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. _____
ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LTD.,	)	
Defendants.	)	

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 Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus") and Cadila Healthcare Ltd. ("Cadila") (collectively, "Defendants"), 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 Defendants' recent submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 211146 (hereinafter, "Defendants' ANDA"). Through Defendants' ANDA, Defendants seek 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"); and United States Patent No. 9,227,946 ("the '946 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 Patent, '279 Patent, '684 Patent, the '355 Patent, and the '946 Patent.

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, and '946 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, and '946 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, and '946 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 Zydus is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

9. On information and belief, Zydus is a wholly owned subsidiary of Cadila.

10. On information and belief, Defendant Cadila is a corporation organized and existing under the laws of the Republic of India, with a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380 015, Gujarat, India.

11. On information and belief, Zydus acts at the direction, and for the benefit, of Cadila, and is controlled and/or dominated by Cadila.

12. On further information and belief, Zydus and Cadila collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Defendants are agents of each other and/or operate

in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

13. On information and belief, Zydus acts as the U.S. agent for Cadila for purposes of regulatory submissions to the U.S. Food and Drug Administration ("FDA") in seeking approval for generic drugs.

14. On information and belief, Zydus and Cadila acted collaboratively in the preparation and submission of ANDA No. 211146.

15. On information and belief, Defendants caused ANDA No. 211146 to be submitted to FDA and seek FDA approval of ANDA No. 211146.

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

17. On information and belief, Defendants intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell the ANDA Products, in the event FDA approves Defendants' ANDA.

JURISDICTION AND VENUE

18. 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, and '946 Patents.

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

20. This Court has personal jurisdiction over Defendants because, on information and belief, Defendants, *inter alia*, have continuous and systematic contacts with the State of

Delaware, regularly conduct business in the State of Delaware, either directly or through one or more wholly owned subsidiaries, agents, and/or alter egos, have purposefully availed themselves of the privilege of doing business in the State of Delaware, and intend to sell the ANDA Products in the State of Delaware upon approval of ANDA No. 211146.

21. On information and belief, Defendants are 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 Defendants manufacture, distribute, market, and/or sell throughout the United States and in this judicial district.

22. On information and belief, Defendants are licensed to sell generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos.

23. Defendants have 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 dated December 14, 2017 sent by Zydus to Lundbeck and Takeda USA pursuant to 21 U.S.C. § 355(j)(2)(B) (hereinafter, the "Notice Letter"), ANDA No. 211146 was prepared and filed with the intention of seeking to market the ANDA Products nationwide, including within this judicial district.

24. On information and belief, Defendants plan 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 their wholly owned subsidiaries, agents, and/or alter egos.

25. On information and belief, Defendants know and intend that their proposed ANDA Products will be distributed and sold in Delaware and will thereby displace sales of TRINTELLIX®, causing injury to Lundbeck and Takeda. Defendants intend to take advantage of their established channels of distribution in Delaware for the sale of their proposed ANDA Products.

26. Alternatively, this Court has personal jurisdiction over Cadila because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Cadila is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Cadila has sufficient contacts in the United States as a whole, including, but not limited to, preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Cadila satisfies due process.

27. Zydus and Cadila regularly engage in patent litigation concerning FDA-approved drug products in this judicial district, have not contested personal jurisdiction or venue in such litigation in this judicial district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Biogen International GmBH et al v. Zydus Pharmaceuticals (USA) Inc.*, 17-cv-00954, D.I. 8 (D. Del. Oct. 16, 2017); *Millenium Pharmaceuticals, Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, 17-cv-00423, D.I. 9 (D. Del. May 24, 2017); *Bristol-Meyers Squibb Company et al v. Zydus Pharmaceuticals (USA) Inc.*, 17-cv-00412, D.I. 9 (D. Del. May 31, 2017); *Pfizer Inc. et al v.*

Zydus Pharmaceuticals (USA) Inc. et al, 17-cv-00214, D.I. 13 (D. Del. June 5, 2017); *Sanofi-aventis US LLC et al v. Zydus Pharmaceuticals (USA) Inc. et al*, 17-cv-00034, D.I. 9 (D. Del. Apr. 10, 2017); *Astellas Pharma Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, 16-cv-01167, D.I. 11 (D. Del. Feb. 27, 2017); *Genzyme Corporation et al v. Zydus Pharmaceuticals (USA) Inc.*, 16-cv-00540, D.I. 10 (D. Del. July 20, 2016); *Upsher-Smith Laboratories Inc. v. Zydus Pharmaceuticals (USA) Inc. et al*, 16-cv-00248, D.I. 15 (D. Del. Oct. 31, 2016).

28. Venue is proper in this district for Zydus pursuant to 28 U.S.C. §§ 1391 and 1400(b).

29. Venue is proper in this district for Cadila pursuant to 28 U.S.C. §§ 1391 and 1400(b).

PLAINTIFFS' APPROVED TRINTELLIX® DRUG PRODUCT AND PATENTS

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

31. 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.

