IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, TAKEDA PHARMACEUTICAL COMPANY LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS INTERNATIONAL AG, and TAKEDA PHARMACEUTICALS AMERICA, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
APICORE US LLC,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

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"), by their undersigned attorneys, bring this action against Defendant Apicore US LLC ("Apicore" or "Defendant"), and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, arises from Defendant's recent submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 210982 ("Apicore's ANDA"). Through its ANDA, Apicore seeks approval to market generic versions of Plaintiffs' pharmaceutical product TRINTELLIX®, prior to the expiration 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. Plaintiff H. Lundbeck A/S ("Lundbeck") is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Lundbeck is the assignee and owner of the '884, '279, '684, '355, '946, and '630 Patents.

3. Plaintiff 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, Chuo-ku, Osaka 540-8645, Japan. Lundbeck has granted Takeda Japan an exclusive license to the '884, '279, '684, '355, '946, and '630 Patents in connection with the use, importation, distribution, marketing, promotion, and sale of TRINTELLIX® in the United States.

4. Plaintiff 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. Takeda International is an indirect wholly owned subsidiary of Takeda Japan. Takeda International has an exclusive sublicense to the '884, '279, '684, '355, '946, and '630 Patents from Takeda Japan in connection with the commercialization of TRINTELLIX® in the United States.

5. Plaintiff 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. Takeda International and Takeda Japan own Takeda USA. Takeda USA holds the New Drug Application ("NDA") No. 204447 for TRINTELLIX® and has an exclusive sublicense to the '884, '279, '684, '355, '946, and '630 Patents from

Takeda International, which grants it the right to import, distribute, and sell TRINTELLIX® in the United States on behalf of Takeda.

6. Plaintiff Takeda Pharmaceuticals America, 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. Takeda America is a wholly owned subsidiary of Takeda USA. Takeda America distributes and markets TRINTELLIX® in the United States on behalf of Takeda USA.

7. Lundbeck and Takeda are engaged in the business of creating, researching, developing, and bringing to market revolutionary pharmaceutical products to help treat serious diseases, including major depressive disorder.

8. On information and belief, Defendant Apicore is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 49 Napoleon Court, Somerset, New Jersey 08873.

9. On information and belief, Apicore caused ANDA No. 210982 to be submitted to FDA and seeks FDA approval of ANDA No. 210982.

10. On information and belief, Apicore intends to commercially manufacture, market, offer for sale, and sell the vortioxetine hydrobromide tablets described in Apicore's ANDA ("the ANDA Products") throughout the United States, including in the State of Delaware, in the event FDA approves Apicore's ANDA.

11. On information and belief, Apicore submitted Drug Master File ("DMF") 31759 for vortioxetine hydrobromide to FDA and is the holder of DMF 31759.

JURISDICTION AND VENUE

12. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the '884, '279, '684, '355, '946, and '630 Patents.

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

14. This Court has personal jurisdiction over Apicore because, on information and belief, Apicore, *inter alia*, has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell the ANDA Products in the State of Delaware upon approval of ANDA No. 210982.

15. Apicore is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Apicore is registered to do business as a domestic corporation in Delaware (File Number 5549828).

16. On information and belief, Apicore is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter-egos, which Apicore manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

17. On information and belief, Apicore sells generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of its agents, alter egos, and/or wholly owned subsidiaries.

18. Apicore has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture TRINTELLIX® for sale and use throughout the United States, including this judicial district. On information and belief, and as indicated by a letter sent by Apicore to Lundbeck and Takeda USA pursuant to 21 U.S.C. § 355(j)(2)(B) ("Notice Letter"), ANDA No. 210982 was prepared and filed with the intention of seeking to market the ANDA Products nationwide, including within this judicial district.

19. On information and belief, Apicore plans to sell the ANDA Products in the State of Delaware, list the ANDA Products on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the ANDA Products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

20. On information and belief, Apicore knows and intends that its proposed ANDA Products will be distributed and sold in Delaware and will thereby displace sales of TRINTELLIX®, causing injury to Lundbeck and Takeda. Apicore intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed ANDA Products.

21. Venue is proper in this district for Apicore pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Apicore is a corporation organized and existing under the laws of the State of Delaware.

