APPROVED TRINTELLIX® DRUG PRODUCT AND PATENTS

22. Apicore admits that the electronic version of the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), identifies

Takeda USA as the purported holder of New Drug Application ("NDA") No. 204447 for TRINTELLIX® (vortioxetine hydrobromide). Apicore further admits that the Orange Book identifies the approval date of the 5 mg, 10 mg, 15 mg, and 20 mg dosage strengths as September 30, 2013. Apicore is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 22 of the Complaint, and therefore denies the same.

23. Apicore admits that the "Indication and Usage" section of the TRINTELLIX® label states that TRINTELLIX® is indicated for the treatment of Major Depressive Disorder (MDD). Apicore is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 23 of the Complaint, and therefore denies the same.

24. Apicore admits that 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") are listed in the Orange Book for TRINTELLIX®.

25. Apicore admits that the '884 Patent is entitled "Phenyl-piperazine Derivatives as Serotonin Reuptake Inhibitors" and bears an issue date of December 5, 2006. Apicore further admits that what purports to be a copy of the '844 patent was attached to the Complaint as Exhibit A.

26. Apicore admits that the '279 Patent is entitled "Phenyl-piperazine Derivatives as Serotonin Reuptake Inhibitors" and bears an issue date of July 2, 2013. Apicore further admits that what purports to be a copy of the '279 patent was attached to the Complaint as

Exhibit B.

27. Apicore admits that the ’684 Patent is entitled “1-[2-(2, 4-dimethylphenylsufanyl- phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment” and bears an issue date of May 13, 2014. Apicore further admits that what purports to be a copy of the ’684 patent was attached to the Complaint as Exhibit C.

28. Apicore admits that the ’355 Patent is entitled “1-[2-(2, 4-dimethylphenylsufanyl- phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment” and bears an issue date of March 3, 2015. Apicore further admits that what purports to be a copy of the ’355 patent was attached to the Complaint as Exhibit D.

29. Apicore admits that the ’946 Patent is entitled “1-[2-(2, 4-dimethylphenylsufanyl- phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment” and bears an issue date of January 5, 2016. Apicore further admits that what purports to be a copy of the ’946 patent was attached to the Complaint as Exhibit E.

30. Apicore admits that the ’630 Patent is entitled “1-[2-(2, 4-dimethylphenylsufanyl- phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment” and bears an issue date of January 9, 2018. Apicore further admits that what purports to be a copy of the ’630 patent was attached to the Complaint as Exhibit F.

APICORE’S ANDA NO. 210982

31. Apicore admits that Apicore filed ANDA No. 210982 under 21 U.S.C. § 355(j),

seeking FDA regulatory approval of its proposed vortioxetine hydrobromide tablets. Apicore denies the rest of the allegations of Paragraph 31.

32. Apicore admits the allegations of Paragraph 32.

33. Apicore admits that it sent a Notice Letter referencing the submission of ANDA No. 210982, which included a Paragraph IV certification to the '884, '279, '684, '355, and '946 patents. Apicore denies the rest of the allegations in Paragraph 33.

34. Paragraph 34 contains legal conclusions to which no response is required. To the extent a response is required, Apicore denies the allegations in Paragraph 34.

35. Apicore admits that it offered confidential access to portions of its ANDA No. 210982 on terms and conditions set forth in the Notice Letter. Apicore denies the rest of the allegations in Paragraph 35.

36. Apicore admits that on June 21, 2018, twenty days after receiving the Notice Letter, outside counsel for Plaintiffs sent correspondence to Apicore regarding Apicore's offer of confidential access to portions of the ANDA. Apicore denies the rest of the allegations of Paragraph 36.

37. Paragraph 37 contains legal conclusions to which no response is required.

38. Apicore denies the allegations of Paragraph 38.

39. Apicore denies the allegations of Paragraph 39.

40. Apicore denies the allegations of Paragraph 40.

41. Apicore denies the allegations of Paragraph 41.

42. Paragraph 42 contains legal conclusions to which no response is required. To the extent a response is required, Apicore denies the allegations in Paragraph 42.

COUNT I

ALLEGED INFRINGEMENT OF THE '884 PATENT

43. Paragraph 43 contains no allegations of fact to which a response is required. To the extent an answer is required, Apicore repeats and incorporates by reference paragraphs 1-42 of the Answer as if fully set forth herein.

44. Apicore admits that it filed ANDA No. 210982 to seek FDA regulatory approval. Apicore denies the remaining allegations in Paragraph 44.