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

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

33. 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.

34. 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.

35. 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.

36. 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.

37. 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.

DEFENDANTS’ ANDA NO. 211146

38. On information and belief, Defendants have submitted ANDA No. 211146 to FDA, or caused ANDA No. 211146 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, and '946 Patents.

39. On information and belief, FDA has not approved Defendants' ANDA.

40. On information and belief, Zydus sent Lundbeck and Takeda USA a Notice Letter dated December 14, 2017. The Notice Letter represented that Zydus had submitted to FDA ANDA No. 211146 and a purported Paragraph IV certification for the '884, '279, '684, '355, and '946 Patents. Plaintiffs reserve all rights to challenge the sufficiency of Defendants' ANDA and Notice Letter.

41. On information and belief, the purpose of an ANDA and Paragraph IV certification is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the ANDA Products before expiration of the '884, '279, '684, '355, and '946 Patents. Hence, Defendants' purpose in submitting ANDA No. 211146 is to market the products described therein before the expiration of the '884, '279, '684, '355, and '946 Patents.

42. According to applicable regulations, Notice Letters such as Defendants' 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 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.

43. For at least one claim of each of the '884 and '279 Patents, Zydus's Notice Letter failed to allege that its ANDA Products do not meet the limitations of that claim. Accordingly,

Zydus's Notice Letter did not assert a non-infringement position for at least one claim of each of the '884 and '279 Patents.

44. Zydus's Notice Letter did not allege that any claim of the '684, '355, or '946 Patents is invalid or unenforceable.

45. 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. 211146 for the ANDA Products is the treatment of major depressive disorder (MDD).

46. On information and belief, if FDA approves Defendants' ANDA, Defendants 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.

47. On information and belief, if FDA approves Defendants' ANDA, Defendants 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, and '946 Patents.

48. 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

49. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–48 as if fully set forth herein.

50. On information and belief, Defendants submitted or caused the submission of ANDA No. 211146 to FDA, and thereby seek FDA approval of Defendants' ANDA.

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

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

53. Zydus does not contest infringement of at least claims 1-9, 11, 12, and 17 of the '884 Patent in its Notice Letter. If Zydus had a factual or legal basis to contest infringement of claims 1-9, 11, 12, and 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.

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

55. 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).

56. Unless enjoined by this Court, upon FDA approval, Defendants will actively induce infringement of the '884 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Defendants' ANDA, Defendants 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, Defendants will intentionally encourage acts of direct infringement with knowledge of the '884 Patent and knowledge that their acts are encouraging infringement.

57. Unless enjoined by this Court, upon FDA approval, Defendants will contributorily infringe the '884 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendants' ANDA, Defendants 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, Defendants have had and continue to have knowledge of the '884 Patent and knowledge that their acts will lead to infringement of the patent. On information and belief, Defendants have had and continue 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.

58. Defendants had actual and constructive notice of the '884 Patent prior to filing Defendants' ANDA, and were aware that the filing of Defendants' 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. Defendants have 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.

59. Defendants filed Defendants' 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. Defendants' 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 entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

60. Plaintiffs will be irreparably harmed if Defendants are 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 Defendants, 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

61. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–60 as if fully set forth herein.

62. On information and belief, Defendants submitted or caused the submission of ANDA No. 211146 to FDA, and thereby seek FDA approval of Defendants' ANDA.

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

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

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

66. Zydus does not contest infringement of at least claims 1-5 and 12-15 of the '279 Patent in its Notice Letter. If Zydus had a factual or legal basis to contest infringement of claims 1-5 and 12-15 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.

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

68. 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).

69. Unless enjoined by this Court, upon FDA approval, Defendants will actively induce infringement of the '279 Patent under 35 U.S.C. § 271(b). On information and belief,

upon FDA approval of Defendants' ANDA, Defendants 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, Defendants will intentionally encourage acts of direct infringement with knowledge of the '279 Patent and knowledge that their acts are encouraging infringement.

70. Unless enjoined by this Court, upon FDA approval, Defendants will contributorily infringe the '279 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendants' ANDA, Defendants 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, Defendants have had and continue to have knowledge of the '279 Patent and knowledge that their acts will lead to infringement of the patent. On information and belief, Defendants have had and continue 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.

71. Defendants had actual and constructive notice of the '279 Patent prior to filing Defendants' ANDA, and were aware that the filing of Defendants' 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. Defendants have 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.

72. Defendants filed Defendants' 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. Defendants' 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 entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

73. Plaintiffs will be irreparably harmed if Defendants are 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 Defendants, 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

74. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–73 as if fully set forth herein.

75. On information and belief, Defendants submitted or caused the submission of ANDA No. 211146 to FDA, and thereby seek FDA approval of Defendants' ANDA.