PLAINTIFFS' APPROVED TRINTELLIX® DRUG PRODUCT AND PATENTS

22. Takeda USA is the holder of New Drug Application ("NDA") No. 204447 for TRINTELLIX® tablets (5 mg, 10 mg, 15 mg, and 20 mg dosage strengths).[1] The active

[1] Plaintiffs do not sell 15 mg TRINTELLIX® tablets in the United States.

ingredient in TRINTELLIX® is vortioxetine hydrobromide. FDA approved NDA No. 204447 on September 30, 2013.

23. TRINTELLIX® is an oral antidepressant indicated for the treatment of Major Depressive Disorder (MDD). It is an inhibitor of serotonin (5-HT) reuptake, an agonist at 5-HT1A receptors, a partial agonist at 5-HT1B receptors, and an antagonist at 5-HT3, 5-HT1D and 5-HT7 receptors. It is considered to be the first and only drug with this combination of pharmacodynamic activity. It represents a major advancement in the treatment of depression.

24. The ’884, ’279, ’684, ’355, ’946, and ’630 Patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the “Orange Book”) for TRINTELLIX®.

25. The ’884 Patent, entitled “Phenyl-piperazine Derivatives as Serotonin Reuptake Inhibitors,” was duly and lawfully issued by the USPTO on December 5, 2006. A true and correct copy of the ’884 Patent is attached hereto as Exhibit A.

26. The ’279 Patent, entitled “Phenyl-piperazine Derivatives as Serotonin Reuptake Inhibitors,” was duly and lawfully issued by the USPTO on July 2, 2013. A true and correct copy of the ’279 Patent is attached hereto as Exhibit B.

27. The ’684 Patent, entitled “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,” was duly and lawfully issued by the USPTO on May 13, 2014. A true and correct copy of the ’684 Patent is attached hereto as Exhibit C.

28. The ’355 Patent, entitled “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," was duly and lawfully issued by the USPTO on March 3, 2015. A true and correct copy of the '355 Patent is attached hereto as Exhibit D.

29. The '946 Patent, entitled "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," was duly and lawfully issued by the USPTO on January 5, 2016. A true and correct copy of the '946 Patent is attached hereto as Exhibit E.

30. The '630 Patent, entitled "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," was duly and lawfully issued by the USPTO on January 9, 2018. A true and correct copy of the '630 Patent is attached hereto as Exhibit F.

APICORE'S ANDA NO. 210982

31. On information and belief, Apicore has submitted ANDA No. 210982 to FDA, or caused ANDA No. 210982 to be submitted to FDA, under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of vortioxetine hydrobromide tablets as purported generic versions of TRINTELLIX® tablets prior to the expiration of the '884, '279, '684, '355, '946, and '630 Patents.

32. On information and belief, FDA has not approved Apicore's ANDA.

33. On information and belief, no earlier than June 1, 2018 Apicore sent Lundbeck and Takeda USA a Notice Letter. The Notice Letter represented that Apicore US LLC had submitted to FDA ANDA No. 210982 with purported Paragraph IV certifications for the '884, '279, '684, '355, '946, and '630 Patents. Plaintiffs reserve all rights to challenge the sufficiency of Apicore's ANDA and Notice Letter.

34. On information and belief, Apicore's purpose in submitting ANDA No. 210982 with Paragraph IV certifications is to market the products described therein before the expiration of the '884, '279, '684, '355, '946, and '630 Patents.

35. In Apicore's Notice Letter, Apicore purported to offer confidential access to portions of its ANDA No. 210982 on terms and conditions set forth in the Notice Letter ("the Apicore Offer"). Apicore requested that Lundbeck and Takeda accept the Apicore Offer before receiving access to ANDA No. 210982. The Apicore Offer contained unreasonable restrictions on who could view the ANDA, well beyond those that would apply under a protective order. For example, the Apicore Offer did not permit any of Plaintiffs' in-house attorneys or outside scientific consultants to access ANDA No. 210982. Additionally, the Apicore Offer contained provisions that unreasonably restricted the ability of counsel receiving access to ANDA No. 210982 to engage in patent prosecution, work relating to the FDA, and litigation relating to vortioxetine. The restrictions Apicore placed on access to ANDA No. 210982 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, ***as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information***" (emphasis added).