45. Apicore is without knowledge sufficient to admit the allegations in Paragraph 45, and therefore denies the same.

46. Apicore denies the allegations in Paragraph 46.

47. Apicore denies the allegations in Paragraph 47.

48. Apicore denies the allegations in Paragraph 48.

49. Apicore denies the allegations in Paragraph 49.

50. Apicore denies the allegations in Paragraph 50.

51. Apicore denies the allegations in Paragraph 51.

52. Apicore denies the allegations in Paragraph 52.

53. Apicore denies the allegations in Paragraph 53.

54. Apicore denies the allegations in Paragraph 54.

COUNT II

ALLEGED INFRINGEMENT OF THE '279 PATENT

55. Paragraph 55 contains no allegations of fact to which a response is required. To the extent an answer is required, Apicore repeats and incorporates by reference paragraphs 1-54 of the Answer as if fully set forth herein.

56. Apicore admits that it filed ANDA No. 210982 to seek FDA regulatory approval. Apicore denies the remaining allegations in Paragraph 56.

57. Apicore is without knowledge sufficient to admit the allegations in Paragraph 57, and therefore denies the same.

58. Apicore denies the allegations of Paragraph 58.

59. Apicore denies the allegations of Paragraph 59.

60. Apicore denies the allegations of Paragraph 60.

61. Apicore denies the allegations of Paragraph 61.

62. Apicore denies the allegations of Paragraph 62.

63. Apicore denies the allegations of Paragraph 63.

64. Apicore denies the allegations of Paragraph 64.

65. Apicore denies the allegations of Paragraph 65.

66. Apicore denies the allegations of Paragraph 66.

67. Apicore denies the allegations of Paragraph 67.

COUNT III

ALLEGED INFRINGEMENT OF THE '684 PATENT

68. Paragraph 68 contains no allegations of fact to which a response is required. To the extent an answer is required, Apicore repeats and incorporates by reference paragraphs 1-67 of the Answer as if fully set forth herein.

69. Apicore admits that it filed ANDA No. 210982 to seek FDA regulatory approval. Apicore denies the remaining allegations in Paragraph 69.

70. Apicore is without knowledge sufficient to admit the allegations in Paragraph 70, and therefore denies the same.

71. Apicore denies the allegations of Paragraph 71.

72. Apicore denies the allegations of Paragraph 72.

73. Apicore denies the allegations of Paragraph 73.

74. Apicore denies the allegations of Paragraph 74.

75. Apicore denies the allegations of Paragraph 75.

76. Apicore denies the allegations of Paragraph 76.

77. Apicore denies the allegations of Paragraph 77.

78. Apicore denies the allegations of Paragraph 78.

COUNT IV

ALLEGED INFRINGEMENT OF THE '355 PATENT

79. Paragraph 79 contains no allegations of fact to which a response is required. To the extent an answer is required, Apicore repeats and incorporates by reference paragraphs 1-78 of the Answer as if fully set forth herein.

80. Apicore admits that it filed ANDA No. 210982 to seek FDA regulatory approval. Apicore denies the remaining allegations in Paragraph 80.

81. Apicore is without knowledge sufficient to admit the allegations in Paragraph 81, and therefore denies the same.

82. Apicore denies the allegations in Paragraph 82.

83. Apicore denies the allegations in Paragraph 83.

84. Apicore denies the allegations in Paragraph 84.

85. Apicore denies the allegations in Paragraph 85.

86. Apicore denies the allegations in Paragraph 86.

87. Apicore denies the allegations in Paragraph 87.

88. Apicore denies the allegations in Paragraph 88.

89. Apicore denies the allegations in Paragraph 89.

90. Apicore denies the allegations in Paragraph 90.

COUNT V

ALLEGED INFRINGEMENT OF THE '946 PATENT

91. Paragraph 91 contains no allegations of fact to which a response is required. To the extent an answer is required, Apicore repeats and incorporates by reference paragraphs 1-90 of the Answer as if fully set forth herein.

92. Apicore admits that it filed ANDA No. 210982 to seek FDA regulatory approval. Apicore denies the remaining allegations in Paragraph 92.