76. Plaintiffs own all rights, title, and interest in and to the '684 Patent.

77. The ANDA Products fall within one or more claims of the '684 Patent.

78. Zydus's Notice Letter did not allege that any claim of the '684 Patent is invalid or unenforceable. If Zydus had a factual or legal basis to contest the validity or unenforceability of the '684 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.

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

80. 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).

81. Unless enjoined by this Court, upon FDA approval, Defendants will actively induce infringement of the '684 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Defendants' ANDA, Defendants 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, Defendants will intentionally encourage acts of direct infringement with knowledge of the '684 Patent and knowledge that their acts are encouraging infringement.

82. Unless enjoined by this Court, upon FDA approval, Defendants will contributorily infringe the '684 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendants' ANDA, Defendants 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, Defendants have had and continue to have knowledge of the '684 Patent and knowledge that their acts will lead to infringement of the patent. On information and belief, Defendants have had and continue 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.

83. Defendants had actual and constructive notice of the ’684 Patent prior to filing Defendants’ ANDA, and were aware that the filing of Defendants’ 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. Defendants have 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.

84. Defendants filed Defendants’ 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. Defendants’ 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 entitle Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

85. Plaintiffs will be irreparably harmed if Defendants are 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 Defendants, 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

86. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–85 as if fully set forth herein.

87. On information and belief, Defendants submitted or caused the submission of ANDA No. 211146 to FDA, and thereby seek FDA approval of Defendants' ANDA.

88. Plaintiffs own all rights, title, and interest in and to the '355 Patent.

89. The ANDA Products fall within one or more claims of the '355 Patent.

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

91. Zydus's Notice Letter did not allege that any claim of the '355 Patent is invalid or unenforceable. If Zydus had a factual or legal basis to contest the validity or unenforceability of the '355 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.

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

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

94. Unless enjoined by this Court, upon FDA approval, Defendants will actively induce infringement of the '355 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Defendants' ANDA, Defendants 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, Defendants will intentionally encourage acts of

direct infringement with knowledge of the '355 Patent and knowledge that their acts are encouraging infringement.

95. Unless enjoined by this Court, upon FDA approval, Defendants will contributorily infringe the '355 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendants' ANDA, Defendants 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, Defendants have had and continue to have knowledge of the '355 Patent and knowledge that their acts will lead to infringement of the patent. On information and belief, Defendants have had and continue 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.

96. Defendants had actual and constructive notice of the '355 Patent prior to filing Defendants' ANDA, and were aware that the filing of Defendants' 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. Defendants have 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.

97. Defendants filed Defendants' 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. Defendants' 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 entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

98. Plaintiffs will be irreparably harmed if Defendants are 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 Defendants, 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

99. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–98 as if fully set forth herein.

100. On information and belief, Defendants have submitted or caused the submission of ANDA No. 211146 to FDA, and thereby seek FDA approval of Defendants' ANDA.

101. Plaintiffs own all rights, title, and interest in and to the '946 Patent.

102. The ANDA Products fall within one or more claims of the '946 Patent.

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

104. Zydus's Notice Letter did not allege that any claim of the '946 Patent is invalid or unenforceable. If Zydus had a factual or legal basis to contest the validity or unenforceability of the '946 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.

105. Defendants have infringed at least one claim of the '946 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA with a Paragraph IV certification and thereby

seeking FDA approval of generic versions of TRINTELLIX® prior to the expiration of the '946 Patent.

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

107. Unless enjoined by this Court, upon FDA approval, Defendants will actively induce infringement of the '946 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Defendants' ANDA, Defendants 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, Defendants will intentionally encourage acts of direct infringement with knowledge of the '946 Patent and knowledge that their acts are encouraging infringement.

108. Unless enjoined by this Court, upon FDA approval, Defendants will contributorily infringe the '946 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendants' ANDA, Defendants 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, Defendants have had and continue to have knowledge of the '946 Patent and knowledge that their acts will lead to infringement of the patent. Upon information and belief, Defendants have had and continue 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.

109. Defendants had actual and constructive notice of the '946 Patent prior to filing Defendants' ANDA, and were aware that the filing of Defendants' 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. Defendants have 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.

110. In addition, Defendants filed Defendants' 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. Defendants' 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 entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

111. Plaintiffs will be irreparably harmed if Defendants are 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 Defendants, 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 Defendants have infringed the '884, '279, '684, '355, and '946 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 Defendants' ANDA shall be no earlier than the last expiration date of any of

the ’884, ’279, ’684, ’355, or ’946 Patents, or any later expiration of exclusivity for any of the ’884, ’279, ’684, ’355, or ’946 Patents, including any extensions or regulatory exclusivities;

(C) Entry of a permanent injunction enjoining Defendants, their officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Defendants or on their 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, and ’946 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, and ’946 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(E) A declaration under 28 U.S.C. § 2201 that if Defendants, their officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Defendants or on their behalf, engage 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 Defendants engage 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, or ’946 Patents, or induce or contribute 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 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.

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