36. On June 21, 2018, outside counsel for Plaintiffs sent correspondence to Apicore's Chief Financial Officer, Rahul Devnani, the only contact person identified in Apicore's Notice Letter, by fax and mail in an effort to negotiate reasonable terms of confidential access to the ANDA. Plaintiffs' correspondence included proposed modifications to Apicore's unduly restrictive Offer. To date, Apicore has not responded to Plaintiffs' correspondence regarding confidential access to Apicore's ANDA.

37. According to applicable regulations, Notice Letters such as Defendant's must contain a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed which includes a claim-by-claim analysis, describing "for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 CFR § 314.95(c)(7); *see also* 21 CFR § 314.52.

38. For at least one claim of each of the '884 and '279 Patents, Apicore's Notice Letter failed to allege that its ANDA Products or their administration do not meet the limitations of that claim. Accordingly, Apicore's Notice Letter did not assert a non-infringement position for at least one claim of each of the '884 and '279 Patents.

39. On information and belief, if approved, the ANDA Products will have the same indication as TRINTELLIX®. On further information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 210982 for the ANDA Products is the treatment of major depressive disorder (MDD).

40. On information and belief, if FDA approves Apicore's ANDA, Apicore will manufacture, offer for sale, or sell the ANDA Products, within the United States, including within the State of Delaware, or will import the ANDA Products into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of the ANDA Products will directly infringe the '884, '279, '684, '355, '946, and '630 Patents.

41. On information and belief, if FDA approves Apicore's ANDA, Apicore will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Products in a manner that infringes the '884, '279, '684, '355, '946, and '630 Patents.

42. This action is being brought within forty-five days of Plaintiffs' receipt of the Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C). Accordingly, Plaintiffs are entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and U.S.C. § 355(j)(5)(F)(ii).

COUNT I
INFRINGEMENT OF THE '884 PATENT

43. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–42 as if fully set forth herein.

44. On information and belief, Apicore submitted or caused the submission of ANDA No. 210982 to FDA, and thereby seeks FDA approval of Apicore's ANDA.

45. Plaintiffs own all rights, title, and interest in and to the '884 Patent.

46. The ANDA Products fall within one or more claims of the '884 Patent.

47. Apicore does not contest infringement of at least claims 1–12 and 17 of the '884 Patent in its Notice Letter. If Apicore had a factual or legal basis to contest infringement of claims 1–12 or 17 of the '884 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

48. Apicore has infringed at least one claim of the '884 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA with a Paragraph IV certification and thereby seeking FDA approval of generic versions of TRINTELLIX® prior to the expiration of the '884 Patent.

49. If approved, the importation, manufacture, sale, offer for sale, or use of the ANDA Products will infringe one or more claims of the '884 Patent under 35 U.S.C. § 271(a).

50. Unless enjoined by this Court, upon FDA approval, Apicore will actively induce infringement of the '884 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Apicore's ANDA, Apicore will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will

thereby induce infringement of one or more claims of the ’884 Patent. On information and belief, upon FDA approval, Apicore will intentionally encourage acts of direct infringement with knowledge of the ’884 Patent and knowledge that its acts are encouraging infringement.

51. Unless enjoined by this Court, upon FDA approval, Apicore will contributorily infringe the ’884 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Apicore’s ANDA, Apicore will offer to sell or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of one or more claims of the ’884 Patent. On information and belief, Apicore has had and continues to have knowledge of the ’884 Patent and knowledge that its acts will lead to infringement of the patent. On information and belief, Apicore has had and continues to have knowledge that the ANDA Products are especially made or especially adapted for a use that infringes the ’884 Patent and that there are no substantial non-infringing uses for the ANDA Products.

52. Apicore had actual and constructive notice of the ’884 Patent prior to filing its ANDA, and was aware that the filing of its ANDA with the request for FDA approval prior to the expiration of the ’884 Patent would constitute an act of infringement of the ’884 Patent. Apicore has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, and/or induce the infringement of the ’884 Patent.

53. Apicore filed its ANDA without adequate justification for asserting the ’884 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Apicore’s conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’884 Patent renders this case

"exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

54. Plaintiffs will be irreparably harmed if Apicore is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '884 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Apicore, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II
INFRINGEMENT OF THE '279 PATENT

55. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–54 as if fully set forth herein.

56. On information and belief, Apicore submitted or caused the submission of ANDA No. 210982 to FDA, and thereby seeks FDA approval of Apicore's ANDA.