93. Apicore is without knowledge sufficient to admit the allegations in Paragraph 93, and therefore denies the same.

94. Apicore denies the allegations in Paragraph 94.

95. Apicore denies the allegations in Paragraph 95.

96. Apicore denies the allegations in Paragraph 96.

97. Apicore denies the allegations in Paragraph 97.

98. Apicore denies the allegations in Paragraph 98.

99. Apicore denies the allegations in Paragraph 99.

100. Apicore denies the allegations in Paragraph 100.

101. Apicore denies the allegations in Paragraph 101.

102. Apicore denies the allegations in Paragraph 102.

COUNT VI

ALLEGED INFRINGEMENT OF THE '630 PATENT

103. Paragraph 103 contains no allegations of fact to which a response is required. To the extent an answer is required, Apicore repeats and incorporates by reference paragraphs 1-102 of the Answer as if fully set forth herein.

104. Apicore admits that it filed ANDA No. 210982 to seek FDA regulatory approval. Apicore denies the remaining allegations in Paragraph 104.

105. Apicore is without knowledge sufficient to admit the allegations in Paragraph 105, and therefore denies the same.

106. Apicore denies the allegations in Paragraph 106.

107. Apicore denies the allegations in Paragraph 107.

108. Apicore denies the allegations in Paragraph 108.

109. Apicore denies the allegations in Paragraph 109.

110. Apicore denies the allegations in Paragraph 110.

111. Apicore denies the allegations in Paragraph 111.

112. Apicore denies the allegations in Paragraph 112.

113. Apicore denies the allegations in Paragraph 113.

114. Apicore denies the allegations in Paragraph 114.

115. Apicore denies the allegations in Paragraph 115.

PRAYER FOR RELIEF

Apicore denies all remaining allegations not specifically admitted herein. Apicore denies that Plaintiffs are entitled to any judgment or relief against Apicore and therefore specifically denies paragraphs (A) through (I) of Plaintiffs' Prayer for Relief.

DEFENSES

Without prejudice to the denials set forth in this Answer, without admitting any allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs, Apicore incorporates the above denials, and alleges and asserts the following defenses to the Complaint:

First Defense

The proposed products of ANDA No. 210982 do not infringe, and would not infringe any valid claim of the '884, '279, '684, '355, '946, and '630 Patents if made, used, sold, offered for sale, or marketed in the United States, or imported into the United States. Plaintiffs cannot prove either literal infringement, indirect infringement, or infringement under the doctrine of equivalents.

Second Defense

The '884, '279, '684, '355, '946, and '630 Patents and all their claims are invalid under 35 § 101 *et seq*., including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, 282, and/or double patenting.

Third Defense

The '884, '279, '684, '355, '946, and '630 Patents and all their claims are invalid for failing to meet judicially-created requirements for patentability.

Fourth Defense

Plaintiffs are estopped from asserting any scope for one or more of the claims of the '884, '279, '684, '355, '946, and '630 Patents that would cover Apicore's ANDA Products because of amendments, representations, assertions, disclaimers and/or admissions made during the course of proceedings in the United States Patent and Trademark Office ("PTO") during prosecution of the application(s) leading to the issuance of the '884, '279, '684, '355, '946, and '630 Patents.

Fifth Defense

To the extent not encompassed by Defendants' Fourth Defense, Plaintiffs are estopped from construing the claims of the '884, '279, '684, '355, '946, and '630 Patents to cover and include Apicore's ANDA Products.

Sixth Defense

The Complaint fails to state a claim upon which relief can be granted. The Complaint at least fails to state a cause of action under 35 U.S.C. § 271(a), (b), (c) and/or (g) against Apicore because the Plaintiffs have not pleaded with particularity facts regarding any post-ANDA approval activities.

Seventh Defense

The Court does not have subject matter jurisdiction over Plaintiffs' claims against Apicore under 35 U.S.C. § 271(a), (b), (c) and/or (g) because there is no real and immediate case or controversy because Apicore's ANDA No. 210982 has not been approved.

Eighth Defense

Apicore has not infringed and is not infringing, directly or indirectly, any valid claim of the '884, '279, '684, '355, '946, and '630 Patents and all activities performed by Apicore in relation to Apicore's proposed ANDA products have solely been for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

Ninth Defense

Any additional defenses or counterclaims that discovery may reveal, including unenforceability.

COUNTERCLAIMS

Counterclaim Plaintiff Apicore US LLC ("Apicore") brings the following counterclaims 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, "Lundbeck and Takeda" or "Plaintiffs").

PARTIES

1. Apicore is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 49 Napoleon Court, Sommerset, New Jersey 08873.

2. Based on Plaintiffs' Complaint, Lundbeck is a corporation organized and existing under the laws of Denmark, having a principal place of business at Ottiliavej 9, DK-2500 Valby, Denmark.

3. Based on Plaintiffs' Complaint, Takeda Pharmaceuticals Ltd. is a corporation organized and existing under the laws of Japan, having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka 540-8645, Japan.