57. Plaintiffs own all rights, title, and interest in and to the '279 Patent.

58. The ANDA Products fall within one or more claims of the '279 Patent.

59. On information and belief, the ANDA Products will be indicated for the treatment of major depressive disorder.

60. Apicore does not contest infringement of any claim of the '279 Patent in its Notice Letter. If Apicore had a factual or legal basis to contest infringement of any claim of the '279 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

61. Apicore has infringed at least one claim of the '279 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA with a Paragraph IV certification and thereby seeking FDA approval of generic versions of TRINTELLIX® prior to the expiration of the '279 Patent.

62. If approved, the importation, manufacture, sale, offer for sale, or use of the ANDA Products will infringe one or more claims of the ’279 Patent under 35 U.S.C. § 271(a).

63. Unless enjoined by this Court, upon FDA approval, Apicore will actively induce infringement of the ’279 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Apicore’s ANDA, Apicore will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby induce infringement of one or more claims of the ’279 Patent. On information and belief, upon FDA approval, Apicore will intentionally encourage acts of direct infringement with knowledge of the ’279 Patent and knowledge that its acts are encouraging infringement.

64. Unless enjoined by this Court, upon FDA approval, Apicore will contributorily infringe the ’279 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Apicore’s ANDA, Apicore will offer to sell or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of one or more claims of the ’279 Patent. On information and belief, Apicore has had and continues to have knowledge of the ’279 Patent and knowledge that its acts will lead to infringement of the patent. On information and belief, Apicore has had and continues to have knowledge that the ANDA Products are especially made or especially adapted for a use that infringes the ’279 Patent and that there are no substantial non-infringing uses for the ANDA Products.

65. Apicore had actual and constructive notice of the ’279 Patent prior to filing its ANDA, and was aware that the filing of its ANDA with the request for FDA approval prior to the expiration of the ’279 Patent would constitute an act of infringement of the ’279 Patent. Apicore has no reasonable basis for asserting that the commercial manufacture, use, offer for

sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, and/or induce the infringement of the ’279 Patent.

66. Apicore filed its ANDA without adequate justification for asserting the ’279 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Apicore’s conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’279 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

67. Plaintiffs will be irreparably harmed if Apicore is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’279 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Apicore, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT III
INFRINGEMENT OF THE ’684 PATENT

68. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–67 as if fully set forth herein.

69. On information and belief, Apicore submitted or caused the submission of ANDA No. 210982 to FDA, and thereby seeks FDA approval of Apicore’s ANDA.

70. Plaintiffs own all rights, title, and interest in and to the ’684 Patent.

71. The ANDA Products fall within one or more claims of the ’684 Patent.

72. Apicore has infringed at least one claim of the ’684 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA with a Paragraph IV certification and thereby seeking FDA approval of generic versions of TRINTELLIX® prior to the expiration of the ’684 Patent.

73. If approved, the importation, manufacture, sale, offer for sale, or use of the ANDA Products will infringe one or more claims of the ’684 Patent under 35 U.S.C. § 271(a).

74. Unless enjoined by this Court, upon FDA approval, Apicore will actively induce infringement of the ’684 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of its ANDA, Apicore will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby induce infringement of one or more claims of the ’684 Patent. On information and belief, upon FDA approval, Apicore will intentionally encourage acts of direct infringement with knowledge of the ’684 Patent and knowledge that its acts are encouraging infringement.

75. Unless enjoined by this Court, upon FDA approval, Apicore will contributorily infringe the ’684 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Apicore’s ANDA, Apicore will offer to sell or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of one or more claims of the ’684 Patent. On information and belief, Apicore has had and continues to have knowledge of the ’684 Patent and knowledge that its acts will lead to infringement of the patent. On information and belief, Apicore has had and continues to have knowledge that the ANDA Products are especially made or especially adapted for a use that infringes the ’684 Patent and that there are no substantial non-infringing uses for the ANDA Products.

76. Apicore has actual and constructive notice of the ’684 Patent prior to filing its ANDA, and was aware that the filing of its ANDA with the request for FDA approval prior to the expiration of the ’684 Patent would constitute an act of infringement of the ’684 Patent. Apicore has no reasonable basis for asserting that the commercial manufacture, use, offer for

sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, and/or induce the infringement of the ’684 Patent.

77. Apicore filed its ANDA without adequate justification for asserting the ’684 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Apicore’s conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’684 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

78. Plaintiffs will be irreparably harmed if Apicore is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’684 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Apicore, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT IV
INFRINGEMENT OF THE ’355 PATENT

79. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–78 as if fully set forth herein.

80. On information and belief, Apicore submitted or caused the submission of ANDA No. 210982 to FDA, and thereby seeks FDA approval of Apicore’s ANDA.

81. Plaintiffs own all rights, title, and interest in and to the ’355 Patent.

82. The ANDA Products fall within one or more claims of the ’355 Patent.

83. On information and belief, the ANDA Products will be indicated for the treatment of major depressive disorder.

84. Apicore has infringed at least one claim of the '355 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA with a Paragraph IV certification and thereby seeking FDA approval of generic versions of TRINTELLIX® prior to the expiration of the '355 Patent.

85. If approved, use of the ANDA Products in accordance with the proposed labeling will directly infringe one or more claims of the '355 Patent.

86. Unless enjoined by this Court, upon FDA approval, Apicore will actively induce infringement of the '355 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Apicore's ANDA, Apicore will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby induce infringement of one or more claims of the '355 Patent. On information and belief, upon FDA approval, Apicore will intentionally encourage acts of direct infringement with knowledge of the '355 Patent and knowledge that its acts are encouraging infringement.

87. Unless enjoined by this Court, upon FDA approval, Apicore will contributorily infringe the '355 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Apicore's ANDA, Apicore will offer to sell or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of one or more claims of the '355 Patent. On information and belief, Apicore has had and continues to have knowledge of the '355 Patent and knowledge that its acts will lead to infringement of the patent. On information and belief, Apicore has had and continues to have knowledge that the ANDA Products are especially made or especially adapted for a use that infringes the '355 Patent and that there are no substantial non-infringing uses for the ANDA Products.

88. Apicore had actual and constructive notice of the ’355 Patent prior to filing its ANDA, and was aware that the filing of its ANDA with the request for FDA approval prior to the expiration of the ’355 Patent would constitute an act of infringement of the ’355 Patent. Apicore has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, and/or induce the infringement of the ’355 Patent.

89. Apicore filed its ANDA without adequate justification for asserting the ’355 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Apicore’s conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’355 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

90. Plaintiffs will be irreparably harmed if Apicore is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’355 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Apicore, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT V
INFRINGEMENT OF THE ’946 PATENT

91. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–90 as if fully set forth herein.

92. On information and belief, Apicore has submitted or caused the submission of ANDA No. 210982 to FDA, and thereby seeks FDA approval of Apicore’s ANDA.

93. Plaintiffs own all rights, title, and interest in and to the ’946 Patent.

94. The ANDA Products fall within one or more claims of the ’946 Patent.

95. On information and belief, the ANDA Products will be indicated for the treatment of major depressive disorder.

96. Apicore has infringed at least one claim of the ’946 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA with a Paragraph IV certification and thereby seeking FDA approval of generic versions of TRINTELLIX® prior to the expiration of the ’946 Patent.

97. If approved, use of the ANDA Products in accordance with the proposed labeling will directly infringe one or more claims of the ’946 Patent.

98. Unless enjoined by this Court, upon FDA approval, Apicore will actively induce infringement of the ’946 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Apicore’s ANDA, Apicore will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby induce infringement of one or more claims of the ’946 Patent. On information and belief, upon FDA approval, Apicore will intentionally encourage acts of direct infringement with knowledge of the ’946 Patent and knowledge that its acts are encouraging infringement.

99. Unless enjoined by this Court, upon FDA approval, Apicore will contributorily infringe the ’946 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Apicore’s ANDA, Apicore will offer to sell or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of one or more claims of the ’946 Patent. On information and belief, Apicore has had and continues to have knowledge of the ’946 Patent and knowledge that its acts will lead to infringement of the patent. Upon information and belief, Apicore has had and continues to have knowledge that the ANDA Products are especially made or especially adapted

for a use that infringes the ’946 Patent and that there are no substantial non-infringing uses for the ANDA Products.

100. Apicore had actual and constructive notice of the ’946 Patent prior to filing its ANDA, and was aware that the filing of its ANDA with the request for FDA approval prior to the expiration of the ’946 Patent would constitute an act of infringement of the ’946 Patent. Apicore has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, and/or induce the infringement of the ’946 Patent.