4. Based on Plaintiffs' Complaint, Takeda Pharmaceuticals International AG is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Thurgauerstrasse 130, 8152 Glattpark-Opfikon, Zurich, Switzerland.

5. Based on Plaintiffs' Complaint, Takeda Pharmaceuticals U.S.A. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at One Takeda Parkway, Deerfield IL 60015.

6. Based on Plaintiffs' Complaint, Takeda Pharmaceuticals America, Inc., is a

corporation organized and existing under the laws of the State of Delaware, having a principal place of business at One Takeda Parkway, Deerfield IL 60015.

JURISDICTION AND VENUE

7. These counterclaims concerning U.S. Patent Nos. 7,144,884 ("the '884 Patent"), 8,476,279 ("the '279 Patent"), 8,722,684 ("the '684 Patent"), 8,969,355 ("the '355 Patent"), 9,227,946 ("the '946 Patent") and 9,861,630 ("the '630 Patent") arise under the Patent Laws of the United States, 35 U.S.C. § 101 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has personal jurisdiction over Lundbeck because it has availed itself of the rights and privileges of this forum by bringing this action in this District.

9. This Court has personal jurisdiction over Takeda Pharmaceuticals International AG because it has availed itself of the rights and privileges of this forum by bringing this action in this District.

10. This Court has personal jurisdiction over Takeda Pharmaceuticals U.S.A., because it has availed itself of the rights and privileges of this forum by bringing this action in this District.

11. This Court has personal jurisdiction over Takeda Pharmaceuticals America, Inc., because it has availed itself of the rights and privileges of this forum by bringing this action in this District.

12. Venue is proper in this District because this suit was filed in this District by the Plaintiffs.

THE CONTROVERSY

13. Counterclaim Plaintiff Apicore repeats and incorporates by reference the

allegations of the foregoing paragraphs 1-12 of the Counterclaims as if fully set forth herein.

14. This is an action based on an actual controversy between Counterclaim Plaintiff and Counterclaim Defendants Lundbeck, Takeda Pharmaceutical Company Ltd., Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International AG, and Takeda Pharmaceuticals America, Inc. concerning the invalidity and/or non-infringement of the '884, '279, '684, '355, '946, and '630 Patents, and Apicore's right to seek approval of its ANDA for its proposed vortioxetine tablets, 5 mg, 10 mg, 20 mg ("Apicore's Proposed ANDA Products").

15. The '884 Patent indicates on its face that it was issued by the United States Patent and Trademark Office on December 5, 2006, and is entitled "Phenyl-piperazine Derivatives as Serotonin Reuptake Inhibitors."

16. The '279 Patent indicates on its face that it was issued on July 2, 2013 and is entitled "Phenyl-piperazine Derivatives as Serotonin Reuptake Inhibitors."

17. The '684 Patent indicates on its face that it was issued on May 13, 2014 and is entitled "1-[2-(2, 4-dimethylphenylsufanyl-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment."

18. The '355 Patent indicates on its face that it was issued on March 3, 2015 and is entitled "1-[2-(2, 4-dimethylphenylsufanyl-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment."

19. The '946 Patent indicates on its face that it was issued on January 5, 2016 and is entitled "1-[2-(2, 4-dimethylphenylsufanyl-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive

Impairment."

20. The '630 Patent indicates on its face that it was issued on January 9, 2018 and is entitled "1-[2-(2, 4-dimethylphenylsufanyl-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment."

21. The '884, '279, '684, '355, '946, and '630 Patents were submitted to the United States Food and Drug Administration ("FDA") for listing in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), in connection with approved New Drug Application No. 204447 for TRINTELLIX®.

22. Plaintiffs have alleged that one or more claims of the '884, '279, '684, '355, '946 and '630 Patents would be infringed by Apicore's Proposed ANDA Products and that the filing of its ANDA constitutes infringement of the '884, '279, '684, '355, '946 and '630 Patents.

23. Apicore continues to seek FDA approval of an ANDA directed to products containing vortioxetine hydrobromide before the expiration of the '884, '279, '684, '355, '946, and '630 Patents.

24. Apicore has undertaken substantial efforts in developing and seeking approval for the Proposed ANDA Products set forth in its ANDA.

25. In view of the foregoing, an actual justiciable controversy exists by virtue of Apicore's notification to Plaintiffs of its ANDA filing, and Plaintiffs' subsequent filing of the present suit.