101. Apicore filed its ANDA without adequate justification for asserting the ’946 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Apicore’s conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’946 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

102. Plaintiffs will be irreparably harmed if Apicore is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’946 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Apicore, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VI
INFRINGEMENT OF THE ’630 PATENT

103. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–102 as if fully set forth herein.

104. On information and belief, Apicore submitted or caused the submission of ANDA No. 210982 to FDA, and thereby seeks FDA approval of Apicore's ANDA.

105. Plaintiffs own all rights, title, and interest in and to the '630 Patent.

106. The ANDA Products fall within one or more claims of the '630 Patent.

107. On information and belief, the ANDA Products will be indicated for the treatment of major depressive disorder.

108. Apicore has infringed at least one claim of the '630 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA with a Paragraph IV certification and thereby seeking FDA approval of generic versions of TRINTELLIX® prior to the expiration of the '630 Patent.

109. If approved, use of the ANDA Products in accordance with the proposed labeling will directly infringe one or more claims of the '630 Patent.

110. Unless enjoined by this Court, upon FDA approval, Apicore will actively induce infringement of the '630 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Apicore's ANDA, Apicore will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby induce infringement of one or more claims of the '630 Patent. On information and belief, upon FDA approval, Apicore will intentionally encourage acts of direct infringement with knowledge of the '630 Patent and knowledge that its acts are encouraging infringement.

111. Unless enjoined by this Court, upon FDA approval, Apicore will contributorily infringe the '630 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Apicore's ANDA, Apicore will offer to sell or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of one or more claims of the '630 Patent. On information and

belief, Apicore has had and continues to have knowledge of the '630 Patent and knowledge that its acts will lead to infringement of the patent. On information and belief, Apicore has had and continues to have knowledge that the ANDA Products are especially made or especially adapted for a use that infringes the '630 Patent and that there are no substantial non-infringing uses for the ANDA Products.

112. Apicore had actual and constructive notice of the '630 Patent prior to filing its ANDA, and was aware that the filing of its ANDA with the request for FDA approval prior to the expiration of the '630 Patent would constitute an act of infringement of the '630 Patent. Apicore has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, and/or induce the infringement of the '630 Patent.

113. Apicore filed its ANDA without adequate justification for asserting the '630 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Apicore's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '630 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

114. Plaintiffs will be irreparably harmed if Apicore is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '630 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Apicore, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A judgment that Apicore has infringed the ’884, ’279, ’684, ’355, ’946, or ’630 Patents under 35 U.S.C. § 271(e)(2)(A);

(B) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Apicore’s ANDA shall be no earlier than the last expiration date of any of the ’884, ’279, ’684, ’355, ’946, or ’630 Patents, or any later expiration of exclusivity for any of the ’884, ’279, ’684, ’355, ’946, or ’630 Patents, including any extensions or regulatory exclusivities;

(C) Entry of a permanent injunction enjoining Apicore, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Apicore or on its behalf from commercially manufacturing, using, offering for sale, or selling the ANDA Products within the United States, or importing the ANDA Products into the United States, until the expiration of the ’884, ’279, ’684, ’355, ’946, and ’630 Patents;

(D) A judgment declaring that making, using, selling, offering to sell, or importing the ANDA Products, or inducing or contributing to such conduct, would constitute infringement of the ’884, ’279, ’684, ’355, ’946, and ’630 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(E) A declaration under 28 U.S.C. § 2201 that if Apicore, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Apicore or on its behalf, engages in the commercial manufacture, use, offer for sale, sale or importation of the ANDA Products, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(F) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Apicore engages in the commercial manufacture, use, offer for sale, sale, and/or importation of

the ANDA Products, or any product that infringes the '884, '279, '684, '355, '946, or '630 Patents, or induces or contributes to such conduct, prior to the expiration of the patents;

(G) A finding that this is an exceptional case, and an award of attorneys' fees in this action to Plaintiffs pursuant to 35 U.S.C. § 285;

(H) Costs and expenses in this action; and

(I) Such other and further relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
Megan Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com
mdellinger@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

George F. Pappas
Einar Stole
Christopher N. Sipes
Brianne Bharkhda
Priscilla G. Dodson
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001-4956
(202) 662-6000

Yiye Fu
COVINGTON & BURLING LLP
333 Twin Dolphin Drive, Suite 700
Redwood Shores, CA 94065-1418
(650) 632-4700

July 12, 2018