Count I

(Declaration of Non-infringement of the ’884, ’279, ’684, ’355, ’946 and ’630 Patents)

26. Counterclaim Plaintiff repeats and incorporates by reference the allegations of the foregoing paragraphs 1-25 of the Counterclaims as if fully set forth herein.

27. A justiciable case or controversy exists between Counterclaim Plaintiff and Counterclaim Defendants, Lundbeck, Takeda Pharmaceutical Company Ltd., Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International AG, and Takeda Pharmaceuticals America, Inc., concerning the non-infringement of the ’884, ’279, ’684, ’355, ’946 and ’630 Patents, which requires a declaration of rights by this Court.

28. Apicore’s Proposed ANDA Products do not infringe any claim of the ’884, ’279, ’684, ’355, ’946 and ’630 Patents, either literally or under the doctrine of equivalents. Apicore’s Proposed ANDA Products do not infringe, and would not infringe any valid claim of the ’884, ’279, ’684, ’355, ’946, and ’630 Patents if made, used, sold, offered for sale, or marketed in the United States, or imported into the United States. Apicore’s actions have not and would not induce anyone else to commit an act of infringement, nor would Apicore’s activities or Proposed ANDA Products constitute contributory infringement, of any claim of the ’884, ’279, ’684, ’355, ’946, and ’630 Patents.

29. Counterclaim Plaintiff has no adequate remedy at law and is entitled to a declaratory judgment that the filing of its ANDA and the commercial manufacture, use, offer for sale, or importation of Apicore’s Proposed ANDA Products do not and will not infringe any valid claim of the ’884, ’279, ’684, ’355, ’946, and ’630 Patents.

Count II

(Declaratory Judgment of Invalidity of the '884, '279, '684, '355, '946 and '630 Patents)

30. Counterclaim Plaintiff repeats and incorporates by reference the allegations of the foregoing paragraphs 1-29 of the Counterclaims as if fully set forth herein.

31. A justiciable case or controversy exists between Apicore and Counterclaim Defendants, Lundbeck, Takeda Pharmaceutical Company Ltd., Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International AG, and Takeda Pharmaceuticals America, Inc., concerning the non-infringement of the '884, '279, '684, '355, '946, and '630 Patents, which requires a declaration of rights by this Court.

32. The '884, '279, '684, '355, '946, and '630 Patents are invalid for failure to meet the patentability requirements under 35 U.S.C. § 101 *et seq*., including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, 282 and/or double patenting.

33. Apicore has no adequate remedy at law and is entitled to a declaratory judgment that the '884, '279, '684, '355, '946, and '630 Patents are invalid and/or unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Defendant/Counterclaim Plaintiff prays that the Court enter judgment in their favor and against Plaintiffs/Counterclaim Defendants as follows:

a. Declaring that the manufacture, use, offer for sale, sale, or importation of the proposed products that are the subject of ANDA No. 210982 have not infringed, do not infringe, and would not infringe any valid and enforceable claim of the '884, '279, '684, '355, '946, and '630 Patents;

b. Declaring that the claims of the '884, '279, '684, '355, '946, and '630 Patents are invalid and/or unenforceable;

c. Declaring that Apicore has a lawful right to seek and obtain FDA approval of its ANDA for Apicore's Proposed ANDA Products, and that based on the noninfringement, invalidity, and/or unenforceability of the '884, '279, '684, '355, '946, and '630 Patents, Apicore has a right to import, manufacture, use, offer for sale and sell Apicore's Proposed ANDA Products once approved by FDA;

d. Ordering that Plaintiffs/Counterclaim Defendants, their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them, be preliminarily and permanently enjoined from threatening or initiating further infringement litigation against Apicore or any of its customers, dealers or suppliers, or any prospective sellers, dealers, distributors or customers of Apicore, relating to Apicore's Proposed ANDA Products;

e. Ordering that Plaintiffs' Complaint be dismissed with prejudice and judgment entered in favor of Apicore;

f. Awarding Apicore its costs and expenses; and

g. Awarding any and all such other relief as the Court determines to be just and proper.

Dated: September 4, 2018

/s/ Kenneth L. Dorsney

Kenneth L. Dorsney (#3726)
MORRIS JAMES LLP
500 Delaware Ave., Suite 1500
Wilmington, DE 19801-1494
(302) 888-6800
kdorsney@morrisjames.com

Counsel for Defendant, Apicore US LLC

Of Counsel:
Howard S. Suh
Holland & Knight LLP
31 West 52nd Street
New York, NY 10019
T: (212) 513-3491